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# Presidential Documents

**Title 3—**

## The President

**Memorandum of April 7, 2010**

## Delegation of a Reporting Authority

**Memorandum for the Secretary of State**

By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, I hereby delegate to you the functions and authority conferred upon the President by section 301 of the Enhanced Partnership with Pakistan Act of 2009, Public Law 111–73, to make the specified report to the Congress.

You are authorized and directed to notify the appropriate congressional committees and publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
*WASHINGTON, April 7, 2010*

[FR Doc. 2010–8789
Filed 4–14–10; 8:45 am]
Billing code 4710–10–P

# Presidential Documents

**Presidential Determination No. 2010–06 of April 7, 2010**

## Waiver of Restriction on Providing Funds to the Palestinian Authority

**Memorandum for the Secretary of State**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 7040(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Public Law 111–117) (the "Act"), I hereby certify that it is important to the national security interests of the United States to waive the provisions of section 7040(a) of the Act, in order to provide funds appropriated to carry out Chapter 4 of Part II of the Foreign Assistance Act, as amended, to the Palestinian Authority.

You are directed to transmit this determination to the Congress, with a report pursuant to section 7040(d) of the Act and to publish the determination in the *Federal Register*.

THE WHITE HOUSE,
*WASHINGTON, April 7, 2010*

[FR Doc. 2010–8793
Filed 4–14–10; 8:45 am]
Billing code 4710–10–P

# Presidential Documents

**Presidential Determination No. 2010–05 of April 7, 2010**

## Waiver of and Certification of Statutory Provisions Regarding the Palestine Liberation Organization Office

**Memorandum for the Secretary of State**

Pursuant to the authority and conditions contained in section 7034(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Public Law 111–117), I hereby determine and certify that it is important to the national security interests of the United States to waive the provisions of section 1003 of the Anti-Terrorism Act of 1987, Public Law 100–204.

This waiver shall be effective for a period of 6 months. You are hereby authorized and directed to transmit this determination to the Congress and to publish it in the *Federal Register*.

THE WHITE HOUSE,
*WASHINGTON, April 7, 2010*

[FR Doc. 2010–8791
Filed 4–14–10; 8:45 am]
Billing code 4710–10–P

# Rules and Regulations

Federal Register
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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 TRANSPORTATION

### 14 CFR Part 97

**[Docket No. 30717; Amdt. No. 3367]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective April 15, 2010. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 15, 2010.

**ADDRESSES:** Availability of matter incorporated by reference in the amendment is as follows:

*For Examination*—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,
4. 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/code_of_federal_regulations/ibr_locations.html.*

*Availability*—All SIAPs are available online free of charge. Visit *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

**FOR FURTHER INFORMATION CONTACT:** Harry J. Hodges, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC/P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

### Conclusion

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

FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 97**

Air traffic control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on March 19, 2010.

**John M. Allen,**

*Director, Flight Standards Service.*

**Adoption of the Amendment**

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

| AIRAC date | State | City | Airport | FDC No. | FDC date | Subject |
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| 6–May–10 | IN | Muncie | Delaware County-Johnson Field | 0/0116 | 3/17/10 | RNAV (GPS) RWY 14, ORIG. |
| 6-May–10 | IN | Muncie | Delaware County-Johnson Field | 0/0117 | 3/17/10 | ILS RWY 32, AMDT 9A. |
| 6–May–10 | MI | Ontonagon | Ontonagon County–Schuster Field | 0/0147 | 3/17/10 | NDB OR GPS A, AMDT 4. |
| 6–May–10 | MI | Port Huron | St Clair County Intl | 0/0149 | 3/17/10 | ILS RWY 4, AMDT 3A. |
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| 6–May–10 | MI | Sturgis | Kirsch Muni | 0/0152 | 3/17/10 | RNAV (GPS) RWY 18, ORIG. |
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| 6–May–10 | MA | Westfield/Springfield. | Barnes Muni | 0/8385 | 3/4/10 | VOR OR TACAN RWY 2, AMDT 4C. |
| 6–May–10 | IA | Guthrie Center | Guthrie County Rgnl | 0/8435 | 3/4/10 | NDB RWY 18, ORIG. |
| 6–May–10 | GA | Carrollton | West Georgia Regional-O V Gray Field. | 0/8726 | 3/3/10 | RNAV (GPS) RWY 17, ORIG. |
| 6–May–10 | IL | Galesburg | Galesburg Muni | 0/8790 | 3/11/10 | ILS RWY 3, AMDT 9A. |
| 6–May–10 | IL | Galesburg | Galesburg Muni | 0/8792 | 3/11/10 | VOR OR GPS RWY 21, AMDT 6C. |
| 6–May–10 | IL | Galesburg | Galesburg Muni | 0/8793 | 3/11/10 | VOR OR GPS RWY 3, AMDT 6A. |
| 6–May–10 | KY | Lewisport | Hancock Co-Ron Lewis Field | 0/8830 | 3/8/10 | RNAV (GPS) RWY 5, ORIG. |
| 6–May–10 | KY | Lewisport | Hancock Co-Ron Lewis Field | 0/8831 | 3/8/10 | RNAV (GPS) RWY 23, ORIG. |
| 6–May–10 | SC | Georgetown | Georgetown County | 0/9026 | 3/8/10 | NDB OR GPS RWY 5, AMDT 5A. |
| 6–May–10 | GA | Canton | Cherokee County | 0/9072 | 3/8/10 | RNAV (GPS) RWY 22, ORIG. |
| 6–May–10 | SC | Conway | Conway-Horry County | 0/9131 | 3/8/10 | RNAV (GPS) RWY 4, ORIG. |
| 6–May–10 | SC | Conway | Conway-Horry County | 0/9132 | 3/8/10 | NDB RWY 4, ORIG. |
| 6–May–10 | SC | Conway | Conway-Horry County | 0/9133 | 3/8/10 | NDB RWY 22, ORIG. |
| 6–May–10 | GA | Douglas | Douglas Muni | 0/9144 | 3/8/10 | RNAV (GPS) RWY 22, ORIG. |
| 6–May–10 | GA | Douglas | Douglas Muni | 0/9146 | 3/8/10 | RNAV (GPS) RWY 4, ORIG. |
| 6–May–10 | GA | Douglas | Douglas Muni | 0/9147 | 3/8/10 | ILS OR LOC RWY 4, AMDT 1. |
| 6–May–10 | OH | Lorain/Elyria | Lorain County Regional | 0/9306 | 3/8/10 | ILS OR LOC RWY 7, AMDT 6B. |
| 6–May–10 | MI | Tecumseh | Meyers-Diver's | 0/9316 | 3/11/10 | VOR OR GPS A, AMDT 7. |
| 6–May–10 | GA | Blakely | Early County | 0/9322 | 3/8/10 | RNAV (GPS) RWY 5, AMDT 1. |
| 6–May–10 | GA | Blakely | Early County | 0/9323 | 3/8/10 | LOC/NDB RWY 23, AMDT 1. |
| 6–May–10 | GA | Blakely | Early County | 0/9324 | 3/8/10 | RNAV (GPS) RWY 23, AMDT 1. |
| 6–May–10 | SC | Orangeburg | Orangeburg Muni | 0/9338 | 3/8/10 | TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 3. |
| 6–May–10 | MN | Windom | Windom Muni | 0/9400 | 3/11/10 | NDB RWY 17, AMDT 5. |
| 6–May–10 | MN | Brainerd | Brainerd Lakes Rgnl | 0/9579 | 3/11/10 | TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 5. |
| 6–May–10 | MI | New Hudson | Oakland Southwest | 0/9583 | 3/17/10 | VOR OR GPS A, AMDT 3A. |
| 6–May–10 | MI | Cadillac | Wexford County | 0/9586 | 3/17/10 | NDB RWY 7, AMDT 2. |
| 6–May–10 | MI | Cadillac | Wexford County | 0/9587 | 3/17/10 | RNAV (GPS) RWY 7, ORIG. |
| 6–May–10 | MI | Cadillac | Wexford County | 0/9588 | 3/17/10 | ILS OR LOC RWY 7, ORIG–A. |
| 6–May–10 | MI | Detroit | Detroit Metropolitan Wayne County | 0/9684 | 3/17/10 | ILS OR LOC RWY 27R, AMDT 11A. |

| AIRAC date | State | City | Airport | FDC No. | FDC date | Subject |
|---|---|---|---|---|---|---|
| 6–May–10 | ME | Caribou | Caribou Muni | 0/9838 | 3/17/10 | RNAV (GPS) RWY 19, ORIG. |
| 6–May–10 | FL | Tampa | Tampa Intl | 0/9917 | 3/17/10 | ILS OR LOC RWY 18R, AMDT 4B. |

[FR Doc. 2010–6654 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 97

**[Docket No. 30716; Amdt. No. 3366]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective April 15, 2010. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 15, 2010.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

*For Examination*—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/code_of_federal_regulations/ibr_locations.html.*

*Availability*—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit *http://www.nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

**FOR FURTHER INFORMATION CONTACT:** Harry J. Hodges, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPS, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPS and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPS and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPS, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

### Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which

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

### List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC on March 19, 2010.

**John M. Allen,**

*Director, Flight Standards Service.*

### Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective 8 Apr 2010*

Clinton, MD, Washington Executive/Hyde Field, VOR/DME RWY 5, Orig, CANCELLED

** * * Effective 6 May 2010*

West Palm Beach, FL, Palm Beach Intl, RNAV (RNP) Z RWY 10L, Orig-A
West Palm Beach, FL, Palm Beach Intl, RNAV (RNP) Z RWY 14, Orig-A
West Palm Beach, FL, Palm Beach Intl, RNAV (RNP) Z RWY 28R, Orig-A
West Palm Beach, FL, Palm Beach Intl, RNAV (RNP) Z RWY 32, Orig-A
Clinton, IA, Clinton Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Guthrie Center, IA, Guthrie County Rgnl, Takeoff Minimums and Obstacle DP, Orig
Red Oak, IA, Red Oak Muni, NDB RWY 17, Amdt 9
Flora, IL, Flora Muni, RNAV (GPS) RWY 21, Amdt 1A
Mattoon/Charleston, IL, Coles County Memorial, ILS OR LOC RWY 29, Amdt 6A
Mount Carmel, IL, Mount Carmel Muni, NDB OR GPS RWY 4, Amdt 5, CANCELLED
Mount Carmel, IL, Mount Carmel Muni, VOR RWY 22, Amdt 10
Leonardtown, MD, St. Mary's County Rgnl, VOR OR GPS RWY 29, Amdt 6A, CANCELLED
Flint, MI, Bishop Intl, ILS OR LOC RWY 9, Amdt 22A
Flint, MI, Bishop Intl, ILS OR LOC RWY 27, Amdt 5
Sparta, MI, Paul C. Miller-Sparta, Takeoff Minimums and Obstacle DP, Amdt 2
Alexandria, MN, Chandler Field, RNAV (GPS) RWY 22, Orig
Bemidji, MN, Bemidji Rgnl, RNAV (GPS) RWY 25, Orig
Granite Falls, MN, Granite Falls Muni/Lenzen-Roe Meml Fld, Takeoff Minimums and Obstacle DP, Orig
Long Prairie, MN, Todd Field, RNAV (GPS) RWY 34, Amdt 1
Minneapolis, MN, Anoka County-Blaine Arpt (Janes Field), Takeoff Minimums and Obstacle DP, Amdt 5A
Ainsworth, NE, Ainsworth Muni, RNAV (GPS) RWY 17, Amdt 2
Ainsworth, NE, Ainsworth Muni, RNAV (GPS) RWY 35, Amdt 2
Newark, NJ, Newark Liberty Intl, ILS OR LOC RWY 22L; ILS RWY 22L (CAT II), Amdt 12
Ashland, OH, Ashland County, Takeoff Minimums and Obstacle DP, Amdt 3
Loris, SC, Twin City, Takeoff Minimums and Obstacle DP, Orig
Bridgewater, VA, Bridgewater Airpark, Takeoff Minimums and Obstacle DP, Amdt 2

** * * Effective 3 Jun 2010*

Talkeetna, AK, Talkeetna, GPS RWY 36, Orig, CANCELLED
Talkeetna, AK, Talkeetna, NDB RWY 36, Amdt 2
Talkeetna, AK, Talkeetna, RNAV (GPS) RWY 36, Orig
Talkeetna, AK, Talkeetna, Takeoff Minimums and Obstacle DP, Amdt 2
Talkeetna, AK, Talkeetna, VOR–A, Amdt 10
Talkeetna, AK, Talkeetna, VOR/DME RWY 36, Amdt 2
Palmdale, CA, Palmdale Rgnl/USAF Plant 42, Takeoff Minimums and Obstacle DP, Amdt 2
Panama City, FL, Panama City-Bay County Intl, ILS RWY 14, Amdt 16, CANCELLED
Panama City, FL, Panama City-Bay County Intl, NDB RWY 14, Amdt 5, CANCELLED
Panama City, FL, Panama City-Bay County Intl, RNAV (GPS) RWY 5, ORIG–A, CANCELLED
Panama City, FL, Panama City-Bay County Intl, RNAV (GPS) RWY 14, Amdt 1, CANCELLED
Panama City, FL, Panama City-Bay County Intl, RNAV (GPS) RWY 23, Orig, CANCELLED
Panama City, FL, Panama City-Bay County Intl, RNAV (GPS) RWY 32, Amdt 1, CANCELLED
Panama City, FL, Panama City-Bay County Intl, Takeoff Minimums and Obstacle DP, Amdt 1, CANCELLED
Panama City, FL, Panama City-Bay County Intl, VOR OR TACAN RWY 14, Amdt 16, CANCELLED
Panama City, FL, Panama City-Bay County Intl, VOR OR TACAN RWY 32, Amdt 11, CANCELLED
Panama City, FL, Panama City-Bay County Intl, VOR OR TACAN–A, Amdt 14, CANCELLED
Moultrie, GA, Moultrie Muni, NDB–A, Orig-A
Ames, IA, Ames Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Chicago/Romeoville, IL, Lewis University, Takeoff Minimums and Obstacle DP, Amdt 1
Goshen, IN, Goshen Muni, VOR RWY 27, Amdt 7A
Hettinger, ND, Hettinger Muni, Takeoff Minimums and Obstacle DP, Amdt 2
Reno, NV, Reno/Tahoe Intl, LOC/DME BC RWY 34L, Amdt 1C, CANCELLED
Fostoria, OH, Fostoria Metropolitan, Takeoff Minimums and Obstacle DP, Amdt 1
Kutztown, PA, Kutztown, RNAV (GPS)-A, Orig, CANCELLED
Kutztown, PA, Kutztown, Takeoff Minimums and Obstacle DP, Orig, CANCELLED
Kutztown, PA, Kutztown, VOR–B, Amdt 1B, CANCELLED
Blanding, UT, Blanding Muni, RNAV (GPS) RWY 35, Amdt 1
Brigham City, UT, Brigham City, NDB–A, Amdt 1
Brigham City, UT, Brigham City, RNAV (GPS) RWY 35, Amdt 1
Brigham City, UT, Brigham City, Takeoff Minimums and Obstacle DP, Amdt 6
Danville, VA, Danville Rgnl, GPS RWY 20, Orig-A, CANCELLED
Danville, VA, Danville Rgnl, RNAV (GPS) RWY 2, Orig
Danville, VA, Danville Rgnl, RNAV (GPS) RWY 20, Orig
Farmville, VA, Farmville Rgnl, GPS RWY 21, Orig, CANCELLED
Farmville, VA, Farmville Rgnl, NDB RWY 3, Amdt 6
Farmville, VA, Farmville Rgnl, RNAV (GPS) RWY 3, Orig
Farmville, VA, Farmville Rgnl, RNAV (GPS) RWY 21, Orig
Manitowish Waters, WI, Manitowish Waters, Takeoff Minimums and Obstacle DP, Orig
Casper, WY, Casper/Natrona County Intl, VOR/DME RWY 3, Amdt 5
Rock Springs, WY, Rock Springs-Sweetwater County, VOR–B, Amdt 4A, CANCELLED

[FR Doc. 2010–7663 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–13–P

## PENSION BENEFIT GUARANTY CORPORATION

### 29 CFR Part 4022

### Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans prescribes interest assumptions for valuing and paying certain benefits under terminating single-employer plans. This final rule amends the benefit payments regulation to adopt interest assumptions for plans with valuation dates in May 2010. Interest assumptions are also published on PBGC's Web site (*http://www.pbgc.gov*).

**DATES:** Effective May 1, 2010.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

**SUPPLEMENTARY INFORMATION:** PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

These interest assumptions are found in two PBGC regulations: The regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) and the regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044). Assumptions under the asset allocation regulation are updated quarterly; assumptions under the benefit payments regulation are updated monthly. This final rule updates only the assumptions under the benefit payments regulation.

*Two sets of interest assumptions are prescribed under the benefit payments regulation:* (1) A set for PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by PBGC (found in Appendix B to part 4022), and (2) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology (found in Appendix C to part 4022).

This amendment (1) adds to Appendix B to part 4022 the interest assumptions for PBGC to use for its own lump-sum payments in plans with valuation dates during May 2010, and (2) adds to Appendix C to part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology for valuation dates during May 2010.

The interest assumptions that PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.00 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for April 2010, these interest assumptions represent an increase of 0.25 percent in the immediate annuity rate and are otherwise unchanged. For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during May 2010, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. *See* 5 U.S.C. 601(2).

**List of Subjects in 29 CFR Part 4022**

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

■ In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

## PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 199, as set forth below, is added to the table.

### APPENDIX B TO PART 4022—LUMP SUM INTEREST RATES FOR PBGC PAYMENTS

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | |
|---|---|---|---|---|---|---|---|---|
| | On or after | Before | | $i_1$ | $i_2$ | $i_3$ | $n_1$ | $n_2$ |
| * * | * | * | * | | * | | * | |
| 199 | 5–1–10 | 6–1–10 | 3.00 | 4.00 | 4.00 | 4.00 | 7 | 8 |

■ 3. In appendix C to part 4022, Rate Set 199, as set forth below, is added to the table.

### APPENDIX C TO PART 4022—LUMP SUM INTEREST RATES FOR PRIVATE-SECTOR PAYMENTS

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | |
|---|---|---|---|---|---|---|---|---|
| | On or after | Before | | $i_1$ | $i_2$ | $i_3$ | $n_1$ | $n_2$ |
| * * | * | * | * | | * | | * | |
| 199 | 5–1–10 | 6–1–10 | 3.00 | 4.00 | 4.00 | 4.00 | 7 | 8 |

Issued in Washington, DC, on this 6th day of April 2010.

**Vincent K. Snowbarger,**

*Acting Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 2010–8680 Filed 4–14–10; 8:45 am]

**BILLING CODE 7709–01–P**

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 83

**[Docket No. USCG–2009–0948]**

**RIN 1625–AB43**

## Inland Navigation Rules

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** By this final rule, the Coast Guard is placing the Inland Navigation Rules into the Code of Federal Regulations. This move is in accordance with the Coast Guard and Maritime Transportation Act of 2004, which repeals the Inland Navigation Rules as of the effective date of these regulations. Future updates of the Inland Navigation Rules will be accomplished through rulemaking rather than legislation.

**DATES:** This final rule is effective May 17, 2010.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–0948 and are available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2009–0948 in the "Keyword" box, and then clicking "Search."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Lieutenant Scott Medeiros, Office of Vessel Activities (CG–54133), telephone (202) 372–1565, e-mail *Scott.R.Medeiros@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

### Table of Contents for Preamble

I. Abbreviations
II. Basis and Purpose
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IV. Regulatory Analyses
A. Administrative Procedure Act
B. Regulatory Planning and Review (Executive Order 12866)
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D. Assistance for Small Entities
E. Collection of Information
F. Federalism
G. Unfunded Mandates Reform Act
H. Taking of Private Property
I. Civil Justice Reform
J. Protection of Children
K. Indian Tribal Governments
L. Energy Effects
M. Technical Standards
N. Environment

### I. Abbreviations

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

### II. Basis and Purpose

In section 303 of the Coast Guard and Maritime Transportation Authorization Act of 2004 (Pub. L. 108–293), Congress repealed Section 2 of the Inland Navigation Rules Act of 1980, found in sections 2001–2038 of Title 33 of the United States Code. These sections contain requirements for all vessels navigating on U.S. inland waters and include rules for:

- Navigation lights;
- Day shapes;
- Whistle signals;
- Conduct of vessels in restricted visibility; and
- Conduct of vessels in sight of each other.

These regulations are commonly known as the "inland rules of the road."

Congress also amended Section 3 of the Inland Navigation Rules Act of 1980 to grant the Secretary of Homeland Security authority to issue inland navigation regulations. In doing so, Congress specified that repeal of Section 2 (the inland navigation rules then in effect) would not be effective until the effective date of regulations for the inland navigation rules. This guaranteed there would be no gap in application of the inland navigation rules between being removed from the United States Code and being added to the Code of Federal Regulations (CFR).

The Secretary of Homeland Security has delegated authority to develop and enforce navigation safety regulations to the Commandant of the Coast Guard through Department of Homeland Security Delegation 0170.1, Delegation to the Commandant of the Coast Guard. The Coast Guard has decided to use the authority granted by Congress and delegated by the Secretary to move the inland navigation rules to a new Part 83 of Title 33, Code of Federal Regulations. This is the most logical place for the inland navigation rules, as 33 CFR parts 84 through 90 also contain requirements for inland navigation rules as shown in table 1. Moving the main body of the inland navigation rules to a new part 83 is consistent with the intent of Congress and puts all of the inland navigation rules in one place in the Code of Federal Regulations.

TABLE 1—EXISTING INLAND NAVIGATION RULES IN 33 CFR

| | |
|---|---|
| 33 CFR part 84 | Annex I: Positioning and technical details of lights and shapes. |
| 33 CFR part 85 | Annex II: Additional signals for fishing vessels fishing in close proximity. |
| 33 CFR part 86 | Annex III: Technical details of sound and signal appliances. |
| 33 CFR part 87 | Annex IV: Distress signals. |
| 33 CFR part 88 | Annex V: Pilot rules. |
| 33 CFR part 89 | Inland navigation rules: Implementing rules. |
| 33 CFR part 90 | Inland rules: Interpretive rules. |

In addition to having all of the inland navigation rules in one location, moving the inland navigation rules from the United States Code to the CFR will make it easier for the Coast Guard to update or revise the rules, and improve the public's opportunity for input regarding changes to the rules. Future updates to the inland navigation rules will be accomplished through rulemaking rather than legislation, and interested persons will be able to participate as required by law through the notice and comment process.

## III. Discussion of Rule

Through this final rule, the Coast Guard moves the inland navigation rules in their entirety from 33 U.S.C. 2001–2038 to new 33 CFR part 83, Inland Navigation Rules.

Although the substance of the Inland Navigation Rules has not changed, a number of conforming changes were made to maintain clarity in the Final Rule:

The subparagraphs of each rule were renumbered as necessary to conform to the CFR standard paragraph structure. To conform to CFR standard paragraph structure, second-level (level "(i)") and third-level (level "(1)") subparagraphs were renumbered to conform to the CFR standard (now designated as subparagraphs "(1)" and "(i)", respectively). For example, Rule 38 paragraph (d)(iv)(2) was renumbered to become Rule 38 paragraph (d)(4)(ii).

In § 83.185 Exemptions (Rule 38), paragraphs (a)–(c), references to "chapters 3, 4, and 5 of this title" were changed to the names of the Acts which were codified in the referenced chapter.

Also in § 83.185 Exemptions (Rule 38), in paragraph (d), references to "the effective date of these Rules" were changed to "the effective date of the Inland Navigation Rules Act of 1980 (Pub. L. 96–591). This change avoids the ambiguous term "these Rules" which in the old text referred to the statute, not the new regulations at 33 CFR part 83, and avoids inadvertently resetting compliance deadlines for vessels built before the effective date of this final rule.

Note that most of the statutes referred to in § 83.185 Exemptions (Rule 38) have been repealed. The Coast Guard intends to address the necessity of maintaining these exemptions through a future rulemaking.

## IV. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below, we summarize our analyses based on 14 of these statutes or executive orders.

### *A. Administrative Procedure Act*

The Coast Guard did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM.

Under the Administrative Procedure Act (APA) "good cause" exception at 5 U.S.C. 553(b)(B), an agency may dispense with notice and comment procedures if the agency finds that following these APA requirements would be "impracticable, unnecessary, or contrary to the public interest." *See* Jeffrey L. Lubbers, *A Guide to Federal Agency Rulemaking* (4th ed.) 105–109 (2006) for a discussion of agency findings of good cause in lieu of notice and comment procedures.

"Unnecessary" for the purpose of the good cause exceptions to the requirements of the APA, refers to "the issuance of a minor rule in which the public is not particularly interested." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act at 31 (1947). Its use should be "confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public." *Utility Solid Waste Activities Group* v. *EPA,* 236 F.3d 749, 755 (DC Cir. 2001), citing *South Carolina* v. *Block,* 558 F.Supp. 1004, 1016 (D.S.C. 1983).

This rulemaking makes no change to the substance of the Inland Navigation Rules; the only changes are to which branch of the Federal government manages the Inland Navigation Rules (the Executive, through the Department of Homeland Security and the U.S. Coast Guard, instead of Congress) and where those rules are written (the CFR instead of the U.S.C.). There will be no impact on the mariner or the public, with the exception that a mariner who seeks a change in the inland rules will have the option of requesting a regulatory change under 33 CFR 1.05–20 instead of being required to petition Congress for a legislative change. The APA's good cause exception thus applies to the notice and comment requirement, as that requirement is unnecessary for this rulemaking.

### *B. Regulatory Planning and Review (Executive Order 12866)*

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

By this final rule, the Coast Guard moves the Inland Navigation Rules in their entirety from Title 33 U.S.C. to Title 33 CFR part 83. This final rule contains requirements for all vessels navigating on U.S. inland waters, including commercial, recreational, and government vessels. We expect no additional costs to the public or industry from this final rule because all vessels that operate in the United States are currently required by statute to follow the inland navigation rules. This rule will not change the current obligations and responsibilities of mariners.

This final rule allows the Coast Guard to make more timely changes to the regulations, easing the burden of revising the rules. In this case, the Coast Guard would use the rulemaking process rather than seeking legislation.

### *C. Small Entities*

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

A Regulatory Flexibility Act (RFA) analysis is not required when the agency finds good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. The Coast Guard determined that this rule is exempt from notice and comment procedures pursuant to 5 U.S.C. 553(b)(B). Therefore, an RFA analysis is not required for this final rule. *See* the "Administrative Procedure Act" section of this rule for additional details on this determination.

### *D. Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Lieutenant

Scott Medeiros, Office of Waterways Management by telephone at 202–372–1565. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

*E. Collection of Information*

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

*F. Federalism*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

*G. Unfunded Mandates Reform Act*

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

*H. Taking of Private Property*

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

*I. Civil Justice Reform*

This 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.

*J. Protection of Children*

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

*K. Indian Tribal Governments*

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

*L. Energy Effects*

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

*M. Technical Standards*

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget (OMB), with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

*N. Environment*

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2–1, paragraphs (34)(a) and (34)(i) of the Instruction. This rule involves regulations which are editorial or procedural, such as those updating addresses or establishing application procedures, and also involves regulations in aid of navigation. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

**List of Subjects in 33 CFR Part 83**

Fishing vessels, Navigation (water), Waterways.

■ For the reasons discussed in the preamble, the Coast Guard adds part 83 to 33 CFR Subchapter E of Chapter I to read as follows:

**SUBCHAPTER E—INLAND NAVIGATION RULES**

## PART 83—RULES

### Subpart A—General

Sec.
83.01 Application (Rule 1).
83.02 Responsibility (Rule 2).
83.03 Definitions (Rule 3).

### Subpart B—Steering and Sailing Rules

**Conduct of Vessels in Any Condition of Visibility**

83.04 Application (Rule 4).
83.05 Look-out (Rule 5).
83.06 Safe speed (Rule 6).
83.07 Risk of collision (Rule 7).
83.08 Action to avoid collision (Rule 8).
83.09 Narrow channels (Rule 9).
83.10 Traffic separation schemes (Rule 10).

**Conduct of Vessels in Sight of One Another**

83.11 Application (Rule 11).
83.12 Sailing vessels (Rule 12).
83.13 Overtaking (Rule 13).
83.14 Head-on situation (Rule 14).
83.15 Crossing situation (Rule 15).
83.16 Action by give-way vessel (Rule 16).
83.17 Action by stand-on vessel (Rule 17).
83.18 Responsibilities between vessels (Rule 18).

**Conduct of Vessels in Restricted Visibility**

83.19 Conduct of vessels in restricted visibility (Rule 19).

### Subpart C—Lights and Shapes

83.20 Application (Rule 20).
83.21 Definitions (Rule 21).
83.22 Visibility of lights (Rule 22).

83.23 Power-driven vessels underway (Rule 23).
83.24 Towing and pushing (Rule 24).
83.25 Sailing vessels underway and vessels under oars (Rule 25).
83.26 Fishing vessels (Rule 26).
83.27 Vessels not under command or restricted in their ability to maneuver (Rule 27).
83.28 [Reserved](Rule 28).
83.29 Pilot vessels (Rule 29).
83.30 Anchored vessels and vessels aground (Rule 30).
83.31 Seaplanes (Rule 31).

**Subpart D—Sound and Light Signals**

83.32 Definitions (Rule 32).
83.33 Equipment for sound signals (Rule 33).
83.34 Maneuvering and warning signals (Rule 34).
83.35 Sound signals in restricted visibility (Rule 35).
83.36 Signals to attract attention (Rule 36).
83.37 Distress signals (Rule 37).

**Subpart E—Exemptions**

83.38 Exemptions (Rule 38).

**Authority:** Sec. 303, Pub. L. 108–293, 118 Stat. 1028 (33 U.S.C. 2001); Department of Homeland Security Delegation No. 0170.1.

## Subpart A—General

### § 83.01 Application (Rule 1).

(a) *United States inland waters and Canadian waters of the Great Lakes.* These Rules apply to all vessels upon the inland waters of the United States, and to vessels of the United States on the Canadian waters of the Great Lakes to the extent that there is no conflict with Canadian law.

(b) *International Regulations.*

(1) These Rules constitute special rules made by an appropriate authority within the meaning of Rule 1(b) of the International Regulations.

(2) All vessels complying with the construction and equipment requirements of the International Regulations are considered to be in compliance with these Rules.

(c) *Special rules.* Nothing in these Rules shall interfere with the operation of any special rules made by the Secretary of the Navy with respect to additional station or signal lights and shapes or whistle signals for ships of war and vessels proceeding under convoy, or by the Secretary with respect to additional station or signal lights and shapes for fishing vessels engaged in fishing as a fleet. These additional station or signal lights and shapes or whistle signals shall, so far as possible, be such that they cannot be mistaken for any light, shape, or signal authorized elsewhere under these Rules. Notice of such special rules shall be published in the **Federal Register** and, after the effective date specified in such notice, they shall have effect as if they were a part of these Rules.

(d) *Traffic regulation schemes; vessel traffic service regulations.* Traffic separation schemes may be established for the purpose of these Rules. Vessel traffic service regulations may be in effect in certain areas.

(e) *Alternative compliance.* Whenever the Secretary determines that a vessel or class of vessels of special construction or purpose cannot comply fully with the provisions of any of these Rules with respect to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, the vessel shall comply with such other provisions in regard to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, as the Secretary shall have determined to be the closest possible compliance with these Rules. The Secretary may issue a certificate of alternative compliance for a vessel or class of vessels specifying the closest possible compliance with these Rules. The Secretary of the Navy shall make these determinations and issue certificates of alternative compliance for vessels of the Navy.

(f) *Acceptance of certificates of alternative compliance from contracting parties to International Regulations.* The Secretary may accept a certificate of alternative compliance issued by a contracting party to the International Regulations if he determines that the alternative compliance standards of the contracting party are substantially the same as those of the United States.

### § 83.02 Responsibility (Rule 2).

(a) *Exoneration.* Nothing in these Rules shall exonerate any vessel, or the owner, master, or crew thereof, from the consequences of any neglect to comply with these Rules or of the neglect of any precaution which may be required by the ordinary practice of seamen, or by the special circumstances of the case.

(b) *Departure from rules when necessary to avoid immediate danger.* In construing and complying with these Rules due regard shall be had to all dangers of navigation and collision and to any special circumstances, including the limitations of the vessels involved, which may make a departure from these Rules necessary to avoid immediate danger.

### § 83.03 Definitions (Rule 3).

For the purpose of these Rules and this chapter, except where the context otherwise requires:

(a) *Vessel* includes every description of water craft, including nondisplacement craft and seaplanes, used or capable of being used as a means of transportation on water;

(b) *Power-driven vessel* means any vessel propelled by machinery;

(c) *Sailing vessel* means any vessel under sail provided that propelling machinery, if fitted, is not being used;

(d) *Vessel engaged in fishing* means any vessel fishing with nets, lines, trawls, or other fishing apparatus which restricts maneuverability, but does not include a vessel fishing with trolling lines or other fishing apparatus which do not restrict maneuverability;

(e) *Seaplane* includes any aircraft designed to maneuver on the water;

(f) *Vessel not under command* means a vessel which, through some exceptional circumstance, is unable to maneuver as required by these Rules and is therefore unable to keep out of the way of another vessel;

(g) *Vessel restricted in her ability to maneuver* means a vessel which, from the nature of her work, is restricted in her ability to maneuver as required by these Rules and is therefore unable to keep out of the way of another vessel; vessels restricted in their ability to maneuver include, but are not limited to:

(1) A vessel engaged in laying, servicing, or picking up a navigation mark, submarine cable, or pipeline;

(2) A vessel engaged in dredging, surveying, or underwater operations;

(3) A vessel engaged in replenishment or transferring persons, provisions, or cargo while underway;

(4) A vessel engaged in the launching or recovery of aircraft;

(5) A vessel engaged in mineclearance operations; and

(6) A vessel engaged in a towing operation such as severely restricts the towing vessel and her tow in their ability to deviate from their course.

(h) *Underway* means that a vessel is not at anchor, or

made fast to the shore, or aground;

(i) *Length* and *breadth* of a vessel mean her length overall and greatest breadth;

(j) Vessels shall be deemed to be in sight of one another only when one can be observed visually from the other;

(k) *Restricted visibility* means any condition in which visibility is restricted by fog, mist, falling snow, heavy rainstorms, sandstorms, or any other similar causes;

(l) *Western Rivers* means the Mississippi River, its tributaries, South Pass, and Southwest Pass, to the navigational demarcation lines dividing the high seas from harbors, rivers, and

other inland waters of the United States, and the Port Allen-Morgan City Alternate Route, and that part of the Atchafalaya River above its junction with the Port Allen-Morgan City Alternate Route including the Old River and the Red River;

(m) *Great Lakes* means the Great Lakes and their connecting and tributary waters including the Calumet River as far as the Thomas J. O'Brien Lock and Controlling Works (between mile 326 and 327), the Chicago River as far as the east side of the Ashland Avenue Bridge (between mile 321 and 322), and the Saint Lawrence River as far east as the lower exit of Saint Lambert Lock;

(n) *Secretary* means the Secretary of the Department in which the Coast Guard is Operating;

(o) *Inland Waters* means the navigable waters of the United States shoreward of the navigational demarcation lines dividing the high seas from harbors, rivers, and other inland waters of the United States and the waters of the Great Lakes on the United States side of the International Boundary;

(p) *Inland Rules* or *Rules* mean the Inland Navigational Rules and the annexes thereto, which govern the conduct of vessels and specify the lights, shapes, and sound signals that apply on inland waters; and

(q) *International Regulations* means the International Regulations for Preventing Collisions at Sea, 1972, including annexes currently in force for the United States.

## Subpart B—Steering and Sailing Rules

### Conduct of Vessels in Any Condition of Visibility

#### § 83.04 Application (Rule 4).

Rules in this subpart apply in any condition of visibility.

#### § 83.05 Look-out (Rule 5).

Every vessel shall at all times maintain a proper look-out by sight and hearing as well as by all available means appropriate in the prevailing circumstances and conditions so as to make a full appraisal of the situation and of the risk of collision.

#### § 83.06 Safe speed (Rule 6).

Every vessel shall at all times proceed at a safe speed so that she can take proper and effective action to avoid collision and be stopped within a distance appropriate to the prevailing circumstances and conditions.

In determining a safe speed the following factors shall be among those taken into account:

(a) By all vessels:

(1) The state of visibility;

(2) The traffic density including concentration of fishing vessels or any other vessels;

(3) The maneuverability of the vessel with special reference to stopping distance and turning ability in the prevailing conditions;

(4) At night the presence of background light such as from shores lights or from back scatter of her own lights;

(5) The state of wind, sea, and current, and the proximity of navigational hazards;

(6) The draft in relation to the available depth of water.

(b) Additionally, by vessels with operational radar:

(1) The characteristics, efficiency and limitations of the radar equipment;

(2) Any constraints imposed by the radar range scale in use;

(3) The effect on radar detection of the sea state, weather, and other sources of interference;

(4) The possibility that small vessels, ice and other floating objects may not be detected by radar at an adequate range;

(5) The number, location, and movement of vessels detected by radar; and

(6) The more exact assessment of the visibility that may be possible when radar is used to determine the range of vessels or other objects in the vicinity.

#### § 83.07 Risk of collision (Rule 7).

(a) *Determination if risk exists.* Every vessel shall use all available means appropriate to the prevailing circumstances and conditions to determine if risk of collision exists. If there is any doubt such risk shall be deemed to exist.

(b) *Radar.* Proper use shall be made of radar equipment if fitted and operational, including long-range scanning to obtain early warning of risk of collision and radar plotting or equivalent systematic observation of detected objects.

(c) *Scanty information.* Assumptions shall not be made on the basis of scanty information, especially scanty radar information.

(d) *Considerations taken into account in determining if risk exists.* In determining if risk of collision exists the following considerations shall be among those taken into account:

(1) Such risk shall be deemed to exist if the compass bearing of an approaching vessel does not appreciably change; and

(2) Such risk may sometimes exist even when an appreciable bearing change is evident, particularly when approaching a very large vessel or a tow or when approaching a vessel at close range.

#### § 83.08 Action to avoid collision (Rule 8).

(a) *General characteristics of action taken to avoid collision.* Any action taken to avoid collision shall, if the circumstances of the case admit, be positive, made in ample time and with due regard to the observance of good seamanship.

(b) *Readily apparent alterations in course or speed.* Any alteration of course or speed to avoid collision shall, if the circumstances of the case admit, be large enough to be readily apparent to another vessel observing visually or by radar; a succession of small alterations of course or speed should be avoided.

(c) *Alteration of course to avoid close-quarters situation.* If there is sufficient sea room, alteration of course alone may be the most effective action to avoid a close-quarters situation provided that it is made in good time, is substantial and does not result in another close-quarters situation.

(d) *Action to result in passing at safe distance.* Action taken to avoid collision with another vessel shall be such as to result in passing at a safe distance. The effectiveness of the action shall be carefully checked until the other vessel is finally past and clear.

(e) *Slackening of vessel speed; stopping or reversing means of propulsion.* If necessary to avoid collision or allow more time to assess the situation, a vessel shall slacken her speed or take all way off by stopping or reversing her means of propulsion.

(f) *Early action to allow room for safe passage:*

(1) A vessel which, by any of these Rules, is required not to impede the passage or safe passage of another vessel shall, when required by the circumstances of the case, take early action to allow sufficient sea room for the safe passage of the other vessel.

(2) A vessel required not to impede the passage or safe passage of another vessel is not relieved of this obligation if approaching the other vessel so as to involve risk of collision and shall, when taking action, have full regard to the action which may be required by the Rules of this part.

(3) A vessel the passage of which is not to be impeded remains fully obliged to comply with the Rules of this part when the two vessels are approaching one another so as to involve risk of collision.

#### § 83.09 Narrow channels (Rule 9).

(a) *Keeping near to outer limit of channel or fairway which lies on vessel's starboard side; exception.*

(1) A vessel proceeding along the course of a narrow channel or fairway

shall keep as near to the outer limit of the channel or fairway which lies on her starboard side as is safe and practicable.

(2) Notwithstanding paragraph (a)(1) and Rule 14(a), a power-driven vessel operating in narrow channels or fairways on the Great Lakes, Western Rivers, or waters specified by the Secretary, and proceeding downbound with a following current shall have the right-of-way over an upbound vessel, shall propose the manner and place of passage, and shall initiate the maneuvering signals prescribed by Rule 34(a)(1), as appropriate. The vessel proceeding upbound against the current shall hold as necessary to permit safe passing.

(b) *Vessels of less than 20 meters in length; sailing vessels.* A vessel of less than 20 meters in length or a sailing vessel shall not impede the passage of a vessel that can safely navigate only within a narrow channel or fairway.

(c) *Vessels engaged in fishing.* A vessel engaged in fishing shall not impede the passage of any other vessel navigating within a narrow channel or fairway.

(d) *Crossing narrow channels or fairways.* A vessel shall not cross a narrow channel or fairway if such crossing impedes the passage of a vessel which can safely navigate only within that channel or fairway. The latter vessel shall use the danger signal prescribed in Rule 34(d) if in doubt as to the intention of the crossing vessel.

(e) *Overtaking vessels.*

(1) In a narrow channel or fairway when overtaking, the power-driven vessel intending to overtake another power-driven vessel shall indicate her intention by sounding the appropriate signal prescribed in Rule 34(c) and take steps to permit safe passing. The power-driven vessel being overtaken, if in agreement, shall sound the same signal and may, if specifically agreed to, take steps to permit safe passing. If in doubt she shall sound the danger signal prescribed in Rule 34(d).

(2) This Rule does not relieve the overtaking vessel of her obligation under Rule 13.

(f) *Areas of obscured visibility due to intervening obstructions.* A vessel nearing a bend or an area of a narrow channel or fairway where other vessels may be obscured by an intervening obstruction shall navigate with particular alertness and caution and shall sound the appropriate signal prescribed in Rule 34(e).

(g) *Avoidance of anchoring in narrow channels.* Every vessel shall, if the circumstances of the case admit, avoid anchoring in a narrow channel.

**§ 83.10 Traffic separation schemes (Rule 10).**

(a) *Obligations under other Rules unaffected.* This Rule applies to traffic separation schemes and does not relieve any vessel of her obligation under any other Rule.

(b) *Duties for vessel using scheme.* A vessel using a traffic separation scheme shall:

(1) Proceed in the appropriate traffic lane in the general direction of traffic flow for that lane;

(2) So far as practicable keep clear of a traffic separation line or separation zone;

(3) Normally join or leave a traffic lane at the termination of the lane, but when joining or leaving from either side shall do so at as small an angle to the general direction of traffic flow as practicable.

(c) *Crossing traffic lanes.* A vessel shall, so far as practicable, avoid crossing traffic lanes but if obliged to do so shall cross on a heading as nearly as practicable at right angles to the general direction of traffic flow.

(d) *Use of inshore traffic lane.*

(1) A vessel shall not use an inshore traffic zone when she can safely use the appropriate traffic lane within the adjacent traffic separation scheme. However, vessels of less than twenty meters in length, sailing vessels, and vessels engaged in fishing may use the inshore traffic zone.

(2) Notwithstanding subparagraph (d)(1), a vessel may use an inshore traffic zone when en route to or from a port, offshore installation or structure, pilot station, or any other place situated within the inshore traffic zone, or to avoid immediate danger.

(e) *Entering separation zone or crossing separation line.* A vessel other than a crossing vessel or a vessel joining or leaving a lane shall not normally enter a separation zone or cross a separation line except:

(1) In cases of emergency to avoid immediate danger; or

(2) To engage in fishing within a separation zone.

(f) *Caution in areas near termination of scheme.* A vessel navigating in areas near the terminations of traffic separation schemes shall do so with particular caution.

(g) *Anchoring.* A vessel shall so far as practicable avoid anchoring in a traffic separation scheme or in areas near its terminations.

(h) *Avoidance of scheme.* A vessel not using a traffic separation scheme shall avoid it by as wide a margin as is practicable.

(i) *Fishing vessels.* A vessel engaged in fishing shall not impede the passage of any vessel following a traffic lane.

(j) *Power-driven vessels.* A vessel of less than twenty meters in length or a sailing vessel shall not impede the safe passage of a power-driven vessel following a traffic lane.

(k) *Exemption; maintenance of safety of navigation.* A vessel restricted in her ability to maneuver when engaged in an operation for the maintenance of safety of navigation in a traffic separation scheme is exempted from complying with this Rule to the extent necessary to carry out the operation.

(l) *Exemption; laying, servicing, or picking up submarine cable.*

A vessel restricted in her ability to maneuver when engaged in an operation for the laying, servicing, or picking up of a submarine cable, within a traffic separation scheme, is exempted from complying with this Rule to the extent necessary to carry out the operation.

## Conduct of Vessels in Sight of One Another

**§ 83.11 Application (Rule 11).**

Rules in this subpart apply to vessels in sight of one another.

**§ 83.12 Sailing vessels (Rule 12).**

(a) Keeping out of the way. When two sailing vessels are approaching one another, so as to involve risk of collision, one of them shall keep out of the way of the other as follows:

(1) When each has the wind on a different side, the vessel which has the wind on the port side shall keep out of the way of the other;

(2) When both have the wind on the same side, the vessel which is to windward shall keep out of the way of the vessel which is to leeward; and

(3) If a vessel with the wind on the port side sees a vessel to windward and cannot determine with certainty whether the other vessel has the wind on the port or on the starboard side, she shall keep out of the way of the other.

(b) *Windward side.* For the purpose of this Rule the windward side shall be deemed to be the side opposite to that on which the mainsail is carried or, in the case of a square-rigged vessel, the side opposite to that on which the largest fore-and-aft sail is carried.

**§ 83.13 Overtaking (Rule 13).**

(a) *Overtaking vessel to keep out of the overtaken vessel's way.* Notwithstanding anything contained in Rules 4 through 18, any vessel overtaking any other shall keep out of the way of the vessel being overtaken.

(b) *Overtaking vessel defined.* A vessel shall be deemed to be overtaking when coming up with another vessel from a direction more than 22.5 degrees abaft her beam; that is, in such a

position with reference to the vessel she is overtaking, that at night she would be able to see only the sternlight of that vessel but neither of her sidelights.

(c) *Assumption that vessel is overtaking another in cases of doubt.* When a vessel is in any doubt as to whether she is overtaking another, she shall assume that this is the case and act accordingly.

(d) *Overtaking vessel to become crossing vessel only when finally past and clear.* Any subsequent alteration of the bearing between the two vessels shall not make the overtaking vessel a crossing vessel within the meaning of these Rules or relieve her of the duty of keeping clear of the overtaken vessel until she is finally past and clear.

**§ 83.14 Head-on situation (Rule 14).**

(a) *Course alterations to starboard; port side passage.* Unless otherwise agreed, when two power-driven vessels are meeting on reciprocal or nearly reciprocal courses so as to involve risk of collision each shall alter her course to starboard so that each shall pass on the port side of the other.

(b) *Existence of head-on situation.* Such a situation shall be deemed to exist when a vessel sees the other ahead or nearly ahead and by night she could see the masthead lights of the other in a line or nearly in a line or both sidelights and by day she observes the corresponding aspect of the other vessel.

(c) *Assumption that head-on situation exists in cases of doubt.* When a vessel is in any doubt as to whether such a situation exists she shall assume that it does exist and act accordingly.

(d) *Vessel operating on Great Lakes, Western Rivers, or other specified waters, and proceeding downbound with following current.* Notwithstanding paragraph (a) of this Rule, a power-driven vessel operating on the Great Lakes, Western Rivers, or waters specified by the Secretary, and proceeding downbound with a following current shall have the right-of-way over an upbound vessel, shall propose the manner of passage, and shall initiate the maneuvering signals prescribed by Rule 34(a)(1), as appropriate.

**§ 83.15 Crossing situation (Rule 15).**

(a) *Vessel which must keep out of the other vessel's way.* When two power-driven vessels are crossing so as to involve risk of collision, the vessel which has the other on her starboard side shall keep out of the way and shall, if the circumstances of the case admit, avoid crossing ahead of the other vessel.

(b) *Vessels crossing river.* Notwithstanding paragraph (a), on the Great Lakes, Western Rivers, or water specified by the Secretary, a power-driven vessel crossing a river shall keep out of the way of a power-driven vessel ascending or descending the river.

**§ 83.16 Action by give-way vessel (Rule 16).**

Every vessel which is directed to keep out of the way of another vessel shall, so far as possible, take early and substantial action to keep well clear.

**§ 83.17 Action by stand-on vessel (Rule 17).**

(a) *Stand-on vessel to keep course and speed; action allowed when give-way vessel fails to take appropriate action.*

(1) Where one of two vessels is to keep out of the way, the other shall keep her course and speed.

(2) The latter vessel may, however, take action to avoid collision by her maneuver alone, as soon as it becomes apparent to her that the vessel required to keep out of the way is not taking appropriate action in compliance with these Rules.

(b) *Action by stand-on vessel allowed when action by give-way vessel alone cannot avoid collision.* When, from any cause, the vessel required to keep her course and speed finds herself so close that collision cannot be avoided by the action of the give-way vessel alone, she shall take such action as will best aid to avoid collision.

(c) *Crossing situations.* A power-driven vessel which takes action in a crossing situation in accordance with subparagraph (a)(2) of this Rule to avoid collision with another power-driven vessel shall, if the circumstances of the case admit, not alter course to port for a vessel on her own port side.

(d) *Give-way vessel not relieved of obligation to keep out of the way.* This Rule does not relieve the give-way vessel of her obligation to keep out of the way.

**§ 83.18 Responsibilities between vessels (Rule 18).**

Except where Rules 9, 10, and 13 otherwise require:

(a) *Power-driven vessels underway.* A power-driven vessel underway shall keep out of the way of:

(1) A vessel not under command;

(2) A vessel restricted in her ability to maneuver;

(3) A vessel engaged in fishing; and

(4) A sailing vessel.

(b) *Sailing vessels underway.* A sailing vessel underway shall keep out of the way of:

(1) A vessel not under command;

(2) A vessel restricted in her ability to maneuver; and

(3) A vessel engaged in fishing.

(c) *Vessels engaged in fishing when underway.* A vessel engaged in fishing when underway shall, so far as possible, keep out of the way of:

(1) A vessel not under command; and

(2) A vessel restricted in her ability to maneuver.

(d) *Seaplanes on the water.* A seaplane on the water shall, in general, keep well clear of all vessels and avoid impeding their navigation. In circumstances, however, where risk of collision exists, she shall comply with the Rules of this part.

## Conduct of Vessels in Restricted Visibility

**§ 83.19 Conduct of vessels in restricted visibility (Rule 19).**

(a) *Vessels to which rule applies.* This Rule applies to vessels not in sight of one another when navigating in or near an area of restricted visibility.

(b) *Safe speed; engines ready for immediate maneuver.* Every vessel shall proceed at a safe speed adapted to the prevailing circumstances and conditions of restricted visibility. A power-driven vessel shall have her engines ready for immediate maneuver.

(c) *Due regard to prevailing circumstances and conditions.* Every vessel shall have due regard to the prevailing circumstances and conditions of restricted visibility when complying with Rules 4 through 10.

(d) *Detection of vessel by radar alone.* A vessel which detects by radar alone the presence of another vessel shall determine if a close-quarters situation is developing or risk of collision exists. If so, she shall take avoiding action in ample time, provided that when such action consists of an alteration of course, so far as possible the following shall be avoided:

(1) An alteration of course to port for a vessel forward of the beam, other than for a vessel being overtaken; and

(2) An alteration of course toward a vessel abeam or abaft the beam.

(e) *Reduction of speed to minimum.* Except where it has been determined that a risk of collision does not exist, every vessel which hears apparently forward of her beam the fog signal of another vessel, or which cannot avoid a close-quarters situation with another vessel forward of her beam, shall reduce her speed to the minimum at which she can be kept on course. She shall if necessary take all her way off and, in any event, navigate with extreme caution until danger of collision is over.

## Subpart C—Lights and Shapes

### § 83.20 Application (Rule 20).

(a) *Compliance in all weathers.* Rules in this part shall be complied with in all weathers.

(b) *Rules concerning lights complied with from sunset to sunrise; other lights.* The Rules concerning lights shall be complied with from sunset to sunrise, and during such times no other lights shall be exhibited, except such lights as cannot be mistaken for the lights specified in these Rules or do not impair their visibility or distinctive character, or interfere with the keeping of a proper lookout.

(c) *Lights during daylight hours in restricted visibility; other circumstances.* The lights prescribed by these Rules shall, if carried, also be exhibited from sunrise to sunset in restricted visibility and may be exhibited in all other circumstances when it is deemed necessary.

(d) *Rules concerning shapes; compliance by day.* The Rules concerning shapes shall be complied with by day.

(e) *Annex.* The lights and shapes specified in these Rules shall comply with the provisions of Annex I of these Rules.

### § 83.21 Definitions (Rule 21).

(a) *Masthead light* means a white light placed over the fore and aft centerline of the vessel showing an unbroken light over an arc of the horizon of 225 degrees and so fixed as to show the light from right ahead to 22.5 degrees abaft the beam on either side of the vessel, except that on a vessel of less than 12 meters in length the masthead light shall be placed as nearly as practicable to the fore and aft centerline of the vessel.

(b) *Sidelights* mean a green light on the starboard side and a red light on the port side each showing an unbroken light over an arc of the horizon of 112.5 degrees and so fixed as to show the light from right ahead to 22.5 degrees abaft the beam on its respective side. On a vessel of less than 20 meters in length the side lights may be combined in one lantern carried on the fore and aft centerline of the vessel, except that on a vessel of less than 12 meters in length the sidelights when combined in one lantern shall be placed as nearly as practicable to the fore and aft centerline of the vessel.

(c) *Sternlight* means a white light placed as nearly as practicable at the stern showing an unbroken light over an arc of the horizon of 135 degrees and so fixed as to show the light 67.5 degrees from right aft on each side of the vessel.

(d) *Towing light* means a yellow light having the same characteristics as the "sternlight" defined in paragraph (c) of this Rule.

(e) *All-round light* means a light showing an unbroken light over an arc of the horizon of 360 degrees.

(f) *Flashing light* means a light flashing at regular intervals at a frequency of 120 flashes or more per minute.

(g) *Special flashing light* means a yellow light flashing at regular intervals at a frequency of 50 to 70 flashes per minute, placed as far forward and as nearly as practicable on the fore and aft centerline of the tow and showing an unbroken light over an arc of the horizon of not less than 180 degrees nor more than 225 degrees and so fixed as to show the light from right ahead to abeam and no more than 22.5 degrees abaft the beam on either side of the vessel.

### § 83.22 Visibility of lights (Rule 22).

The lights prescribed in these Rules shall have an intensity as specified in Annex I to these Rules, so as to be visible at the following minimum ranges:

(a) *Vessel of 50 meters or more in length.* In a vessel of 50 meters or more in length:

(1) A masthead light, 6 miles;

(2) A sidelight, 3 miles;

(3) A sternlight, 3 miles;

(4) A towing light, 3 miles;

(5) A white, red, green or yellow all-round light, 3 miles; and

(6) A special flashing light, 2 miles.

(b) Vessels of 12 meters or more in length but less than 50 meters in length. In a vessel of 12 meters or more in length but less than 50 meters in length:

(1) A masthead light, 5 miles; except that where the length of the vessel is less than 20 meters, 3 miles;

(2) A sidelight, 2 miles;

(3) A sternlight, 2 miles;

(4) A towing light, 2 miles;

(5) A white, red, green or yellow all-round light, 2 miles; and

(6) A special flashing light, 2 miles.

(c) *Vessels of less than 12 meters in length.* In a vessel of less than 12 meters in length:

(1) A masthead light, 2 miles;

(2) A sidelight, 1 mile;

(3) A sternlight, 2 miles;

(4) A towing light, 2 miles;

(5) A white, red, green or yellow all-round light, 2 miles; and

(6) A special flashing light, 2 miles.

(d) *An inconspicuous, partly submerged vessel or objects being towed.* In an inconspicuous, partly submerged vessel or objects being towed:

(1) A white all-round light, 3 miles.

### § 83.23 Power-driven vessels underway (Rule 23).

(a) *Lights exhibited by power-driven vessels underway.* A power-driven vessel underway shall exhibit:

(1) A masthead light forward;

(2) A second masthead light abaft of and higher than the forward one; except that a vessel of less than 50 meters in length shall not be obliged to exhibit such light but may do so;

(3) Sidelights; and

(4) A sternlight.

(b) *Air-cushion vessels.* An air-cushion vessel when operating in the nondisplacement mode shall, in addition to the lights prescribed in paragraph (a) of this Rule, exhibit an all-round flashing yellow light where it can best be seen.

(c) *Alternative lights for power-driven vessels of less than 12 meters in length.* A power-driven vessel of less than 12 meters in length may, in lieu of the lights prescribed in paragraph (a) of this Rule, exhibit an all-round white light and sidelights.

(d) *Power-driven vessels when operating on Great Lakes.* A power-driven vessel when operating on the Great Lakes may carry an all-round white light in lieu of the second masthead light and sternlight prescribed in paragraph (a) of this Rule. The light shall be carried in the position of the second masthead light and be visible at the same minimum range.

### § 83.24 Towing and pushing (Rule 24).

(a) *A power-driven vessel when towing astern.* A power-driven vessel when towing astern shall exhibit:

(1) Instead of the light prescribed either in Rule 23(a)(1) or 23(a)(2), two masthead lights in a vertical line. When the length of the tow, measuring from the stern of the towing vessel to the after end of the tow exceeds 200 meters, three such lights in a vertical line;

(2) Sidelights;

(3) A sternlight;

(4) A towing light in a vertical line above the sternlight; and

(5) When the length of the tow exceeds 200 meters, a diamond shape where it can best be seen.

(b) *Pushing vessel and pushed vessel rigidly connected in composite unit.* When a pushing vessel and a vessel being pushed ahead are rigidly connected in a composite unit they shall be regarded as a power-driven vessel and exhibit the lights prescribed in Rule 23.

(c) *A power-driven vessel when pushing ahead or towing alongside.* A power-driven vessel when pushing

ahead or towing alongside, except as required by paragraphs (b) and (1) of this Rule, shall exhibit:

(1) Instead of the light prescribed either in Rule 23(a)(1) or 23(a)(2), two masthead lights in a vertical line;

(2) Sidelights; and

(3) Two towing lights in a vertical line.

(d) *Compliance with other requirements.* A power-driven vessel to which paragraphs (a) or (c) of this Rule apply shall also comply with Rule 23(a)(1) and 23(a)(2).

(e) *Vessels being towed.* A vessel or object other than those referred to in paragraph (g) of this Rule being towed shall exhibit:

(1) Sidelights;

(2) A sternlight; and

(3) When the length of the tow exceeds 200 meters, a diamond shape where it can best be seen.

(f) *Vessels being towed alongside or pushed in a group.* Provided that any number of vessels being towed alongside or pushed in a group shall be lighted as one vessel, except as provided in paragraph (3)—

(1) A vessel being pushed ahead, not being part of a composite unit, shall exhibit at the forward end, sidelights and a special flashing light;

(2) A vessel being towed alongside shall exhibit a sternlight and at the forward end, sidelights and a special flashing light; and

(3) When vessels are towed alongside on both sides of the towing vessels a sternlight shall be exhibited on the stern of the outboard vessel on each side of the towing vessel, and a single set of sidelights as far forward and as far outboard as is practicable, and a single special flashing light.

(g) *An inconspicuous, partly submerged vessel or object being towed.* An inconspicuous, partly submerged vessel or object being towed shall exhibit:

(1) If it is less than 25 meters in breadth, one all-round white light at or near each end;

(2) If it is 25 meters or more in breadth, four all-round white lights to mark its length and breadth;

(3) If it exceeds 100 meters in length, additional all-round white lights between the lights prescribed in subparagraphs (1) and (2) so that the distance between the lights shall not exceed 100 meters: Provided, that any vessels or objects being towed alongside each other shall be lighted as one vessel or object;

(4) A diamond shape at or near the aftermost extremity of the last vessel or object being towed; and

(5) The towing vessel may direct a searchlight in the direction of the tow to indicate its presence to an approaching vessel.

(h) *Alternative lighting of vessel or object being towed.* Where from any sufficient cause it is impracticable for a vessel or object being towed to exhibit the lights prescribed in paragraph (e) or (g) of this Rule, all possible measures shall be taken to light the vessel or object towed or at least to indicate the presence of the unlighted vessel or object.

(i) *Western Rivers or other specified waters; exception.* Notwithstanding paragraph (c), on the Western Rivers (except below the Huey P. Long Bridge on the Mississippi River) and on waters specified by the Secretary, a power-driven vessel when pushing ahead or towing alongside, except as paragraph (b) applies, shall exhibit:

(1) Sidelights; and

(2) Two towing lights in a vertical line.

(j) *Towing another vessel in distress or otherwise in need of assistance.* Where from any sufficient cause it is impracticable for a vessel not normally engaged in towing operations to display the lights prescribed by paragraph (a), (c) or (i) of this Rule, such vessel shall not be required to exhibit those lights when engaged in towing another vessel in distress or otherwise in need of assistance. All possible measures shall be taken to indicate the nature of the relationship between the towing vessel and the vessel being assisted. The searchlight authorized by Rule 36 may be used to illuminate the tow.

**§ 83.25 Sailing vessels underway and vessels under oars (Rule 25).**

(a) *Sailing vessels underway.* A sailing vessel underway shall exhibit:

(1) Sidelights; and

(2) A sternlight.

(b) *Sailing vessels of less than 20 meters in length.* In a sailing vessel of less than 20 meters in length the lights prescribed in paragraph (a) of this Rule may be combined in one lantern carried at or near the top of the mast where it can best be seen.

(c) *Additional lights.* A sailing vessel underway may, in addition to the lights prescribed in paragraph (a) of this Rule, exhibit at or near the top of the mast, where they can best be seen, two all-round lights in a vertical line, the upper being red and the lower green, but these lights shall not be exhibited in conjunction with the combined lantern permitted by paragraph (b) of this Rule.

(d) *Sailing vessels of less than 7 meters in length; vessels under oars.*

(1) A sailing vessel of less than 7 meters in length shall, if practicable, exhibit the lights prescribed in paragraph (a) or (b) of this Rule, but if she does not, she shall have ready at hand an electric torch or lighted lantern showing a white light which shall be exhibited in sufficient time to prevent collision.

(2) A vessel under oars may exhibit the lights prescribed in this Rule for sailing vessels, but if she does not, she shall have ready at hand an electric torch or lighted lantern showing a white light which shall be exhibited in sufficient time to prevent collision.

(e) *Vessels proceeding under sail.* A vessel proceeding under sail when also being propelled by machinery shall exhibit forward where it can best be seen a conical shape, apex downward. A vessel of less than 12 meters in length is not required to exhibit this shape, but may do so.

**§ 83.26 Fishing vessels (Rule 26).**

(a) *Exhibition of only prescribed lights and shapes.* A vessel engaged in fishing, whether underway or at anchor, shall exhibit only the lights and shapes prescribed in this Rule.

(b) *Vessels engaged in trawling.* A vessel when engaged in trawling, by which is meant the dragging through the water of a dredge net or other apparatus used as a fishing appliance, shall exhibit:

(1) Two all-round lights in a vertical line, the upper being green and the lower white, or a shape consisting of two cones with their apexes together in a vertical line one above the other;

(2) A masthead light abaft of and higher than the all-round green light; a vessel of less than 50 meters in length shall not be obliged to exhibit such a light but may do so; and

(3) When making way through the water, in addition to the lights prescribed in this paragraph, sidelights and a sternlight.

(c)*Vessels engaged in fishing other than trawling.* A vessel engaged in fishing, other than trawling, shall exhibit:

(1) Two all-round lights in a vertical line, the upper being green and the lower white, or a shape consisting of two cones with their apexes together in a vertical line one above the other;

(2) A masthead light abaft of and higher than the all-round green light; a vessel of less than 50 meters in length shall not be obliged to exhibit such a light but may do so; and

(3) When making way through the water, in addition to the lights prescribed in this paragraph, sidelights and a sternlight.

(c) *Vessels engaged in fishing other than trawling.* A vessel engaged in

fishing, other than trawling, shall exhibit:

(1) Two all-round lights in a vertical line, the upper being red and the lower white, or a shape consisting of two cones with apexes together in a vertical line one above the other;

(2) When there is outlying gear extending more than 150 meters horizontally from the vessel, an all-round white light or a cone apex upward in the direction of the gear; and

(3) When making way through the water, in addition to the lights prescribed in this paragraph, sidelights and a sternlight.

(d) *Vessels engaged in fishing in close proximity to other vessels engaged in fishing.* The additional signals described in Annex II to these Rules apply to a vessel engaged in fishing in close proximity to other vessels engaged in fishing.

(e) *Vessels when not engaged in fishing.* A vessel when not engaged in fishing shall not exhibit the lights or shapes prescribed in this Rule, but only those prescribed for a vessel of her length.

**§ 83.27 Vessels not under command or restricted in their ability to maneuver (Rule 27).**

(a) *Vessels not under command.* A vessel not under command shall exhibit:

(1) Two all-round red lights in a vertical line where they can best be seen;

(2) Two balls or similar shapes in a vertical line where they can best be seen; and

(iii) When making way through the water, in addition to the lights prescribed in this paragraph, sidelights and a sternlight.

(b) *Vessels restricted in their ability to maneuver.* A vessel restricted in her ability to maneuver, except a vessel engaged in mineclearance operations, shall exhibit:

(1) Three all-round lights in a vertical line where they can best be seen. The highest and lowest of these lights shall be red and the middle light shall be white;

(2) Three shapes in a vertical line where they can best be seen. The highest and lowest of these shapes shall be balls and the middle one a diamond;

(3) When making way through the water, masthead lights, sidelights and a sternlight, in addition to the lights prescribed in subparagraph (b)(1); and

(4) When at anchor, in addition to the lights or shapes prescribed in subparagraphs (b)(1) and (2), the light, lights or shapes prescribed in Rule 30.

(c) *Vessels engaged in towing operations.* A vessel engaged in a towing operation which severely restricts the towing vessel and her tow in their ability to deviate from their course shall, in addition to the lights or shapes prescribed in subparagraphs (b)(1) and (2) of this Rule, exhibit the lights or shape prescribed in Rule 24.

(d) *Vessels engaged in dredging or underwater operations.* A vessel engaged in dredging or underwater operations, when restricted in her ability to maneuver, shall exhibit the lights and shapes prescribed in subparagraphs (b)(1), (2), and (3) of this Rule and shall in addition, when an obstruction exists, exhibit:

(1) Two all-round red lights or two balls in a vertical line to indicate the side on which the obstruction exists;

(2) Two all-round green lights or two diamonds in a vertical line to indicate the side on which another vessel may pass; and

(3) When at anchor, the lights or shape prescribed by this paragraph, instead of the lights or shapes prescribed in Rule 30 for anchored vessels.

(e) *Vessels engaged in diving operations.* Whenever the size of a vessel engaged in diving operations makes it impracticable to exhibit all lights and shapes prescribed in paragraph (d) of this Rule, the following shall instead be exhibited:

(1) Three all-round lights in a vertical line where they can best be seen. The highest and lowest of these lights shall be red and the middle light shall be white.

(2) A rigid replica of the international Code flag "A" not less than 1 meter in height. Measures shall be taken to insure its all-round visibility.

(f) *Vessels engaged in mineclearance operations.* A vessel engaged in mineclearance operations shall, in addition to the lights prescribed for a power-driven vessel in Rule 23 or to the lights or shape prescribed for a vessel at anchor in Rule 30, as appropriate, exhibit three all-round green lights or three balls. One of these lights or shapes shall be exhibited near the foremast head and one at each end of the fore yard. These lights or shapes indicate that it is dangerous for another vessel to approach within 1,000 meters of the mineclearance vessel.

(g) *Vessels of less than 12 meters in length.* A vessel of less than 12 meters in length, except when engaged in diving operations, is not required to exhibit the lights or shapes prescribed in this Rule.

(h) *Signals of vessels in distress and requiring assistance.* The signals prescribed in this Rule are not signals of vessels in distress and requiring assistance. Such signals are contained in Annex IV to these Rules.

**§ 83.28 [Reserved] (Rule 28).**

**§ 83.29 Pilot vessels (Rule 29).**

(a) *Vessels engaged on pilotage duty.* A vessel engaged on pilotage duty shall exhibit:

(1) At or near the masthead, two all-round lights in a vertical line, the upper being white and the lower red;

(2) When underway, in addition, sidelights and a sternlight; and

(3) When at anchor, in addition to the lights prescribed in subparagraph (1), the anchor light, lights, or shape prescribed in Rule 30 for anchored vessels.

(b) *Vessels when not engaged on pilotage duty.* A pilot vessel when not engaged on pilotage duty shall exhibit the lights or shapes prescribed for a vessel of her length.

**§ 83.30 Anchored vessels and vessels aground (Rule 30).**

(a) *Vessels at anchor.* A vessel at anchor shall exhibit where it can best be seen:

(1) In the fore part, an all-round white light or one ball; and

(2) At or near the stern and at a lower level than the light prescribed in subparagraph (1), an all-round white light.

(b) *Vessels of less than 50 meters in length; alternative light.* A vessel of less than 50 meters in length may exhibit an all-round white light where it can best be seen instead of the lights prescribed in paragraph (a) of this Rule.

(c) *Illumination of decks.* A vessel at anchor may, and a vessel of 100 meters or more in length shall, also use the available working or equivalent lights to illuminate her decks.

(d) *Vessels aground.* A vessel aground shall exhibit the lights prescribed in paragraph (a) or (b) of this Rule and in addition, if practicable, where they can best be seen:

(1) Two all-round red lights in a vertical line; and

(2) Three balls in a vertical line.

(e) *Vessels of less than 7 meters in length when at anchor.* A vessel of less than 7 meters in length, when at anchor, not in or near a narrow channel, fairway, anchorage, or where other vessels normally navigate, shall not be required to exhibit the lights or shape prescribed in paragraphs (a) and (b) of this Rule.

(f) *Vessels of less than 12 meters in length when aground.* A vessel of less than 12 meters in length when aground shall not be required to exhibit the lights or shapes prescribed in

subparagraphs (d)(1) and (2) of this Rule.

(g) *Vessels of less than 20 meters in length while at anchor in special anchorage.* A vessel of less than 20 meters in length, when at anchor in a special anchorage area designated by the Secretary, shall not be required to exhibit the anchor lights and shapes required by this Rule.

### § 83.31 Seaplanes (Rule 31).

Where it is impracticable for a seaplane to exhibit lights and shapes of the characteristics or in the positions prescribed in the Rules of this part she shall exhibit lights and shapes as closely similar in characteristics and position as is possible.

## Subpart D—Sound and Light Signals

### § 83.32 Definitions (Rule 32).

(a) *Whistle* means any sound signaling appliance capable of producing the prescribed blasts and which complies with specifications in Annex III to these Rules.

(b) *Short blast* means a blast of about 1 second's duration.

(c) *Prolonged blast* means a blast of from 4 to 6 second's duration.

### § 83.33 Equipment for sound signals (Rule 33).

(a) *Vessels of 12 meters or more in length.* A vessel of 12 meters or more in length shall be provided with a whistle and a bell and a vessel of 100 meters or more in length shall, in addition, be provided with a gong, the tone and sound of which cannot be confused with that of the bell. The whistle, bell and gong shall comply with the specifications in Annex III to these Rules. The bell or gong or both may be replaced by other equipment having the same respective sound characteristics, provided that manual sounding of the prescribed signals shall always be possible.

(b) *Vessels of less than 12 meters in length.* A vessel of less than 12 meters in length shall not be obliged to carry the sound signaling appliances prescribed in paragraph (a) of this Rule but if she does not, she shall be provided with some other means of making an efficient sound signal.

### § 83.34 Maneuvering and warning signals (Rule 34).

(a) *Whistle signals.* When power-driven vessels are in sight of one another and meeting or crossing at a distance within half a mile of each other, each vessel underway, when maneuvering as authorized or required by these Rules:

(1) Shall indicate that maneuver by the following signals on her whistle: one short blast to mean "I intend to leave you on my port side"; two short blasts to mean "I intend to leave you on my starboard side"; and three short blasts to mean "I am operating astern propulsion".

(2) Upon hearing the one or two blast signal of the other shall, if in agreement, sound the same whistle signal and take the steps necessary to effect a safe passing. If, however, from any cause, the vessel doubts the safety of the proposed maneuver, she shall sound the danger signal specified in paragraph (d) of this Rule and each vessel shall take appropriate precautionary action until a safe passing agreement is made.

(b) *Light signals.* A vessel may supplement the whistle signals prescribed in paragraph (a) of this Rule by light signals:

(1) These signals shall have the following significance: one flash to mean "I intend to leave you on my port side"; two flashes to mean "I intend to leave you on my starboard side"; three flashes to mean "I am operating astern propulsion";

(2) The duration of each flash shall be about 1 second; and

(3) The light used for this signal shall, if fitted, be one all-round white or yellow light, visible at a minimum range of 2 miles, synchronized with the whistle, and shall comply with the provisions of Annex I to these Rules.

(c) *Overtaking situations.* When in sight of one another:

(1) A power-driven vessel intending to overtake another power-driven vessel shall indicate her intention by the following signals on her whistle: one short blast to mean "I intend to overtake you on your starboard side"; two short blasts to mean "I intend to overtake you on your port side"; and

(2) The power-driven vessel about to be overtaken shall, if in agreement, sound a similar sound signal. If in doubt she shall sound the danger signal prescribed in paragraph (d).

(d) *Doubts or failure to understand signals.* When vessels in sight of one another are approaching each other and from any cause either vessel fails to understand the intentions or actions of the other, or is in doubt whether sufficient action is being taken by the other to avoid collision, the vessel in doubt shall immediately indicate such doubt by giving at least five short and rapid blasts on the whistle. This signal may be supplemented by a light signal of at least five short and rapid flashes.

(e) *Vessels in areas of obscured visibility due to intervening obstructions.* A vessel nearing a bend or an area of a channel or fairway where other vessels may be obscured by an intervening obstruction shall sound one prolonged blast. This signal shall be answered with a prolonged blast by any approaching vessel that may be within hearing around the bend or behind the intervening obstruction.

(f) *Use of one whistle only on a vessel.* If whistles are fitted on a vessel at a distance apart of more than 100 meters, one whistle only shall be used for giving maneuvering and warning signals.

(g) *Power-driven vessels leaving dock or berth.* When a power-driven vessel is leaving a dock or berth, she shall sound one prolonged blast.

(h) *Agreement between vessels using radiotelephone.* A vessel that reaches agreement with another vessel in a head-on, crossing, or overtaking situation, as for example, by using the radiotelephone as prescribed by the Vessel Bridge-to-Bridge Radiotelephone Act (85 Stat. 164; 33 U.S.C. 1201 *et seq.*), is not obliged to sound the whistle signals prescribed by this Rule, but may do so. If agreement is not reached, then whistle signals shall be exchanged in a timely manner and shall prevail.

### § 83.35 Sound signals in restricted visibility (Rule 35).

In or near an area of restricted visibility, whether by day or night, the signals prescribed in this Rule shall be used as follows:

(a) *Power-driven vessels making way through the water.* A power-driven vessel making way through the water shall sound at intervals of not more than 2 minutes one prolonged blast.

(b) *Power-driven vessels underway but stopped and making no way through the water.* A power-driven vessel underway but stopped and making no way through the water shall sound at intervals of not more than 2 minutes two prolonged blasts in succession with an interval of about 2 seconds between them.

(c) *Vessels not under command; vessels restricted in ability to maneuver; sailing vessels; vessels engaged in fishing; vessels engaged in towing or pushing.* A vessel not under command; a vessel restricted in her ability to maneuver, whether underway or at anchor; a sailing vessel; a vessel engaged in fishing, whether underway or at anchor; and a vessel engaged in towing or pushing another vessel shall, instead of the signals prescribed in paragraphs (a) or (b) of this Rule, sound at intervals of not more than 2 minutes, three blasts in succession; namely, one prolonged followed by two short blasts.

(d) *Vessels towed.* A vessel towed or if more than one vessel is towed the last vessel of the tow, if manned, shall at

intervals of not more than 2 minutes sound four blasts in succession; namely, one prolonged followed by three short blasts. When practicable, this signal shall be made immediately after the signal made by the towing vessel.

(e) *Pushing and pushed vessels connected in composite unit.* When a pushing vessel and a vessel being pushed ahead are rigidly connected in a composite unit they shall be regarded as a power-driven vessel and shall give the signals prescribed in paragraphs (a) or (b) of this Rule.

(f) *Vessels at anchor.* A vessel at anchor shall at intervals of not more than 1 minute ring the bell rapidly for about 5 seconds. In a vessel of 100 meters or more in length the bell shall be sounded in the forepart of the vessel and immediately after the ringing of the bell the gong shall be sounded rapidly for about 5 seconds in the after part of the vessel. A vessel at anchor may in addition sound three blasts in succession; namely, one short, one prolonged and one short blast, to give warning of her position and of the possibility of collision to an approaching vessel.

(g) *Vessels aground.* A vessel aground shall give the bell signal and if required the gong signal prescribed in paragraph (f) of this Rule and shall, in addition, give three separate and distinct strokes on the bell immediately before and after the rapid ringing of the bell. A vessel aground may in addition sound an appropriate whistle signal.

(h) *Vessels of less than 12 meters in length.* A vessel of less than 12 meters in length shall not be obliged to give the above-mentioned signals but, if she does not, shall make some other efficient sound signal at intervals of not more than 2 minutes.

(i) *Pilot vessels.* A pilot vessel when engaged on pilotage duty may in addition to the signals prescribed in paragraphs (a), (b) or (f) of this Rule sound an identity signal consisting of four short blasts.

(j) *Vessels anchored in special anchorage areas.* The following vessels shall not be required to sound signals as prescribed in paragraph (f) of this Rule when anchored in a special anchorage area designated by the Secretary:

(1) A vessel of less than 20 meters in length; and

(2) A barge, canal boat, scow, or other nondescript craft.

### § 83.36 Signals to attract attention (Rule 36).

If necessary to attract the attention of another vessel, any vessel may make light or sound signals that cannot be mistaken for any signal authorized elsewhere in these Rules, or may direct the beam of her searchlight in the direction of the danger, in such a way as not to embarrass any vessel.

### § 83.37 Distress signals (Rule 37).

When a vessel is in distress and requires assistance she shall use or exhibit the signals described in Annex IV to these Rules.

## Subpart E—Exemptions

### § 83.38 Exemptions (Rule 38).

Any vessel or class of vessels, the keel of which is laid or which is at a corresponding stage of construction before December 24, 1980, provided that she complies with the requirements of—

(a) The Act of June 7, 1897, (30 Stat. 96), as amended (33 U.S.C. 154–232) for vessels navigating the waters subject to that statute;

(b) Section 4233 of the Revised Statutes (33 U.S.C. 301–356) for vessels navigating the waters subject to that statute;

(c) The Act of February 8, 1895 (28 Stat. 645), as amended (33 U.S.C. 241–295) for vessels navigating the waters subject to that statute; or

(d) Sections 3, 4, and 5 of the Act of April 25, 1940 (54 Stat. 163), as amended (46 U.S.C. 526b, c, and d) for motorboats navigating the waters subject to that statute; shall be exempted from compliance with the technical Annexes to these Rules as follows:

(1) The installation of lights with ranges prescribed in Rule 22, until 4 years after the effective date of the Inland Navigational Rules Act of 1980 (Pub. L. 96–591), except that vessels of less than 20 meters in length are permanently exempt;

(2) The installation of lights with color specifications as prescribed in Annex I to these Rules, until 4 years after the effective date of the Inland Navigational Rules Act of 1980 (Pub. L. 96–591), except that vessels of less than 20 meters in length are permanently exempt;

(3) The repositioning of lights as a result of conversion to metric units and rounding off measurement figures, are permanently exempt; and

(4) The horizontal repositioning of masthead lights prescribed by Annex I to these Rules:

(i) On vessels of less than 150 meters in length, permanent exemption.

(ii) On vessels of 150 meters or more in length, until 9 years after the effective date of the Inland Navigational Rules Act of 1980 (Pub. L. 96–591).

(5) The restructuring or repositioning of all lights to meet the prescriptions of Annex I to these, until 9 years after the effective date of the Inland Navigational Rules Act of 1980 (Pub. L. 96–591);

(6) Power-driven vessels of 12 meters or more but less than 20 meters in length are permanently exempt from the provisions of Rule 23(a)(1) and 23(a)(4) provided that, in place of these lights, the vessel exhibits a white light aft visible all round the horizon; and

(7) The requirements for sound signal appliances prescribed in Annex III to these Rules, until 9 years after the effective date of the Inland Navigational Rules Act of 1980 (Pub. L. 96–591).

Dated: March 31, 2010.

**Kevin S. Cook,**

*Rear Admiral, U.S. Coast Guard, Director of Prevention Policy.*

[FR Doc. 2010–8532 Filed 4–14–10; 8:45 am]

BILLING CODE 9110–04–P

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

## 36 CFR Parts 1200, 1253, and 1280

**[FDMS Docket NARA–10–0002]**

**RIN 3095–AB66**

## NARA Facility Locations and Hours

**AGENCY:** National Archives and Records Administration (NARA).

**ACTION:** Direct final rule.

**SUMMARY:** NARA is amending several of its regulations; the amendments include a change to the naming convention for the regional archives, a new logo for NARA's regional records service office, and the addition of facility information for the locations of two NARA records centers. NARA is changing the naming convention for the regional archives, currently identified in the regulations by a geographic location following the name of the region (*e.g.* NARA-Northeast Region (Boston)). The Office of Regional Records Services has determined that the naming convention "The National Archives at [metropolitan city name]" will better identify to the public the services provided by NARA's regional archives located throughout the U.S. In conjunction with the new naming convention, the NARA headquarters office that administers NARA's regional records services, the Office of the Regional Records Services, has designed a new logo for the headquarters office; each of the regional archives will customize the logo by including their specific city name. The Federal Records Center Program of the Office of the Regional Records Services has also added two facilities to its list of locations. Because this rulemaking is

a direct final rulemaking, the effective date will be the date of publication.

**DATES:** Effective April 15, 2010 without further action, unless adverse comment is received by May 17, 2010. If adverse comment is received, NARA will publish a timely withdrawal of the rule in the **Federal Register.**

**FOR FURTHER INFORMATION CONTACT:** Laura McCarthy at 301–837–3023.

**SUPPLEMENTARY INFORMATION:** NARA is revising several of its regulations; a change to the naming convention for the regional archives, addition of a new logo for the regional archives administered by NARA's Regional Records Service Office, and the addition of facility information for the locations of two NARA records centers.

The regional archives are currently identified in the regulations by a geographic location following the name of the region (*e.g.* NARA-Northeast Region (Boston)). The Office of Regional Records Services has determined that the naming convention "The National Archives at [metropolitan city name]" will better connect the public to the services provided by NARA's regional archives located throughout the U.S. This new name, similar to the name long used for "The National Archives at College Park," will be used on brochures, other outreach materials, and signage for better identification by the public. The names are:

The National Archives at Anchorage;
The National Archives at Atlanta;
The National Archives at Boston;
The National Archives at Chicago;
The National Archives at Denver;
The National Archives at Fort Worth;
The National Archives at Kansas City;
The National Archives at New York;
The National Archives at Philadelphia;
The National Archives at Riverside;
The National Archives at San Francisco;
The National Archives at Seattle;
The National Archives at St. Louis, National Personnel Records Center.

In conjunction with the change to the naming convention for the regional archives, the Office of Regional Records Services has designed a new logo. The new logo for the headquarters staff for the regional archives and corresponding logos for the individual regional archives will provide the visual connection for the public akin to the naming convention.

The regional archives facilities in Boston and Kansas City have modified their hours to increase the public access. The new hours in Boston and Kansas City have been changed on the NARA web site and the revisions to the regulations reflect these changes. The new hours are Monday, Tuesday, Wednesday, Friday, 7 a.m. to 4:30 p.m., Thursday, 7 a.m. to 9 p.m., and some Saturday hours; previously, the facility hours were 8 a.m. to 4:30 p.m., Monday through Friday. The National Archives at Kansas City has changed it hours to provide greater public access, also. The facility is open from 8 a.m. to 4 p.m. for research and the exhibit area is open from 9 a.m. to 5 p.m.

The Federal Records Center Program of the Office of the Regional Records Services has added two facilities to its list of locations. The NARA-Great Lakes Region (Dayton-Miamisburg) has been in operation since February 2003, but was not added to the list of facilities. The second facility, NARA-Great Plains Region (Lenexa), was established in February 2003 and since it began operations, it has received records from the Veterans Administration and other federal agencies; the records center at Lenexa also received records formerly stored at the NARA records center on Bannister Road in Kansas City before its closure.

This rule is effective upon publication for "good" cause as permitted by the Administrative Procedure Act (5 U.S.C. 553(d)(3)). NARA believes that delaying the effective date for 30 days is unnecessary as this rule represents minor technical amendments. NARA also believes a comment period provided by notice of proposed rulemaking (5 U.S.C. 553(b)(B) is unnecessary as there are no changes to the public's ability to access the facilities or changes of services to the public. Moreover, the public benefits immediately with correct addresses and hours for NARA's facilities and any delay in the effective date would be contrary to the public interest. The adoption of the logo for the Office of Regional Records Services, as well as the facility name changes also assists the public in recognizing and locating NARA facilities outside the Washington, DC, area.

This direct final rule is not a significant regulatory action for the purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget (OMB). As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on a substantial number of small entities because this rule applies to individual researchers. This rule does not have any federalism implications.

**List of Subjects**

*36 CFR Part 1200*

Seals and insignia.

*36 CFR Part 1253*

Archives and records.

*36 CFR Part 1280*

Federal buildings and facilities.

■ For the reasons set forth in the preamble, NARA amends parts 1200, 1253, and 1280 of title 36, Code of Federal Regulations, as follows:

## PART 1200—OFFICIAL SEALS

■ 1. The authority citation for part 1200 continues to read as follow:

**Authority:** 18 U.S.C. 506, 701, and 1017; 44 U.S.C. 2104(e), 2116(b), 2302.

■ 2. Amend § 1200.7 by adding paragraph (a)(9) to read as follows:

### § 1200.7 What are NARA logos and how are they used?

* * * * *

(a) * * *

(9) Regional archives:

(i)

(ii) Each regional archives has the same logo design with the geographic location of the facility added.

* * * * *

## PART 1253—LOCATION OF RECORDS AND HOURS OF USE

■ 3. The authority citation for part 1253 continues to read as follows:

**Authority:** 44 U.S.C. 2104(a).

■ 4. In § 1253.6:
■ a. Remove paragraph (g);
■ b. Redesignate paragraph (f) as (g);
■ c. Redesignate paragraphs (i) through (m) as (j) through (n); and
■ d. Add paragraphs (f) and (i) as follows:

### § 1253.6 Records Centers.

* * * * *

(f) NARA-Great Lakes Region (Dayton-Miamisburg) is located at 8801 Kingsridge Drive, Dayton, OH 45458. The hours are 8:30 a.m. to 5 p.m., Monday through Friday. The telephone number is (937) 425–0601.

(i) NARA-Central Plains Region (Lenexa) is located at 17501 W. 98th Street, Lenexa, KS 66219. The hours are 8 a.m. to 3:30 p.m., Monday through Friday. The telephone number is 913–563–7600.

* * * * *

■ 5. Revise § 1253.7 to read as follows:

### § 1253.7 Regional Archives.

(a) The National Archives at Boston is located in the Frederick C. Murphy Federal Center, 380 Trapelo Rd., Waltham, MA 02452. Hours are Monday, Tuesday, Wednesday, Friday, 7 a.m. to 4:30 p.m., Thursday, 7 a.m. to 9 p.m., and some Saturday hours. The telephone number is 781–663–0130. The National Archives at Boston, Pittsfield Annex is located at 10 Conte Drive, Pittsfield, MA 01201–8230. The hours are 8 a.m. to 4:30 p.m., Monday through Friday. The telephone number is 413–236–3600.

(b) The National Archives at New York City is located at 201 Varick St., New York, NY 10014–4811 (the entrance is on Houston Street between Varick and Hudson). The hours are 9 a.m. to 5 p.m., Monday through Friday, and some Saturday hours. The telephone number is 212–401–1620, and toll-free at 1–866–840–1752.

(c) The National Archives at Philadelphia is located at the Robert N.C. Nix Federal Building, 900 Market St., Philadelphia, PA 19107–4292 (Entrance is on Chestnut Street between 9th and 10th Streets). The hours are 8 a.m. to 5 p.m., Monday through Friday, and some Saturday hours. The telephone number is 215–606–0100.

(d) The National Archives at Atlanta is located at 5780 Jonesboro Road, Morrow, GA 230260. The hours are 8:30 a.m. to 5 p.m., Tuesday through Saturday. The telephone number is 770–968–2100.

(e) The National Archives at Chicago is located at 7358 S. Pulaski Rd., Chicago, IL 60629–5898. The hours are 8 a.m. to 4:15 p.m., Monday through Friday, and some Saturday hours. The telephone number is 773–948–9000.

(f) The National Archives at Kansas City is located at 400 West Pershing Road, Kansas City, MO 64108–4306. The hours are Tuesday through Saturday: Eexhibits: 9 a.m. to 5 p.m.; research rooms: 8 a.m. to 4 p.m. The telephone number is 816–268–8000.

(g) The National Archives at Fort Worth is located at 1400 John Burgess Drive, Fort Worth, TX 76140 (mailing address: P.O. Box 6216, Fort Worth, TX 76115–0216). The hours are 6:30 a.m. to 4 p.m., Monday through Friday. The telephone number is 817–551–2051.

(h) The National Archives at Denver: The Textual Research room is located at Building 48, Denver Federal Center, West 6th Ave. and Kipling Street, Denver, CO. The hours are 7:30 a.m. to 3:45 p.m., Monday through Friday. The telephone number is 303–407–5740. The Microfilm Research room is located at Building 46, Denver Federal Center, West 6th Ave. and Kipling Street, Denver, CO. (The mailing address is: P.O. Box 25307, Denver, CO 80225–0307). The hours are 7:30 a.m. to 3:45 p.m., Monday through Friday. The telephone number is 303–407–5751.

(i) The National Archives at Riverside is located at 23123 Cajalco Road, Perris, CA 92570. The hours are 8 a.m. to 4:30 p.m., Monday through Friday. The telephone number is 951–956–2000.

(j) The National Archives at San Francisco is located at 1000 Commodore Dr., San Bruno, CA 94066–2350. The hours are 7:30 a.m. to 4 p.m., Monday through Friday. The telephone number is 650–238–3501.

(k) The National Archives at Seattle is located at 6125 Sand Point Way, NE., Seattle, WA 98115–7999. The hours are 7:45 a.m. to 4:15 p.m., Monday through Friday, and some Saturday hours. The telephone number is 206–336–5115.

(l) The National Archives at Anchorage is located at 654 West Third Avenue, Anchorage, AK 99501–2145. The hours are 8 a.m. to 4 p.m., Monday through Friday, and some Saturday hours. The telephone number is 907–261–7820.

(m) The National Archives at St. Louis, the National Personnel Records Center archival research room is located at 9700 Page Ave., St. Louis, MO 63132–5100. The hours are 10 a.m. to 4 p.m., Tuesday through Friday, except Federal holidays.

## PART 1280—USE OF NARA FACILITIES

■ 6. The authority citation for part 1280 continues to read as follows:

**Authority:** 44 U.S.C. 2102 notes, 2104(a), 2112, 2903.

■ 7. Amend § 1280.2 by revising paragraph (d) to read as follows:

### § 1280.2 What property is under the control of the Archivist of the United States?

* * * * *

(d) *The National Archives at Atlanta.* The National Archives at Atlanta in

Morrow, Georgia, as specified in 36 CFR 1253.7(d).

* * * * *

■ 8. Amend § 1280.12 by revising paragraph (c) to read as follows:

**§ 1280.12 Is parking available?**

* * * * *

(c) *Records services facilities.* Most records services facilities have onsite parking available for researchers. Parking at these facilities and at the Washington National Records Center is governed by GSA regulations, Management of Buildings and Grounds, found at 41 CFR part 101–20. The National Archives at Philadelphia on Market Street (in Philadelphia) and the National Archives at New York City do not have onsite parking. However, there is ample parking in commercial parking garages near these facilities.

* * * * *

Dated: April 7, 2010.

**David S. Ferriero,**

*Archivist of the United States.*

[FR Doc. 2010–8567 Filed 4–14–10; 8:45 am]

**BILLING CODE 7515–01–P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

### 37 CFR Part 41

**[Docket No. PTO–P–2010–0032]**

**RIN 0651–AC46**

## Cancellation of Rule of Practice 41.200(b) Before the Board of Patent Appeals and Interferences in Interference Proceedings

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Final rule.

**SUMMARY:** The United States Court of Appeals for the Federal Circuit issued a decision in *Agilent Technologies, Inc.* v. *Affymetrix, Inc.,* 567 F.3d 1366 (Fed. Cir. 2009). That decision impacted the continuing viability of portions of a patent interference rule. The United States Patent and Trademark Office (USPTO or Office) is therefore cancelling the affected portion of the interference rule.

**DATES:** *Effective date:* This final rule is effective on April 15, 2010.

*Applicability date:* This final rule is applicable in interferences declared before, on, or after April 15, 2010.

**FOR FURTHER INFORMATION CONTACT:** James T. Moore, Vice Chief Administrative Patent Judge, Board of Patent Appeals and Interferences (BPAI or Board), by telephone at (571) 272–9797, or by mail addressed to: Mail Stop Interference, Director of the United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of James T. Moore, at the BPAI.

**SUPPLEMENTARY INFORMATION:** 37 CFR 41.200(b) (2004) provides: "A claim shall be given its broadest reasonable construction in light of the specification of the application or patent in which it appears." On June 4, 2009, the Federal Circuit in *Agilent* determined that 37 CFR 41.200(b) does not apply in an interference proceeding in the instance where one party challenges another's written description. The Court held: "[W]hen a party challenges written description support for an interference count or the copied claim in an interference, the originating disclosure provides the meaning of the pertinent claim language." *Agilent,* 567 F.3d at 1375. The Court also noted that "[w]hen a party challenges a claim's validity under 35 U.S.C. 102 or 103, however, this court and the Board must interpret the claim in light of the specification in which it appears." *Id.* Addressing the issue again in *Koninklijke Philips Electronics N.V.* v. *Cardiac Science Operating Co.,* 590 F.3d 1326, 1335 (Fed. Cir. 2010), the Court stated that "[A]ny conflict between [Agilent and Rule 200(b)] must be resolved as directed in *Agilent.*"). Accordingly, the Board in an interference will construe a claim in a manner consistent with *Agilent.*

### Rulemaking Considerations

*A. Administrative Procedure Act:* The change in this final rule merely revises the USPTO's rules of practice to eliminate any inconsistency with the Federal Circuit's determination. Furthermore, this rule change involves an interpretive rule or rule of agency practice and procedure under 5 U.S.C. 553(b)(A). Accordingly, the change in this final rule may be adopted without prior notice and opportunity for public comment under 5 U.S.C. 553(b) and (c), or thirty-day advance publication under 5 U.S.C. 553(d). *See Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37, 87 U.S.P.Q.2d 1705, 1710 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rule making for "'interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.'" (quoting 5 U.S.C. 553(b)(A))).

*B. Regulatory Flexibility Act:* As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. *See* 5 U.S.C. 603.

*C. Executive Order 12866 (Regulatory Planning and Review):* This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

*D. Executive Order 13132 (Federalism):* This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

*E. Executive Order 13175 (Tribal Consultation):* This rule making will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

*F. Executive Order 13211 (Energy Effects):* This rule making is not a significant energy action under Executive Order 13211 because this rule making is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

*G. Executive Order 12988 (Civil Justice Reform):* This rule making meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

*H. Executive Order 13045 (Protection of Children):* This rule making does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

*I. Executive Order 12630 (Taking of Private Property):* This rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

*J. Congressional Review Act:* Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. However, this

action is not a major rule as defined by 5 U.S.C. 804(2).

*K. Unfunded Mandates Reform Act of 1995:* This rule making does not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

*L. National Environmental Policy Act:* This rule making will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

*M. National Technology Transfer and Advancement Act:* The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rule making does not contain provisions which involve the use of technical standards.

*N. Paperwork Reduction Act:* This rule making involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this notice has been reviewed and approved by OMB under OMB control number 0651–0032. The USPTO is not resubmitting an information collection package to OMB for its review and approval because the changes in this rule making do not affect the information collection requirements associated with the information collection under OMB control number 0651–0032.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

**List of Subjects in 37 CFR Part 41**

Administrative practice and procedure, Inventions and patents, Lawyers.

■ For the reasons stated in the preamble, the Patent and Trademark Office amends 37 CFR part 41 as follows:

## PART 41—PRACTICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

■ 1. The authority citation for 37 CFR part 41 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135.

### Subpart E—Patent Interferences

**§ 41.200 [Amended]**

■ 2. In § 41.200, paragraph (b) is removed and reserved.

Dated: April 10, 2010.

**David J. Kappos,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2010–8626 Filed 4–14–10; 8:45 am]

BILLING CODE 3510–16–P

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 11

**[EB Docket No. 04–296; DA 10–500]**

## Public Safety and Homeland Security Bureau Seeks Informal Comment Regarding Revisions to the Federal Communication Commission's Rules Governing the Emergency Alert System Pending Adoption of the Common Alerting Protocol by the Federal Emergency Management Agency

**AGENCY:** Federal Communications Commission.

**ACTION:** Request for comments.

**SUMMARY:** In this document, the Federal Communication Commission's (Commission) Public Safety and Homeland Security Bureau (PSHSB) seeks informal comment regarding what, if any, changes to the Commission's rules governing the Emergency Alert System (EAS) might be necessitated by the introduction of the Common Alerting Protocol (CAP), as well as the Federal Emergency Management Agency's (FEMA) deployment of its Integrated Public Alert and Warning System (IPAWS).

**DATES:** Comments are due on or before May 17, 2010 and reply comments are due on or before June 14, 2010.

**ADDRESSES:** You may submit comments, identified by EB Docket No. 04–296 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People With Disabilities:* Contact the Commission to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

**FOR FURTHER INFORMATION CONTACT:** Gregory M. Cooke, Associate Chief, Policy Division, Public Safety and Homeland Security Bureau, at (202) 418–2351, or by e-mail at *gregory.cooke@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Federal Communication Commission's Public Notice in EB Docket No. 04–296, DA 10–500, released on March 25, 2010. This document is available to the public at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA–10–500A1.doc.*

**Synopsis of the Public Notice**

1. CAP is an open, interoperable, data interchange format for collecting and distributing all-hazard safety notifications and emergency warnings to multiple information networks, public safety alerting systems, and personal communications devices. In conjunction with appropriate alert transmission architectures, CAP will allow FEMA, the National Weather Service (NWS), a State Governor, or any other authorized initiator of a public alert and warning to

automatically format and geo-target a particular alert simultaneously to the public over multiple media platforms such as television radio, cable, cell phones and electronic highway signs. CAP will also allow an alert initiator to send alerts specifically formatted for people with disabilities and for non-English speakers.

2. The Commission, in its *Emergency Alert System (EAS) Second Report and Order and Further Notice of Proposed Rulemaking (Second Report and Order),* FCC No. 07–109 (adopted May 31, 2007; released July 12, 2007) mandated that all EAS Participants must accept CAP-based EAS alerts 180 days after the date on which FEMA publishes the applicable technical standards for its adoption of CAP as the basis for FEMA-generated alerts. On July 30, 2008, FEMA announced its intention to adopt a version of CAP, and more recently announced that this adoption may occur as early as the third quarter of 2010. Such action would trigger the Commission's 180 day requirement.

3. The Commission's EAS rules, 47 CFR part 11, were not written to accommodate a CAP-based EAS and will likely require significant revision or replacement once CAP is adopted and implemented, even if CAP-formatted messages continue to be utilized in connection with the alert transmission architectures of the current or "legacy" EAS. In advance of any rulemaking that may need to be conducted by the Commission once FEMA announces its adoption of standards for CAP, PSHSB seeks informal comment regarding what, if any, part 11 changes might be necessitated by the introduction of CAP. PSHSB asks commenters to identify, with specificity, those rules that need to be modified or deleted, and to suggest new rules for Part 11—or a new rules framework to replace part 11 rules. Accordingly, commenters should feel free to address the entirety of part 11 rules in this regard. For example, commenters may address rules for a CAP-based EAS system architecture, equipment requirements, organization, operations, testing, and access for people with disabilities and non-English speakers. PSHSB also asks commenters to consider the degree to which the Commission can implement flexibility into any new rules adopted for part 11, such that future versions of CAP can be accommodated without further rule changes.

4. Further, FEMA's adoption of CAP anticipates FEMA´s deployment of IPAWS, which will combine new and innovative technologies and distribution systems with greater redundancy and resiliency for the delivery of emergency alerts. In its *EAS Second Report and Order,* the Commission requires EAS Participants to configure their networks to receive CAP-formatted alerts delivered via any new delivery systems, whether wireline, internet, satellite, or other, within 180 days after the date that FEMA announces the technical standards for the Next Generation EAS. However, the Commission's rules presently also do not address such alert distribution methods.

5. Accordingly, PSHSB also takes this opportunity to ask commenters to identify specific rule changes or additions that they foresee could advance or facilitate introduction of a CAP-based Next Generation EAS architecture. In this regard, PSHSB seeks comment on the extent to which states already are adopting CAP-based systems for distribution of state and local EAS alerts, and the extent to which any revisions to Part 11 can be adopted in manner consistent with those systems. Again, PSHSB urges commenters to consider the degree to which the Commission can and should implement flexibility into its new rules, in order to accommodate future changes to EAS delivery systems without necessitating repeated revisions to Part 11. What factors should the Commission weigh in determining whether and-or when to implement future rule changes? Should the structure and content of state EAS Plans covered by § 11.21 of the EAS rules be altered to accommodate CAP and, if so, how?

6. Finally, PSHSB seeks comment on what rules changes, if any, are necessary to our Part 11 rules to ensure access to a CAP-based EAS by people with disabilities and those who do not speak English. We seek comment on how states that have adopted CAP currently address this issue. We also seek comment on the status of any initiatives or programs developed by, as well as any ongoing discussions among, interested stakeholders to address these issues.

## Procedural Matters

### *A. Ex Parte Presentations*

7. This matter shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. Other requirements pertaining to oral and written presentations are set forth in § 1.1206(b) of the Commission's rules.

### *B. Comment Filing Procedures*

8. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. All filings related to this Notice of Proposed Rulemaking should refer to EB Docket No. 04–296. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998.

9. *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Filers should follow the instructions provided on the Web site for submitting comments.

10. For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov,* and include the following words in the body of the message, "get form." A sample form and directions will be sent in response.

11. *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

12. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

13. Effective December 28, 2009, all hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC

Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. **Please Note:** The Commission's former filing location at 236 Massachusetts Avenue, NE., is permanently closed.

Federal Communications Commission.

**David L. Furth,**

*Deputy Bureau Chief, Public Safety and Homeland Security Bureau.*

[FR Doc. 2010–8636 Filed 4–14–10; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 679

**[Docket No. 0910131363–0087–02]**

**RIN 0648–XV79**

## Fisheries of the Economic Exclusive Zone Off Alaska; Pacific Cod in the Bering Sea and Aleutian Islands

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; modification of a closure.

**SUMMARY:** NMFS is opening directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to fully use the 2010 total allowable catch (TAC) of Pacific cod specified for the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), April 30, 2010, through 2400 hrs, A.l.t., December 31, 2010. Comments must be received at the following address no later than 4:30 p.m., A.l.t., April 29, 2010.

**ADDRESSES:** Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by RIN 0648–XV79, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov*.
- Mail: P.O. Box 21668, Juneau, AK 99802.
- Fax: (907) 586–7557.
- Hand delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comment will generally be posted without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

NMFS closed directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI under § 679.20(d)(1)(iii) on March 25, 2010 (75 FR 15626, March 26, 2010).

NMFS has determined that as of April 9, 2010, approximately 400 metric tons of Pacific cod remain in the 2010 Pacific cod apportionment for catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully use the 2010 TAC of Pacific cod in the BSAI, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI.

### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the opening of the Pacific cod fishery by Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet and processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 9, 2010.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until April 29, 2010.

This action is required by § 679.25 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 12, 2010.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010–8639 Filed 4–14–10; 8:45 am]

**BILLING CODE 3510–22–S**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

**[Docket No. 0910131363–0087–02]**

**RIN 0648–XV78**

## Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; reallocation.

**SUMMARY:** NMFS is reallocating the projected unused amount of Pacific cod from vessels using jig gear to catcher vessels less than 60 feet (18.3 meters) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to allow the B season apportionment of the 2010 total allowable catch (TAC) of Pacific cod to be harvested.

**DATES:** Effective April 12, 2010, through 2400 hrs, Alaska local time (A.l.t.), December 31, 2010.

**FOR FURTHER INFORMATION CONTACT:** Obren Davis, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season apportionment of the 2010 Pacific cod TAC specified for vessels using jig gear in the BSAI is 422 metric tons (mt) as established by the final 2010 and 2011 harvest specifications for groundfish in the BSAI (75 FR 11788, March 12, 2010), for the period 1200 hrs, A.l.t., April 30, 2010, through 1200 hrs, A.l.t., August 31, 2010.

The Administrator, Alaska Region, NMFS, has determined that jig vessels will not be able to harvest 400 mt of the B season apportionment of the 2010 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*1*). Therefore, in accordance with § 679.20(a)(7)(iii)(A), NMFS apportions 400 mt of Pacific cod from the B season jig gear apportionment to catcher vessels less than 60 feet (18.3 meters (m)) LOA using hook-and-line or pot gear.

The harvest specifications for Pacific cod included in the final harvest specifications for groundfish in the BSAI (75 FR 11788, March 12, 2010) are revised as follows: 22 mt to the B season apportionment for vessels using jig gear and 4,598 mt to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear.

### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod specified from jig vessels to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear. Since the fishery is currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 9, 2010.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 12, 2010.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010–8637 Filed 4–12–10; 4:15 pm]

**BILLING CODE 3510–22–S**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

**[Docket No. 0910131362–0087–02]**

**RIN 0648–XV80**

## Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 610 in the Gulf of Alaska

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for pollock in Statistical Area 610 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the B season allowance of the 2010 total allowable catch (TAC) of pollock for Statistical Area 610 in the GOA.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), April 12, 2010, through 1200 hrs, A.l.t., August 25, 2010.

**FOR FURTHER INFORMATION CONTACT:** Josh Keaton, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season allowance of the 2010 TAC of pollock in Statistical Area 610 of the GOA is 5,551 metric tons (mt) as established by the final 2010 and 2011 harvest specifications for groundfish of the GOA (publication in **Federal Register** pending).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the B season allowance of the 2010 TAC of pollock in Statistical Area 610 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,451 mt, and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of pollock in Statistical Area 610 of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 9, 2010.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 12, 2010.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010–8640 Filed 4–12–10; 4:15 pm]

BILLING CODE 3510–22–S

# Proposed Rules

Federal Register

Vol. 75, No. 72

Thursday, April 15, 2010

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

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2010–0036; Directorate Identifier 2009–NM–077–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; The Boeing Company Model 737–200, –200C, –300, –400, and– 500 Series Airplanes

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

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

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Model 737–200, –200C, –300, –400, and– 500 series airplanes. This proposed AD would require repetitive inspections for cracking and corrosion of the skin and surrounding structure under the number 3 very high frequency (VHF) antenna, and corrective actions if necessary. Also, for certain airplanes, this proposed AD would require replacing bonded skin panels with solid skin panels. This proposed AD results from reports of cracks in the skin and surrounding structure under the number 3 VHF antenna on the lower external surface of the airplane at Buttock Line 0.0, aft of the main landing gear wheel well. We are proposing this AD to detect and correct cracks and corrosion of the skin and surrounding structure under the number 3 VHF antenna, which could result in separation of the antenna from the airplane, and rapid depressurization of the airplane.

**DATES:** We must receive comments on this proposed AD by June 1, 2010.

**ADDRESSES:** You may send comments by any of the following methods:

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6447; fax (425) 917–6590.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2010–0036; Directorate Identifier 2009–NM–077–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

### Discussion

We have received reports of cracks of the skin and surrounding structure under the number 3 (very high frequency) VHF antenna on the lower external surface of the airplane at Buttock Line 0.0, aft of the main landing gear wheel well on Model 737–200, –200C, –300, –400, and– 500 series airplanes. One report indicated there was a 15-inch longitudinal crack in the skin near Buttock Line 0.0 just forward of the number 3 VHF antenna cutout, running forward. The first 14 inches of the crack was hidden beneath the number 3 VHF antenna. Five other reports indicated there were skin cracks between 1.5 and 3 inches in length in the same area. The reports also indicated that the main antenna support channel and other support structure were cracked. The earliest reported cracks were at 18,289 flight cycles. This condition, if not corrected, could result in crack growth, possibly leading to separation of the antenna from the airplane, and rapid depressurization of the airplane.

### Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009. The service bulletin describes procedures for repetitive external detailed and external high frequency eddy current (HFEC) inspections for cracking and corrosion in the skin; and repetitive internal detailed inspections for cracking and corrosion in the skin, antenna support structure, and surrounding frames and stringers; depending on the airplane configuration. For Group 1–4, configuration 2 airplanes, having a cover plate at the number 3 VHF antenna location, accomplishing the HFEC inspection eliminates the need for repetitive external detailed inspections.

Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, also specifies contacting Boeing

for certain inspection instructions, and for all repair instructions.

The initial compliance time is 15,000 total flight cycles, or within 1,100 or 6,000 flight cycles (depending on configuration and inspection type) from the date on the service bulletin, whichever occurs later, for the following inspections:

- External detailed inspections for any crack in the skin;
- External HFEC inspections for any crack in the skin;
- Internal detailed inspection for any crack in the skin, antenna support structure, and surrounding frames and stringers; and
- Internal detailed inspection for any crack or corrosion in the skin, antenna support structure, and surrounding frames and stringers.

*The initial compliance time is within 18,000 flight cycles (depending on configuration and inspection type) from the date on the service bulletin, for the following inspections:*

- External detailed and HFEC inspection for any crack or corrosion in the skin; and
- Internal detailed inspection for any crack or corrosion in the skin.

The repetitive inspection intervals, which depend on the airplane configuration and inspection type, range between 1,100 flight cycles and 18,000 flight cycles.

Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, specifies prior or concurrent accomplishment, for certain airplanes, of the replacement of bonded skin panels with solid skin panels in accordance with Part 5 of Boeing Service Bulletin 737–53A1042, Revision 5, dated October 5, 1984. The actions specified in Boeing Service Bulletin 737–53A1042, Revision 5, dated October 5, 1984, are necessary to comply with AD 90–06–02, Amendment 39–6489 (55 FR 8372, March 7, 1990).

## FAA's Determination and Requirements of This Proposed AD

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Difference Between the Proposed AD and Service Bulletin."

## Difference Between the Proposed AD and Service Bulletin

Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings.

## Interim Action

We consider this proposed AD interim action. If final action is later identified, we might consider further rulemaking then.

## Costs of Compliance

We estimate that this proposed AD would affect 1,016 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

TABLE—ESTIMATED COSTS

| Action | Work hours | Average labor rate per hour | Parts | Cost per product | Number of U.S.-registered airplanes | Fleet cost |
|---|---|---|---|---|---|---|
| Inspection | Between 3 and 9. | $85 | None | Between $255 and $765, per inspection cycle. | 629 | Between $160,395 and $481,185, per inspection cycle. |
| Concurrent Replacement for Group 2 airplanes.[1] | 2,112 | $85 | $35,000 | $214,520 | 387 | $83,019,240. |

[1] The concurrent modification for Group 2 airplanes required by this AD is already required by AD 90–06–02. AD 90–06–02 mandated the skin replacement per Boeing Service Bulletin 737–53A1042 within 20 years of the manufacture date of the airplane. All group 2 airplanes have exceeded the 20-year threshold.

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

## List of Subjects in 14 CFR Part 39

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

## The Proposed Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

**The Boeing Company:** Docket No. FAA–2010–0036; Directorate Identifier 2009–NM–077–AD.

**Comments Due Date**

(a) We must receive comments by June 1, 2010.

**Affected ADs**

(b) AD 90–06–02, Amendment 39–6489, affects this AD.

**Applicability**

(c) This AD applies to The Boeing Company Model 737–200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009.

**Subject**

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

**Unsafe Condition**

(e) This AD results from reports of cracks of the skin and surrounding structure under the number 3 very high frequency (VHF) antenna on the lower external surface of the airplane at Buttock Line 0.0, aft of the main landing gear wheel well. The Federal Aviation Administration is issuing this AD to detect and correct cracks and corrosion of the skin and surrounding structure under the number 3 VHF antenna, which could result in separation of the antenna from the airplane, and rapid depressurization of the airplane.

**Compliance**

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

**Inspections**

(g) Except as required by paragraphs (m) and (n) of this AD, at the applicable time in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009: Do external detailed and high frequency eddy current (HFEC) inspections for cracking in the skin, and for cracking and corrosion in the skin, as applicable; and an internal detailed inspection for cracking or corrosion in the skin, antenna support structure, and surrounding frames and stringers, under the number 3 VHF antenna, as applicable; in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, except as provided by paragraph (h) of this AD. Repeat the inspections, as applicable, thereafter at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009 except as provided by paragraph (i) of this AD.

(h) For airplanes on which any external detailed, or external detailed and HFEC inspection is done, and an external doubler exists under the cover plate that extends a minimum of 3 rows of fasteners all around the cover plate: Do the applicable inspections on the doubler instead of the skin.

(i) For Group 1–4, configuration 2 airplanes having a cover plate at the number 3 VHF antenna location: Accomplishing the HFEC inspection terminates the repetitive external detailed inspections.

**Corrective Actions**

(j) If any cracking or corrosion is found during any inspection required by this AD, before further flight, repair the crack or corrosion using a method approved in accordance with the procedures specified in paragraph (o) of this AD.

**Concurrent Requirement**

(k) For Group 2 airplanes, as identified in Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009: Before or concurrently with accomplishing the requirements of paragraph (g) of this AD, replace the bonded skin panels with solid skin panels, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1042, Revision 9, dated July 25, 1991.

**Note 1:** The concurrent requirement for replacement of bonded skin panels with solid skin panels is already required by AD 90–06–02, Amendment 39–6489.

**Replacements Accomplished According to Previous Issue of Service Bulletin**

(l) Replacements accomplished before the effective date of this AD in accordance with the Accomplishment Instructions of the service bulletins specified in Table 1 of this AD are considered acceptable for compliance with the corresponding action specified in paragraph (k) of this AD.

TABLE 1—PREVIOUSLY ISSUED SERVICE BULLETIN

| Document | Revision | Date |
|---|---|---|
| Boeing Service Bulletin 737–53A1042 | 5 | October 5, 1984. |
| Boeing Service Bulletin 737–53A1042 | 6 | August 10, 1989. |
| Boeing Service Bulletin 737–53A1042 | 7 | October 19, 1989. |
| Boeing Service Bulletin 737–53A1042 | 8 | July 19, 1990. |

**Exceptions to Service Bulletin**

(m) Where Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, specifies a compliance time after the date on that service bulletin, this AD requires compliance after the effective date of this AD.

(n) The Compliance Time column of Table 5 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, is missing the phrase "(Whichever Occurs Later)." Compliance with the actions in the Action column of Table 5 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009, is required by the later of the corresponding times specified in the Compliance Time column of Table 5 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1287, dated March 11, 2009.

**Alternative Methods of Compliance (AMOCs)**

(o)(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. Send information to ATTN: Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 917–6447; fax (425) 917–6590. Or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(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. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Issued in Renton, Washington on April 2, 2010.

**Ali Bahrami,**

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

[FR Doc. 2010–8570 Filed 4–14–10; 8:45 am]

**BILLING CODE 4910–13–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 51 and 52

**[EPA–HQ–OAR–2003–0064; FRL–9133–7]**

**RIN 2060–AP80**

## Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Aggregation; Reconsideration

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Pursuant to a proceeding for reconsideration, the EPA requests comment on a Clean Air Act (CAA) rule, the New Source Review (NSR) Aggregation Amendments, which was promulgated on January 15, 2009. The NSR Aggregation Amendments established a new interpretation of the existing NSR rules governing the modification of major sources by requiring sources and permitting authorities to combine emissions from nominally-separate activities at a major stationary source only when the activities are "substantially related." This proposed reconsideration is in response to a petition from the Natural Resources Defense Council (NRDC) received on January 30, 2009. EPA requests public comment on all issues included in NRDC's petition. In light of the legal and policy issues raised in the petition and in our own review of the rule, EPA's preferred option is to revoke the NSR Aggregation Amendments. EPA is also proposing to extend the effective date of the stay by an additional 6 months, and soliciting comment on a longer extension of the stay.

**DATES:** *Comments.* Comments must be received on or before May 17, 2010.

*Public Hearing.* If anyone contacts EPA requesting the opportunity to speak at a public hearing concerning the proposed regulation by April 26, 2010, EPA will hold a public hearing on April 30, 2010. If a hearing is held, the record for the hearing will remain open until June 1, 2010.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2003–0064, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to the applicable docket. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* 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 either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, 20460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1742, and the telephone number for the Air Docket is (202) 566–1744.

*Public Hearing.* If a public hearing is held, it will be held in Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Svendsgaard, Air Quality Policy Division (C504–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541–2380; fax number: (919) 541–5509, e-mail address: *svendsgaard.dave@epa.gov.*

To request a public hearing or information pertaining to a public hearing on this document, contact Ms. Pamela Long, Air Quality Policy Division (C504–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541–0641; fax number (919) 541–5509; e-mail address: *long.pam@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this sction spply to me?*

Entities potentially affected by this action include sources in all industry groups and state, local, and tribal governments.

*B. How is this preamble organized?*

The preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. How is this preamble organized?
II. Overview
A. What is "Aggregation"?
B. What events have led to this action?
III. This Action
A. What is the standard for reconsideration?
B. What issues are being reconsidered?
C. Key Issues Under Reconsideration
1. Lack of Adequate Opportunity for Notice and Comment on the Adopted Rule
2. Rule may be Inconsistent with a Court of Appeals Decision for Previous NSR Rule
a. Background for Our Historic Approach
b. Our Explanation of Our Authority in the NSR Aggregation Amendments
c. The CAA Requires Aggregation of Nominally-Separate Changes When They Collectively can be Seen as One Change
3. Questioning the Need for a Policy Change
4. State Plan Adoption
5. Proposal to Revoke Rule
6. Proposal to Extend Effective Date

IV. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
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
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions to Address
K. Determination Under Section 307(d)
V. Statutory Authority

## II. Overview

### *A. What is "Aggregation"?*

When undergoing a physical or operational change, a source determines major NSR applicability through a two-step analysis that first considers whether the increased emissions from a particular proposed change alone are significant, followed by a calculation of the change's net emissions increase considering all contemporaneous increases and decreases at the source (*i.e.,* source-wide netting calculation) to determine if a major modification has occurred. *See,* for example, 40 CFR 52.21(b)(2)(i). The term "aggregation" comes into play in the first step (Step 1), and describes the process of grouping together multiple, nominally-separate but related physical changes or changes in the method of operation ("nominally-separate changes") into one physical or operational change, or "project." The emission increases of the nominally-separate but related changes must be combined in Step 1 for purposes of determining whether a significant emissions increase has occurred from the project. *See,* for example, 40 CFR 52.21(b)(40). When undertaking multiple nominally-separate changes, the source must consider whether NSR applicability should be determined collectively (*i.e.,* "aggregated") or whether the emissions from each of these changes should separately undergo a Step 1 analysis.[1]

Neither the CAA nor current EPA rules specifically address the basis upon which to aggregate nominally-separate changes for the purpose of making NSR applicability determinations. Instead, our[2] aggregation policy developed over time through statutory and regulatory interpretation and applicability determinations in response to a need to deter sources from attempting to expedite construction by permitting several changes separately as minor modifications. When related changes are evaluated separately, the source may circumvent the purpose of the NSR program by showing a less than significant emission increase for Step 1 of the applicability analysis, that could result in avoiding major NSR permitting requirements.[3] This, in turn, could result in increases of emissions of air pollutants from the facility that would be higher than the increases would be had the changes been subject to NSR control requirements. The associated emissions increases could endanger the air quality health standard and adversely affect public health.

Under our longstanding aggregation policy, we evaluate all relevant and objective criteria specific to a case in determining if multiple changes at a source should be aggregated as a single project for NSR purposes. *See* section III.C.2.a of this notice. Our policy aims to ensure the proper permitting of modifications that involve multiple physical and/or operational changes.

### *B. What events have led to this action?*

On January 15, 2009, we issued a final rule that changed our interpretation of the PSD and nonattainment NSR regulations relating to the definition of "modification" in the CAA 111(a)(4). The new rule addressed when a source must aggregate emissions from nominally-separate changes for the purpose of determining whether they are a single project resulting in a significant emission increase. The final rule retained the prior rule language relevant to aggregation, but interpreted that rule text to mean that sources and permitting authorities should combine emissions only when nominally-separate changes are "substantially related." We described in the final rule preamble the factors that may be considered when evaluating whether changes are substantially related, and we specifically stated that two nominally-separate changes are not substantially related if they are only related to the extent that they both support the plant's overall basic purpose. At the same time, we adopted a rebuttable presumption that nominally-separate changes at a source that occur three or more years apart are presumed to not be substantially related. Collectively, this rulemaking is known as the "NSR Aggregation Amendments." For further information on the NSR Aggregation Amendments, *see* 74 FR 2376 (January 15, 2009).

On January 30, 2009, NRDC submitted a petition for reconsideration of the NSR Aggregation Amendments as provided for in CAA section 307(d)(7)(B).[4] Under that CAA provision, the Administrator may convene a reconsideration proceeding if the petitioner raises an objection to a rule that was impracticable to raise during the comment period or if the grounds for the objection arose after the comment period. In either case, the objection must be of central relevance to the outcome of the rule.

On February 13, 2009, we announced the convening of a reconsideration proceeding in response to the NRDC petition. *See* 74 FR 7193. In order to allow for completion of the reconsideration prior to the NSR Aggregation Amendments becoming effective, we also announced a 90-day administrative stay of the rule. *See* 74 FR 7284 (Feb. 13, 2009). We subsequently completed a rulemaking further delaying the effective date until May 18, 2010. *See* 74 FR 22693 (May 14, 2009). The extensions enable us to take comment on issues that are in question and complete any revisions of the rule that become necessary as a result of the reconsideration process.

## III. This Action

### *A. What is the standard for reconsideration?*

As noted above, pursuant to CAA 307(d)(7)(B) of the CAA, an individual can petition an agency to reconsider a final rule issued under CAA 307(d)(1) if the individual can show that:

- It was impracticable to raise the objection during the public comment period on the proposed rule, or the grounds for the objection arose after the public comment period; and
- The objection is centrally relevant to the outcome of the rule.

As to the first procedural criterion for reconsideration, a petitioner must show why the issue could not have been presented during the comment period, either because it was impracticable to raise the issue during that time or because the grounds for the issue arose after the period for public comment (but within 60 days of publication of the final action). Thus, CAA 307(d)(7)(B) does not provide a forum to request EPA

[1] Even if activities are determined to be separate and subject to an individual Step 1 analysis, the emission increases and decreases may still be included together in the source-wide netting calculation if the projects occur within a contemporaneous period.

[2] In this notice, the terms "we," "us," and "our" refer to the EPA.

[3] Of course, if a source has a significant increase in emissions from a change (or aggregated changes), it is not necessarily subject to NSR; rather, not until the source also has a "significant net emission increase" would it be subject to NSR permitting requirements.

[4] John Walke, Natural Resources Defense Council, EPA–HQ–OAR–2003–0064–0116.1.

to reconsider issues that actually were raised, or could have been raised, prior to promulgation of the final rule.

An agency can deny the reconsideration of issues when they fail to meet the procedural test for reconsideration under CAA 307(d)(7)(B). If, however, there are adequate grounds for the objections raised in this petition, the EPA Administrator must "* * *convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed." CAA 307(d)(7)(B). In this case, the final rule adopted interpretations that were not described in the proposal and on which the public did not have an opportunity to offer comment, as described more specifically below.

*B. What issues are being reconsidered?*

The basis for this reconsideration proceeding is NRDC's petition of January 30, 2009, in which NRDC requested reconsideration of many aspects of the January 15, 2009, final rule. The reader is directed to the petition for an exact explanation of each objection raised by NRDC. *See* Docket EPA–HQ–OAR–2003–0064–0116.1. In summary, NRDC's main points of concern include:

- The NSR Aggregation Amendments are inconsistent with the DC Circuit Court ruling on the NSR "Equipment Replacement Provision," by creating an illegal exclusion to the broad "any physical change" provision in the CAA.
- The EPA failed to identify any actual problems or inconsistencies with longstanding policy.
- The 2006 proposal sought to clarify aggregation rules through proposing new rule text, but the 2009 final rule reinterpreted the existing rule text and was described as a change in policy.
- The term "substantially related" is vague and undefined, did not appear in the proposal, retreats from the factors used in previous aggregation determinations by EPA (*e.g.,* adopting the 3-year timing presumption against aggregation), and eliminates consideration of EPA's policy on circumvention by failure to consider a company's intent.
- The final rule is silent, and therefore confusing, on whether States must implement the new rule in their own programs.
- The EPA violated relevant executive orders through failure to adequately consult with states during the development of the rule.

Through this notice, we are taking comment on a broad range of legal and policy issues related to the NSR Aggregation Amendments. We also acknowledge an interdependence among several objections raised in NRDC's petition, such that granting reconsideration on one issue that meets the standard for reconsideration may warrant taking comment on a second issue that may, on its own, not meet the standard for reconsideration. However, the basis for the second issue is at stake depending on what comments are received on the first issue.

For example, under CAA 307(d)(3)(C), EPA is required to present for public comment "the major legal interpretations and policy considerations underlying the proposed rule." We acknowledge through this reconsideration proceeding that portions of the legal basis for the NSR Aggregation Amendments did not undergo comment solicitation, and it is necessary to allow the public an opportunity to comment fully on the basic authority for the rule. However, as is the case with many rules, the statutory basis of this rule provides the underpinning for most every aspect of the rule, and could call into question the legitimacy of other aspects of the rule. Therefore, in addition to granting reconsideration on the legal basis for the rule, we are also taking comment on other aspects of the final rule that are dependent upon a sound legal basis. For instance, although we requested comment on a 3-year presumption against aggregation through our 2006 proposal, in light of the broad legal issue that is currently under reconsideration, we believe it is justified to open for additional comment the issue of having a presumption against aggregation because such a presumption would be necessarily dependent on, and an outgrowth of, the legal basis of our rule.

Moreover, a few of the issues raised in the NRDC petition demonstrate that there are fundamental components of the final rule that elicit confusion, such as whether states with approved implementation plans must adopt the new rule and whether their State Implementation Plans (SIPs) must be amended. Since the aim of the rule was to reduce, not promote, confusion with regard to project aggregation, we are particularly concerned with this comment from the petitioner, and it is one of the primary reasons for delaying the effective date of the rule while we reconsider issues raised in the petition.

For these reasons, we invite comment on all issues raised by the petitioner. In the sections below, we specifically describe several key issues on which we seek comment.

*C. Key Issues Under Reconsideration*

1. Lack of Adequate Opportunity for Notice and Comment on the Adopted Rule

As noted above, NRDC identifies as grounds for reconsideration several issues related to the adoption and implementation of the "substantially related" test for aggregating nominally-separate changes. The proposed rule did not mention the "substantially related" test adopted in the final rule.[5] Additionally, the proposed rule offered new regulatory text to clarify the criteria for aggregation, while the final rule retains the existing text. Our proposed rule did not discuss the possibility of changing the interpretation of the existing text.

A commenter would not have been on notice of the possibility that we would adopt the "substantially related" test without amending the rule text, nor would a commenter have been on notice of the need to comment on whether the existing text was susceptible to this interpretation. The issue of adopting this rule in the form and manner we did is an issue that arose after the comment period and is of central relevance to the rulemaking proceeding.

In soliciting comment on the option of creating time-based presumptions regarding aggregation, we did not raise the issue of whether the existing regulatory text could support the creation of this presumption. We "acknowledge[d] that the establishment of a presumption* * * would go beyond the codification of the status quo." *See* 71 FR 54248. Therefore, we did not characterize a time-based presumption as a clarification. We recognized it could only apply prospectively. Nevertheless, the final rule announced the 3-year presumption against aggregation as an interpretation of the regulatory text despite the regulation's silence on this issue.

In context, commenters could not have been aware that we were suggesting the presumption was an interpretation of the existing regulatory text rather than a proposal to add a presumption to the text. Therefore, commenters did not have an adequate opportunity to comment on whether the existing regulatory text could be interpreted to have a time-based presumption.

We solicit comment on the change in approach from the pre-rule policy on

[5] Furthermore, subsumed within the "substantially related test" is another feature of the final rule that was not introduced as a possible change in policy at proposal—i.e., to not aggregate projects when their sole common ground is that they each support the plant's overall basic purpose.

aggregation to the "substantially related" test set forth in the preamble to the January 15, 2009, final rule. We specifically request comment on any rule changes that may be needed to implement the new test. For example, if we were to retain the "substantially related" test, then must we amend the regulatory text for the definition of "project" to say that nominally-separate changes must be aggregated into a project if they are substantially related? Must we also add new regulatory text in order to establish a time-based presumption for or against aggregation? We also solicit comment on whether we would need new or revised rule language to adopt a time-based presumption against aggregation.

Furthermore, we specifically request comment on whether "substantially related" is the proper measurement to apply when determining whether to aggregate projects. Or does it, as the petitioner has expressed, add confusion for sources and permitting authorities trying to apply the test? Is there another benchmark that would be more sensible to use to determine when the emissions of nominally-separate changes at a source should be aggregated for evaluating NSR applicability? If we decide to retain the substantially related test or revert to our former test, is the 3-year presumption against aggregation appropriate?

2. Rule May Be Inconsistent With a Court of Appeals Decision for Previous NSR Rule

The NRDC petition identifies our interpretation of the controlling statutory term, "modification," and a key case discussing that definition as issues that were impractical to raise during the comment period and of central relevance to the rule. While NRDC and other commenters identified these matters as being at issue in their comments, we did not include an explanation in the proposed rule of how the EPA aggregation interpretation was consistent with the statute and the court decision. In a sense, the rulemaking process required by CAA 307(d) was inverted: rather than the EPA providing a "statement of basis [summarizing] the major legal interpretations* * *underlying the proposed rule," as required by CAA 307(d)(3)(C), the commenters provided their views of the law, and we then provided a legal basis in the final rule and in the response-to-comment document. Moreover, the rulemaking did not simply adopt a theory that was a logical outgrowth of the theory or theories suggested in the proposal. The portion of the proposal discussing aggregation was completely silent on how we interpreted CAA section 111(a)(4) to authorize aggregation and provided no analysis of the relevant case law.

Below we set out our understanding of the statute and case law. We invite comment on our understanding and what we believe would be the result from that understanding—*i.e.,* the revocation of the NSR Aggregation Amendments and the reversion to our pre-existing policy on project aggregation.

a. Background for our Historic Approach

Under both the nonattainment NSR provisions of the CAA as well as the PSD provisions, a modification of a major stationary source is treated as construction of a new source subject to permitting. Modification is a defined term under the statute: "The term 'modification' means any physical change in, or change in the method of operation of, a stationary source which increases the amount of any air pollutant emitted by such source or which results in the emission of any air pollutant not previously emitted" (CAA section 111(a)(4)). This definition requires analyzing whether a physical or operational change will take (or, *post hoc,* has taken) place, and whether it results in an emission increase. As noted above, in situations involving multiple nominally-separate changes at a source, EPA's "aggregation" policy interprets what is the physical or operational change that must be assessed for an emission increase.

We calculate the emissions increase associated with a physical or operational change at a major stationary source by reference to *de minimis* thresholds (also known as "significance levels"). From the earliest days of the NSR program, we recognized that a party seeking to avoid major source NSR might attempt to break up a single physical or operational change into nominally-separate changes in order to make the emission increase associated with each change appear to be less than significant. *See* 45 FR 52702 (Aug. 7, 1980). As subsequent case law confirmed, even a small physical or operational change may satisfy the first portion of the definition of modification. *State of New York* v. *EPA,* 443 F.3d 880, 890 (DC Cir. 2006), *cert. den.* 127 S. Ct. 2127 (2007) (*New York II*); *Wisconsin Elec. Power Co.* v. *Reilly,* 893 F.2d 901, 908 (7th Cir. 1990). We recognized that an owner or operator might apply for multiple minor permits for nominally-separate, small changes that by themselves result in *de minimis* emission increases, instead of obtaining a permit for the collection of changes that, when examined as a single project, resulted (or would result) in a significant emission increase.

We issued several letters since the early 1980s explaining that we may enforce the major source permitting requirements in such cases when a source "circumvents" major source NSR by dividing one change and its emission increase into nominally-separate physical or operational changes.[6] Some of these letters discussed intent to evade NSR, but focused more on objective factors such as the closeness in the timing of nominally-separate changes and the integrated planning of these changes.[7] In 1993, we issued a letter analyzing a series of minor permit applications for 3M Company's research and development facility in Maplewood, Minnesota.[8] This letter has been widely cited for its discussion of objective factors that could support a conclusion that nominally-separate changes should be treated as one project. These factors include the filing of multiple minor source or minor modification permits for a single source within a short period of time, funding information indicating one project, other reporting on consumer demand and project levels, other statements from the business indicating one project, EPA's assessment of the economic realities of the project, as well as the relationship of the changes to the overall basic purpose of the plant. Subsequently, we have issued additional letters discussing aggregation at particular plants in certain circumstances.[9] Collectively, these

[6] Memorandum from John Calcagni, Director, Air Quality Management Division, to William B. Hathaway, Director, Air, Pesticides, and Toxics Division, EPA Region 6, entitled "Request for Clarification of Policy Regarding the 'Net Emissions Increase' " (Sept. 18, 1989).

[7] *See, e.g.,* Letter from James Wilburn, Chief, Air Management Branch, EPA Region 4, to Harold Hodges, Director, Division of Air Pollution Control, Tennessee Department of Public Health (Aug. 15, 1983); Memorandum from Darryl Tyler, Director, Control Programs Development Division, EPA Office of Air Quality Planning and Standards (OAQPS), to David Kee, Director, Air Management Division, EPA Region 5, entitled "Applicability of PSD to Portions of Plan Constructed in Phases Without Permits" (Oct. 21, 1986); Letter from Don Clay, Acting Assistant Administrator, EPA Office of Air and Radiation, to John Boston, Vice President, Wisconsin Electric Power Company (Feb. 15, 1989).

[8] Memorandum from John Rasnic, Director, Stationary Source Compliance Division, OAQPS, to George Czerniak, Chief, Air Enforcement Branch, EPA Region 5, entitled "Applicability of New Source Review Circumvention Guidance to 3M–Maplewood, Minnesota" (June 17, 1993).

[9] *See, e.g.,* Letter from Doug Cole, Acting Manager, Federal & Delegated Air Programs Unit, EPA Region 10, to Grant Cooper et al., Frederickson Power L.P. (Oct. 12, 2001); Letter from Gregg

letters outline an approach where we would look at case-specific facts and the relationship between nominally-separate changes to determine whether they were a single project to be assessed for an emission increase under Step 1 of the NSR applicability test.

b. Our Explanation of Our Authority in the NSR Aggregation Amendments

The statute itself defines modification in the singular: "any physical change in, or change in the method of operation of, a stationary source" that increases emissions. Some have argued that we cannot aggregate or accumulate nominally-separate changes to determine NSR applicability because they can be viewed as multiple changes.

In response to this argument in comments on the NSR Aggregation Amendment proposed rule, we cited the recent decision in *New York II,* which held that the definition of modification requires "EPA [to] apply NSR whenever a source conducts an emission-increasing activity that fits within one of the ordinary meanings of 'physical change.' " 443 F.3d at 885. Because "[s]ubstantially related, nominally-separate changes can be seen as one change when viewed as a whole," we viewed "[a]ggregation of nominally separate changes that are substantially related as 'fit[ting] within one of the ordinary meanings of physical change.' "[10] Therefore, we viewed aggregation as allowed under the statute and the "substantially related" test for aggregation as a permissible interpretation of the modification definition.

Having seen EPA's analysis of *New York II* for the first time in the response-to-comment document supporting the NSR Aggregation Amendments, NRDC expressed the view that the foregoing analysis of that case "utterly misses the point." NRDC's petition acknowledges that aggregation of nominally-separate changes that are substantially related is one of the ordinary meanings of physical change. However, NRDC notes that "aggregation of nominally separate changes that are *not* substantially related" also may be within an ordinary meaning of physical change, especially when substantially related is defined in terms of technical or economic interrelationship and dependence. In NRDC's view, because the statute covers "any physical change," and the NSR Aggregation Amendments would omit some of these physical changes from NSR permitting by not aggregating them, the NSR Aggregation Amendments impermissibly narrowed the expansive reading of the statute's "any physical change" required by *New York II. See* NRDC petition at 5–6.

c. The CAA Requires Aggregation of Nominally-Separate Changes When They Collectively Can Be Seen as One Change

The issue NRDC raises goes to the crux of the NSR Aggregation Amendments. What must be treated as one physical or operational change under the definition of "modification" in the act is the legal underpinning for our aggregation policy.

The *New York II* Court held that we have limited authority to exempt from NSR those activities that can be considered a single physical change. Accordingly, "any physical change" should encompass any change that reasonably can be considered an ordinary meaning of the phrase. As the Court noted, "[W]hen Congress places the word 'any' before a phrase with several common meanings, the statutory phrase encompasses each of those meanings; the agency may not pick and choose among them." 443 F.3d at 888. The logic of *New York II* applies not only to physical changes but also to changes in the method of operation of a source.

Much of the emphasis of *New York II* and other cases has been on whether we could exclude small changes from being considered potential modifications as defined in the Act. However, the *New York II* Court's reasoning also applies to a rule that would split apart one change into separate changes in order to limit the applicability of NSR. The Court concludes, "[a]lthough the phrase "physical change" is susceptible to multiple meanings, the word "any" makes clear that activities within each of the common meanings of the phrase are subject to NSR when the activity results in an emission increase." 443 F.3d at 890. The statute prohibits EPA from picking and choosing among meanings of the phrase "any physical change * * * or change in the method of operation" if it would result in omitting a common meaning that would subject an emission increase to review.

Historically, EPA has analyzed the question of whether nominally-separate changes are one change by using a case-by-case review of all relevant and objective factors that looks for "indicia," or indicators, of these changes being one common aggregate change. As noted above, one much-cited example of our analysis of grouping together nominally-separate changes is appropriate is the "3M-Maplewood" memorandum discussed above and in the notices for the proposed and final rules. One concern about the 3M-Maplewood analysis has been that one portion of the analysis suggests that any set of nominally-separate changes that are consistent with "the plant's overall basic purpose" can be aggregated.[11]

The opinion in *New York II* further clarifies this portion of the 3M-Maplewood analysis, which remains EPA's most complete statement of the principles regarding grouping nominally-separate changes. As the Court observed, "[t]he modifier 'any' cannot bring an activity that is never considered a 'physical change' within the ambit of NSR." 443 F.3d at 887–888. Therefore, an important limiting factor in analyzing indicia of whether nominally-separate changes should be grouped into an aggregated, single change is whether the grouping would be under one of the ordinary meanings of physical change or change in the method of operation of a source.

If "substantially related" would omit an ordinary, common meaning of physical change that would bring an emission-increasing project under review, then the definition would eliminate a type of physical change that Congress intended to cover (*i.e.,* the change that consists of the group of nominally-separate changes that comprise a project but do not qualify as "substantially related"). In effect, the interpretation in the NSR Aggregation Amendments is unreasonable because it would create a carve-out from the scope of the statutory definition of modification.

It is our view that *New York II* requires EPA to aggregate any group of small changes that are sufficiently related to "fit[] within one of the ordinary meanings of 'physical change.' " We agree with the contention that, to the extent that our "substantially related" interpretation would exclude meanings that fit within a reasonable understanding of the ordinary meaning of "any physical change," the interpretation in the NSR Aggregation Amendments would impermissibly narrow the scope of CAA section 111(a)(4). We seek comment on our analysis.

We specifically invite comment on the following questions. Do we have the

Worley, Chief, Air Permits Section, EPA Region 4, to Heather Abrams, Georgia Environmental Protection Division (July 5, 2005); Letter from David Campbell, Chief, Permits & Technical Assessment Branch, EPA Region 3, to Matthew Williams, Pennsylvania Department of Environmental Protection (Feb. 21, 2007).

[10] "Response to Comments Document for the Final Action: PSD and Nonattainment New Source Review (NSR): Aggregation and Project Netting", EPA–HQ–OAR–2003–0064–0111, pg. 8.

[11] We do not believe the 3M-Maplewood letter relies solely on this portion of its analysis.

authority to aggregate nominally-separate changes that "fit within one of the ordinary meanings" of a single physical or operational change when they are viewed in the context of the source? Is *New York II* relevant to the question of whether we aggregate? Are there "ordinary meanings" of physical or operational change that do not fit within "substantially related" as we describe it in the NSR Aggregation Amendments? Do we have the authority to exclude these meanings in light of the *New York II* language?

In one respect, the aggregation of nominally-separate changes that are "substantially related" appears to be distinguishable from the legal error underlying the rule at issue in *New York II,* the "Equipment Replacement Provision" or "ERP". In the ERP, we claimed that the excluded activities (*e.g.,* replacements that were functionally equivalent and less than 20 percent of the replacement cost) were not physical changes as meant by the statute. In the NSR Aggregation Amendments, we recognize that a nominally-separate physical or operational change is a change by itself and declare it not to be part of a "larger change" [12] that also meets a common understanding of a single "change." To the extent that one event could be a part of either a change that is smaller or a change that is larger, one may argue that it is ambiguous as to which meaning of change should apply.

We are not persuaded that the same event possibly being part of more than one change is an ambiguity that would allow us to exclude the event from CAA section 111(a)(4). The *New York II* decision requires that, when choosing among meanings of "change" in various contexts, we must choose a meaning that brings the emission-increasing change into the potential scope of the modification definition. Therefore, we do not consider the potential for a nominally-separate change to be either a change by itself or a change that is part of a larger change to be an ambiguity that would allow us to select the less inclusive meaning. Nevertheless, were a reviewing court to find that there is some ambiguity in the statute as it applies to the coverage of nominally-separate changes, we believe there may be policy concerns that would warrant revocation of the NSR Aggregation Amendments.

[12] *i.e.,* a subset of another physical change or change in the method of operation.

3. Questioning the Need for a Policy Change

An objection raised in NRDC's petition is that the EPA's 2006 proposal on Aggregation failed to identify any actual problems or inconsistencies with longstanding aggregation policy as applied and explained in the 3M Maplewood letter. While the issue of whether the historic policy on project aggregation had problems was raised by our proposed rule, we did not request comment on the various factors we historically applied. Given that we now view the state of the record differently, we are taking this opportunity to request comment on the need for a change in policy.

The impetus for developing the NSR Aggregation Amendments emerged from a study conducted by EPA in 2001 on the impact of NSR regulations on investment in new utility and refinery generation. This EPA study took input from a range of stakeholders and resulted in a report to the President in 2002 that included a suite of recommendations for how to change the NSR rules to improve the effectiveness of the program. One of the recommendations was for EPA to make clarifying changes to the approach used for aggregating projects.

However, in reviewing the record for the NSR Aggregation Amendments, we find that the only factual support for the contention that our historic approach caused confusion was anecdotal. The parties supporting a change in policy failed to provide us with any characterization of the overall level of uncertainty or other problems resulting from the existing policy on aggregation. Furthermore, through our Aggregation proposal in 2006, we received countervailing testimony from permitting agencies and other stakeholders that contended that there was little confusion in the application of our aggregation policy. For example, the State of New Mexico wrote that "* * * the current common sense approach of looking at the timing, scope, and interrelationship(s) of projects in determining the occurrence of aggregation is more straightforward than to narrowly evaluate the validity of independent economic justification * * * *or* technical dependence of various projects." [13] We also heard from a local reviewing authority in Ohio, who recommended that "* * * EPA propose a test that more accurately represents current permitting authority practice with regard to evaluating major NSR applicability and aggregation." [14] Finally, the National Association of Clean Air Agencies stated that the proposal left "* * * greater uncertainty than the previous, reasonably well-developed policy." [15] We note that these comments were made in the context of a proposed rule based on technical and economic dependence, not "substantially related," but nevertheless illustrate a basic comfort level with the current practice.

We request comment on whether there was a bona fide need for added clarity over and above what the old aggregation policy provided. If clarity was lacking, we further solicit comment on whether the NSR Aggregation Amendments achieved added clarity.

We also note that it has been our experience that the few applicability determinations we have issued where aggregation was the central issue have not been contested on appeal. The absence of contested applicability determinations tends to support a belief that there was not significant confusion or controversy with our historic policy. Through this reconsideration, we specifically request comment from reviewing authorities on the frequency of disputes with other parties over their aggregation decisions, such as appeals of applicability determinations where this has been an issue, adverse comments in permitting proceedings, or having to brief the issue in litigation.

4. State Plan Adoption

As noted above, the NSR Aggregation Amendments did not include amendatory text for the Code of Federal Registers (CFR). We agree with NRDC's assertion that the state and local implementation requirements of the NSR Aggregation Amendments are unclear. The question of whether a SIP amendment is required when the CFR remains unchanged is likely to cause confusion for reviewing authorities and other stakeholders. We view these difficulties as clear support for the need to have the rule not be effective until the completion of our reconsideration proceeding. We also view it as added support for our preferred position in this notice, which is to revoke the NSR Aggregation Amendments, as discussed in greater detail in the next section of this notice.

In section III.3.a of this notice, we ask for comment on whether the existing NSR regulatory text can support the new interpretation provided by the NSR

[13] Richard Goodyear, State of New Mexico Environment Department, EPA–HQ–OAR–2003–0064–0055.1.

[14] John A. Paul, Regional Air Pollution Control Agency, EPA–HQ–OAR–2003–0064–0089.1.

[15] Bill O'Sullivan and John A. Paul, National Association of Clean Air Agencies, EPA–HQ–OAR–2003–0064–0102.1.

Aggregation Amendments if the rule remains in effect after this reconsideration proceeding. Apart from this important question, we are also taking comment on when and how reviewing authorities with EPA-approved plans in 40 CFR part 51.166 can implement the new policy interpretation given that there are no CFR changes to use as a basis for drafting amendments to their state plans.

In a broader sense, when EPA issues an interpretive rule, have reviewing authorities with EPA-approved implementation programs adopted the new interpretation in their implementation plans? Or have these agencies not required a plan amendment and immediately applied the new interpretation? If a plan revision was required, what was the proper mechanism for State adoption for an interpretive rule where there is no change to the CFR? We solicit comment on all of these questions.

5. Proposal To Revoke Rule

As part of NRDC's petition requesting reconsideration of the Aggregation Amendments, NRDC further asked EPA to "withdraw and abandon the final rule." While rare, the Administrator has in the past withdrawn, or revoked, a promulgated rule prior to its effective date. The reasons for such action by the Administrator are varied, but typically it is done when a final rule is determined to be either error prone, confusing, overly burdensome, or unnecessary, such that leaving the rule in place would not improve the program.[16]

An overarching concern of EPA is that our original policy goal for developing the Aggregation Amendments—*i.e.,* to provide improved clarity in making aggregation determinations—does not appear to have been achieved. This concern is reflected in the petition for reconsideration, and we believe it has sufficient merit that we must consider whether retaining the NSR Aggregation Amendments is justified. While the rule may, in some respects, appear clearer than our past policy, we are not convinced that it achieved enough additional clarity to improve the process of making aggregation assessments by sources and reviewing authorities. As noted above, our reexamination of the record also leads us to believe that the apparent need for additional clarity with the aggregation policy may have been overstated. Furthermore, as discussed above, the rule introduces new ambiguities, particularly with respect to implementation, that may further reduce its effectiveness.

Balancing this against the additional issues raised with respect to the legal and implementation aspects of the final rule, as well as our concern of possible under-inclusiveness of the final rule (*i.e.,* the chance that certain projects that should be aggregated would avoid aggregation under the approach from the NSR Aggregation Amendments), we believe that the prior agency policy may, on balance, provide a more reasonable interpretation than the policy interpretation contained in the final rule. We are therefore proposing as our preferred option to revoke the final rule. If we ultimately decide through reconsideration to revoke the NSR Aggregation Amendments, we believe we should restore the past policy for making case-by-case aggregation determinations.

We specifically solicit comment on the legal concerns and possible under-inclusiveness with the final rule. As noted above, comments received on our proposal from various reviewing authorities show some support for retaining the pre-existing aggregation factors. Thus, we also request comment on whether the old policy framework for aggregating nominally-separate changes is adequate if the NSR Aggregation Amendments is revoked. Has the decision in *New York II* helped to improve the understanding of the past policy direction in 3M-Maplewood and other relevant memoranda?

6. Proposal To Extend Effective Date

As noted, the effective date of the NSR Aggregation Amendments is May 18, 2010. This scheduled date was shifted from the original effective date to allow time for the Agency to conduct a full reconsideration of the final rule.

We are concerned now, however, that our reconsideration rulemaking schedule will not meet the revised effective date. Furthermore, we still have concerns, as noted above, with the final rule becoming effective prior to completion of our reconsideration proceeding. Recognizing this, we are proposing additional time that would enable us to fully evaluate comments on issues that are in question and to complete any revisions of the rule that become necessary as a result of the reconsideration process, without the concern of the rule prematurely becoming effective.

Therefore, we propose to delay the effective date of the NSR Aggregation Amendments, published in the **Federal Register** on January 15, 2009 (74 FR 2376), until November 18, 2010. This delay would be for an additional 6 months, which we believe would provide a reasonable period of time to complete action on the reconsideration. We solicit comment on a 6-month delay of the effectiveness of the final rule, and we also solicit comment on a longer delay (*e.g.,* 9 or 12 months).

## IV. Statutory and Executive Order Reviews

### *A. Executive Order 12866: Regulatory Planning and Review*

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" because it raises novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

### *B. Paperwork Reduction Act*

This action does not impose any new information collection burden. We are not proposing any new paperwork requirements (*e.g.,* monitoring, reporting, recordkeeping) as part of this proposed action. This action simply solicits comment on a number of legal and policy issues raised in a petition for reconsideration on the NSR Aggregation Amendments, and proposes an additional extension of the stay of the rule.

However, the OMB has previously approved the information collection requirements contained in the existing regulations (40 CFR parts 51 and 52) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and has been assigned OMB control number 2060–0003. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

### *C. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

[16] *See, e.g.,* "Withdrawal of Revisions to the Water Quality Planning and Management Regulation and Revisions to the National Pollutant Discharge Elimination System Program in Support of Revisions to the Water Quality Planning and Management Regulation" proposed Dec. 27, 2002 (67 FR 79020) and finalized Mar. 19, 2003 (68 FR 13608).

*For purposes of assessing the impacts of this proposal on small entities, small entity is defined as:* (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any new requirements on small entities. We have determined that small businesses will not incur any adverse impacts because no costs were associated with the NSR Aggregation Amendments, and this proposed reconsideration of that rule simply requests comment on a variety of issues, none of which would create any new requirements or burdens. Therefore, no costs are associated with this proposed amendment.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

*D. Unfunded Mandates Reform Act*

This action does not contain a federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 ("URMA"), 2 U.S.C. 1531–1538 for state, local, and tribal governments or the private sector. This action simply solicits comment on a number of issues raised in a petition for reconsideration on the NSR Aggregation Amendments, and proposes to revoke the rule. Therefore, this action is not subject to the requirements of sections 202 or 205 of UMRA.

This action 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.

*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, as specified in Executive Order 13132. This action simply solicits comment on issues raised in NRDC's petition for reconsideration on the NSR Aggregation Amendments, and proposes to revoke the rule. Thus, Executive Order 13132 does not apply to this proposed rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed rule from state and local officials.

*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.) This action will not impose any new obligations or enforceable duties on tribal governments.

EPA specifically solicits additional comment on this proposed action from tribal officials.

*G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

This action is not subject to EO 13045 (62 FR 19885), April 23, 1997) because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. We do not believe this action creates any environmental health or safety risks.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure.

*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 under Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (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 action will not create any new requirements for sources in the energy supply, distribution, or use sectors.

*I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because any impacts that it will have will be global in nature and will not affect local communities or populations in a manner that adversely affects the level of protection provided to human health or the environment.

*K. Determination Under Section 307(d)*

Pursuant to sections 307(d)(1)(E) and 307(d)(1)(V) of the CAA, the Administrator determines that this action is subject to the provisions of section 307(d). Section 307(d)(1)(V) provides that the provisions of section 307(d) apply to "such other actions as the Administrator may determine."

## V. Statutory Authority

The statutory authority for this action is provided by section 301(a) of the CAA as amended (42 U.S.C. 7601(a)). This notice is also subject to section 307(d) of the CAA (42 U.S.C. 7407(d)).

## List of Subjects in 40 CFR Parts 51 and 52

Administrative practices and procedures, Air pollution control, Environmental protection,

Intergovernmental relations, Aggregation.

Dated: March 29, 2010.

**Lisa P. Jackson,**

*Administrator.*

[FR Doc. 2010–7534 Filed 4–14–10; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**[Docket No. FWS–R8–ES–2009–0038] [92210–1117–0000–B4]**

**RIN 1018–AW22**

## Endangered and Threatened Wildlife and Plants; Revised Critical Habitat for *Navarretia fossalis* (Spreading Navarretia)

**AGENCY:** Fish and Wildlife Service, Interior.

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

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our June 10, 2009, proposed revised designation of critical habitat for *Navarretia fossalis* (spreading navarretia). We also announce the availability of a draft economic analysis (DEA); revisions to proposed critical habitat, including proposed revisions to eight subunits based on the previous public comment period; and an amended required determinations section of the proposal. We are reopening the comment period for an additional 30 days to allow all interested parties an opportunity to comment on all of the above. If you submitted comments previously, you do not need to resubmit them because we have already incorporated them into the public record and will fully consider them in our final determination.

**DATES:** We will consider public comments received on or before May 17, 2010. Any comments that are received after the closing date may not be considered in the final decision on this action.

**ADDRESSES:** 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-R8-ES-2009-0038.

• *U.S. mail or hand-delivery*: Public Comments Processing, Attn: FWS–R8–ES–2009–0038; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

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).

**FOR FURTHER INFORMATION CONTACT:** Jim Bartel, Field Supervisor, U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Suite 101, Carlsbad, CA 92011; telephone (760) 431–9440; facsimile (760) 431–5901. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (800) 877–8339.

**SUPPLEMENTARY INFORMATION:**

### Public Comments

We intend that any final action resulting from the proposed rule is based on the best scientific data available and will be accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or any other interested parties during this reopened comment period on our proposed rule to revise critical habitat for *Navarretia fossalis* (spreading navarretia), which we published in the **Federal Register** on June 10, 2009 (74 FR 27588), including the changes to proposed critical habitat in Subunits 1A, 1B, 3B, 5C, 5I, 6A, 6B, and 6C, the DEA of the proposed revised designation, and the amended required determinations provided in this document. We are particularly interested in comments concerning:

(1) The reasons why we should or should not revise the critical habitat under section 4 of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), including whether there are threats to *Navarretia fossalis* from human activity, the type of human activity causing these threats, and whether the benefit of designation would outweigh any threats to the species caused by the designation, such that the designation of critical habitat is prudent.

(2) Specific information on:

• The current amount and distribution of *Navarretia fossalis* habitat.

• Areas that provide habitat for *N. fossalis* that we did not discuss in our original proposed revised critical habitat rule or in this reopening of the comment period.

• Areas containing the physical and biological features essential to the conservation of *N. fossalis* that we should include in the revised critical habitat designation and why. Include information on the distribution of these essential features and what special management considerations or protections may be required to maintain or enhance them.

• Areas proposed as critical habitat that do not contain the physical and biological features essential for the conservation of the species that should not be designated as critical habitat.

• Areas not occupied at the time of listing that are essential to the conservation of the species and why.

(3) Land use designations and current or planned activities in the areas occupied by the species, and their possible impacts on proposed critical habitat;

(4) How the proposed revised critical habitat boundaries could be refined to more closely circumscribe landscapes identified as containing the physical and biological features essential to the conservation of the species.

(5) Any foreseeable economic, national security, or other relevant impacts that may result from designating particular areas as critical habitat, and, in particular, any impacts to small entities (e.g., small businesses or small governments), and the benefits of including or excluding areas from the proposed revised designation that exhibit these impacts.

(6) Special management considerations or protections that the essential physical and biological features identified in the proposed critical habitat may require.

(7) Information on the extent to which the description of potential economic impacts in the DEA is complete and accurate.

(8) Whether any specific subunits being proposed as critical habitat should be excluded under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any particular area outweigh the benefits of including that area as critical habitat.

(9) Our consideration to exclude the portion of Subunit 4E that we are proposing as critical habitat within the Ramona Grasslands Preserve under section 4(b)(2) of the Act, and whether such exclusion is appropriate and why;

(10) The likelihood of adverse social reactions to the designation of critical habitat, and how the consequences of such reactions, if they occur, would relate to the conservation of the species and regulatory benefits of the proposed revised critical habitat designation.

(11) Information on the extent to which the description of potential economic impacts in the DEA is complete and accurate, and specifically:

• Whether there are incremental costs of critical habitat designation (e.g., costs attributable solely to the designation of critical habitat for *Navarretia fossalis*) that have not been appropriately identified or considered in our economic analysis, including costs associated with future administrative costs or project modifications that may be required by Federal agencies related to section 7 consultation under the Act;

• Whether there are incremental economic benefits of critical habitat designation that have not been appropriately identified or considered in our economic analysis.

(12) The potential effects of climate change on this species and its habitat and whether the critical habitat may adequately account for these potential effects.

If you submitted comments or information on the proposed revised rule (74 FR 27588) during the initial comment period from June 10, 2009, to August 10, 2009, please do not resubmit them. These comments are included in the public record for this rulemaking, and we will fully consider them in the preparation of our final determination. Our final determination concerning the revised critical habitat for *Navarretia fossalis* will take into consideration all written comments and any additional information we receive during both comment periods. On the basis of public comments, we may, during the development of our final determination, find that areas within the proposed revised critical habitat designation do not meet the definition of critical habitat, that some modifications to the described boundaries are appropriate, or that areas may or may not be appropriate for exclusion under section 4(b)(2) of the Act.

You may submit your comments and materials concerning our proposed rule, the associated DEA, our changes to subunits and considered exclusions as identified in this document, and our amended required determinations section by one of the methods listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hard copy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hard copy comments on *http://www.regulations.gov*. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation used to prepare this notice, will be available for public inspection at *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed revision of critical habitat (74 FR 27588) and the DEA on the Internet at *http://www.regulations.gov* at Docket No. FWS-R8-ES-2009-0038, or by mail from the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

## Background

It is our intent to discuss only those topics directly relevant to the proposed revised designation of critical habitat for *Navarretia fossalis* in this notice. For more information on previous Federal actions concerning *N. fossalis*, see the 2005 final designation of critical habitat published in the **Federal Register** on October 18, 2005 (70 FR 60658), or the 2009 proposed revised designation of critical habitat published in the **Federal Register** on June 10, 2009 (74 FR 27588), or contact the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

The Center for Biological Diversity filed a complaint in the U.S. District Court for the Southern District of California on December 19, 2007, challenging our designation of critical habitat for *Navarretia fossalis* and *Brodiaea filifolia* (*Center for Biological Diversity* v. *United States Fish and Wildlife Service et al.*, Case No. 07–CV–2379–W–NLS). This lawsuit challenged the validity of the information and reasoning we used to exclude areas from the 2005 critical habitat designation for *N. fossalis*. We reached a settlement agreement on July 25, 2008, in which we agreed to reconsider critical habitat designation for *N. fossalis*. The settlement stipulated that we submit a proposed revised critical habitat designation for *N. fossalis* to the **Federal Register** for publication by May 29, 2009, and submit a final revised critical habitat designation to the **Federal Register** for publication by May 28, 2010. On June 10, 2009, we published the revised proposed critical habitat designation in the **Federal Register** (74 FR 27588). On January 20, 2010, we were granted an extension to submit a final revised critical habitat designation to the **Federal Register** for publication by September 30, 2010.

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

## Draft Economic Analysis

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific and commercial data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat.

We prepared a DEA (Entrix, Inc. 2010), which identifies and analyzes the potential impacts associated with the proposed revised designation of critical habitat for *Navarretia fossalis* that we published in the **Federal Register** on June 10, 2009 (74 FR 27588). The DEA looks retrospectively at costs incurred since the October 13, 1998 (63 FR 54975), listing of *N. fossalis* as threatened. The DEA quantifies the economic impacts of all potential conservation efforts for *N. fossalis*; some of these costs will likely be incurred regardless of whether or not we finalize the revised critical habitat rule. The economic impact of the proposed revised critical habitat designation is analyzed by comparing a "with critical habitat" scenario with a "without critical habitat" scenario. The "without critical habitat" scenario represents the baseline for the analysis, considering protections already in place for the species (for example, under the Federal listing and other Federal, State, and local regulations). The baseline, therefore, represents the costs incurred regardless of whether critical habitat is designated. The "with critical habitat" scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts are those not expected to occur absent the critical

habitat designation for *N. fossalis*. In other words, the incremental costs are those attributable solely to the designation of critical habitat above and beyond the baseline costs; these are the costs we may consider in the final designation of critical habitat relative to areas that may be excluded under section 4(b)(2) of the Act. The analysis looks retrospectively at baseline impacts incurred since the species was listed, and forecasts both baseline and incremental impacts likely to occur if we finalize the proposed revised critical habitat.

The 2010 DEA (made available with the publication of this notice and referred to as the DEA throughout this document unless otherwise noted) estimates the foreseeable economic impacts of the proposed revised critical habitat designation for *Navarretia fossalis*. The economic analysis identifies potential incremental costs as a result of the proposed revised critical habitat designation, which are those costs attributed to critical habitat over and above those baseline costs coextensive with listing. It also discusses the benefits of critical habitat designation. These benefits are primarily presented in a qualitative manner. The DEA describes economic impacts of *N. fossalis* conservation efforts associated with the following categories of activity: (1) Development, (2) conservation lands management, (3) transportation, (4) pipeline projects, (5) flood control, (6) agriculture, and (7) fire management.

Baseline economic impacts are those impacts that result from listing and other conservation efforts for *Navarretia fossalis*. Conservation efforts related to flood control and development activities constitute the majority of total baseline costs (approximately 84 percent of post-designation, upper-bound, baseline impacts when a 7 percent discount rate is used) in areas of proposed revised critical habitat. Impacts to conservation lands management, transportation, and pipeline projects compose the remaining approximately 16 percent of post-designation, upper-bound, baseline impacts when a 7 percent discount rate is used. Total future baseline impacts are estimated to be $30.1 to $123.5 million ($2.9 to $11.7 million annualized) in present value terms using a 7 percent discount rate, over the next 20 years (2010–2029) in areas proposed as revised critical habitat (Entrix, Inc. 2010, pp. ES-3–ES-4).

Conservation costs associated with section 7 consultations for development, transportation, and flood control projects comprise the quantified incremental impacts for the proposed revised critical habitat rule. Impacts associated with transportation constituted the largest portion of post-designation, upper-bound incremental impacts, accounting for almost 47 percent of the forecast incremental impacts applying a 7 percent discount rate. Conservation efforts related to development and flood control activities constitute the remainder of incremental impacts (37 percent and 16 percent, respectively, of post-designation upper-bound baseline impacts when a 7 percent discount rate is used) in areas of proposed revised critical habitat. The DEA estimated total potential incremental economic impacts in areas proposed as revised critical habitat over the next 20 years (2010–2029) to be $846,000 to $1.2 million ($80,000 to $100,000 annualized) in present value terms applying a 7 percent discount rate (Entrix, Inc. 2010, pp. ES-3–ES-4).

The DEA considers both economic efficiency and distributional effects. In the case of habitat conservation, efficiency effects generally reflect the "opportunity costs" associated with the commitment of resources to comply with habitat protection measures (such as lost economic opportunities associated with restrictions on land use). The DEA also addresses how potential economic impacts are likely to be distributed, including an assessment of any local or regional impacts of habitat conservation and the potential effects of conservation activities on government agencies, private businesses, and individuals. The DEA measures lost economic efficiency associated with residential and commercial development and public projects and activities, such as economic impacts on water management and transportation projects, Federal lands, small entities, and the energy industry. Decision-makers can use this information to assess whether the effects of the revised designation might unduly burden a particular group or economic sector.

## Changes to Proposed Revised Critical Habitat

In this document we are proposing revisions to Subunits 1A, 1B, 3B, 5I, 6A, 6B, and 6C, as identified and described in the revised proposed rule that published in the **Federal Register** on June 10, 2009 (74 FR 27588), and adding a new Subunit 5C. We received comments from the public and from one peer reviewer during the open comment period indicating that we should reevaluate the proposed boundaries of Subunits 1A, 1B, 3B, 5I, 6A, 6B, and 6C and that we should include subunit 5C in the proposed critical habitat. The purpose of the revisions described below is to better delineate the areas that meet the definition of critical habitat for *Navarretia fossalis*. All areas added to the units proposed in the June 10, 2009 (74 FR 27588), proposed rule are within the geographic range occupied by the species at the time it was listed and contain the features essential for the conservation of the species. These areas contain the primary constituent elements (PCEs), which are the physical or biological features essential to the conservation of a species, and which the species' proposed or designated critical habitat is based on, such as space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the species' historic geographic and ecological distribution.

The revisions consist of both additions and removals of land that we proposed as critical habitat (74 FR 27588). The changes made in Subunits 1A, 1B, 3B, 5I, 6A, 6B, and 6C do not alter the description of these subunits in the June 10, 2009, proposed rule (74 FR 27588); however, we include revised maps with this publication. We briefly describe the changes made for each of these subunits below. We did not include Subunit 5C in the proposed rule (74 FR 27588, June 10, 2009), so this notice includes the full description and map for Subunit 5C below. As a result of these revisions, the overall area proposed for critical habitat is 7,609 acres (ac) (3,079 hectares (ha)), an increase of 737 ac (298 ha) from the 6,872 ac (2,781 ha) that we proposed as critical habitat in the June 10, 2009, proposed rule (74 FR 27588). A summary of the total acreage of each proposed subunit is presented in Table 1.

TABLE 1. SUMMARY OF SUBUNITS PROPOSED AS CRITICAL HABITAT.

| Location | Total Subunit Area |
|---|---|
| **Unit 1: Los Angeles Basin-Orange Management Area** | |
| 1A. Cruzan Mesa | 156 ac (63 ha) |
| 1B. Plum Canyon | 20 ac (8 ha) |
| **Unit 2: San Diego: Northern Coastal Mesa Management Area** | |
| 2. Poinsettia Lane Commuter Station | 9 ac (4 ha) |
| **Unit 3: San Diego: Central Coastal Mesa Management Area** | |
| 3A. Santa Fe Valley (Crosby Estates) | 5 ac (2 ha) |
| 3B. Carroll Canyon | 18 ac (7 ha) |
| 3C. Nobel Drive | 37 ac (15 ha) |
| 3D. Montgomery Field | 48 ac (20 ha) |
| **Unit 4: San Diego: Inland Management Area** | |
| 4C1. San Marcos (Upham) | 34 ac (14 ha) |
| 4C2. San Marcos (Universal Boot) | 32 ac (13 ha) |
| 4D. San Marcos (Bent Avenue) | 5 ac (2 ha) |
| 4E. Ramona | 135 ac (55 ha) |
| **Unit 5: San Diego: Southern Coastal Mesa Management Area** | |
| 5A. Sweetwater Vernal Pools (S1-3) | 95 ac (38 ha) |
| 5B. Otay River Valley (M2) | 24 ac (10 ha) |
| 5C. Otay Mesa (J26) | 42 ac (17 ha) |
| 5F. Proctor Valley (R1-2) | 88 ac (36 ha) |
| 5G. Otay Lakes (K3-5) | 140 ac (57 ha) |
| 5H. Western Otay Mesa vernal pool complexes | 143 ac (58 ha) |
| 5I. Eastern Otay Mesa vernal pool complexes | 221 ac (89 ha) |
| **Unit 6: Riverside Management Area** | |
| 6A. San Jacinto River | 4,312 ac (1,745 ha) |
| 6B. Salt Creek Seasonally Flooded Alkali Plain | 943 ac (382 ha) |
| 6C. Wickerd Road and Scott Road Pools | 235 ac (95 ha) |
| 6D. Skunk Hollow | 158 ac (64 ha) |
| 6E. Mesa de Burro | 708 ac (287 ha) |
| **Total** | **7,609 ac (3,079 ha)** |

*Subunit 1A: Cruzan Mesa*

We received comments indicating that we did not capture the entire watershed area necessary to fill the vernal pools supporting *Navarretia fossalis* in Subunit 1A. We reviewed aerial imagery and topographic maps for this area and verified that the subunit needed revision to adequately capture areas that meet the definition of critical habitat and include the watershed for the ponding areas on Cruzan Mesa (PCE 2). The revised subunit consists of 156 ac (63 ha) of private land, an increase of 27 ac (11 ha) from what we proposed as critical habitat in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 1B: Plum Canyon*

We received information indicating that the placement of our proposed critical habitat for Subunit 1B did not capture the vernal pool where *Navarretia fossalis* occurs in the Plum Canyon area. Due to a publication error, the incorrect map was published in the June 10, 2009, proposed rule (74 FR 27588). In reviewing this subunit, we

became aware of more accurate data describing this area (Glenn Lukos Associates 2009, Exhibit 3 (Appendix D-3 of PCR 2009)). As a result of our evaluation of this new information, we remapped the boundaries of Subunit 1B. Our remapping corrects our publication error and incorporates the new information. Subunit 1B contains physical and biological features that are essential to the conservation of *N. fossalis*, including ephemeral wetland habitat (PCE 1), intermixed wetland and upland habitats that act as the local watershed (PCE 2), and the topography and soils that support ponding during winter and spring months (PCE 3). The revised subunit consists of 20 ac (8 ha) of private land, a decrease of 12 ac (5 ha) from what we proposed in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 3B: Carroll Canyon*

We received information indicating that the western portion of Subunit 3B had been graded and does not likely contain the physical and biological features essential to the conservation of *Navarretia fossalis*. We reviewed aerial imagery and found this information to be correct; therefore, we removed 2 ac (1 ha) of land that no longer meets the definition of critical habitat for this species. The revised subunit consists of 18 ac (7 ha) (16 ac (6 ha) of land owned by the City of San Diego and 2 ac (1 ha) of private land), a decrease of 2 ac (1 ha) from what we proposed in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 5C: J26 Vernal Pool Complex*

We received information from the public that we should propose Subunit 5C, a subunit that was designated as critical habitat in our October 18, 2005, final rule (70 FR 60658), as revised critical habitat in this rule. We did not include Subunit 5C in the proposed rule (74 FR 27588, June 10, 2009) because we did not have data in our GIS database indicating this area was occupied by *Navarretia fossalis*. We subsequently reviewed the data in our files on *N. fossalis* in Subunit 5C (the J26 vernal pool complex) and found records of *N. fossalis* occupancy (The Environmental Trust 2001, p. 1; 2000, p. 1). Based on this new information and because this vernal pool complex is also considered one of the best examples of vernal pool habitat on Otay Mesa (The Environmental Trust 2002, p. 2), we are proposing Subunit 5C as revised critical habitat. We have mapped the boundary of this subunit to conform to our current mapping methodology.

Subunit 5C is located on eastern Otay Mesa in San Diego County, California. This subunit is on the far eastern side of Otay Mesa north of Alta Road and south of Lower Otay Reservoir. Subunit 5C consists of 42 ac (17 ha), including 26 ac (11 ha) of State and local government-owned land and 16 ac (6 ha) private land. This subunit meets our criteria for satellite habitat; it supports a stable occurrence of *Navarretia fossalis* and provides potential connectivity between occurrences of *N. fossalis* in Subunits 5G and 5I. Subunit 5C contains the physical and biological features that are essential to the conservation of *N. fossalis*, including ephemeral wetland habitat (PCE 1), intermixed wetland and upland habitats that act as the local watershed (PCE 2), and the topography and soils that support ponding during winter and spring months (PCE 3). The physical and biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats from nonnative plant species, altered hydrology, and human disturbance activities (e.g., unauthorized grazing activity) that occur in the vernal pool basins and associated watershed. Please see the "Special Management Considerations or Protection" section of the proposed rule for a discussion of the threats to *N. fossalis* habitat and potential management considerations (74 FR 27588, June 10, 2009).

*Subunit 5I: Eastern Otay Mesa Vernal Pool Complex*

We are not proposing to revise the boundaries of Subunit 5I; however, due to a publication error, we are providing the correct map for Subunit 5I in this document. For clarification, we reiterate that Subunit 5I consists of 221 ac (89 ha) of private land as described in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 6A: San Jacinto River*

We received information from the public that we had not included some additional areas that meet the definition of critical habitat for *Navarretia fossalis* in Subunit 6A. We reviewed the new information provided, including a 2005 map that provided better survey data along the San Jacinto River (Helix Environmental, Inc. 2005, map). Based on the new information, we included additional areas in this subunit that meet the definition of critical habitat for *N. fossalis*. We expanded the critical habitat designation boundary for Subunit 6A in the following areas: (1) Around 13th Street to the east of the San Jacinto River, (2) east to Dawson Road and north to Ellis Road near Simpson Road, (3) around the Case Road vernal pool, and (4) north of the Green Valley Parkway. The revised subunit consists of 4,312 ac (1,745 ha) of private land, an increase of 762 ac (308 ha) from what we proposed in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 6B: Salt Creek Seasonally Flooded Alkali Plain*

A peer reviewer recommended that we revise the boundaries of the proposed critical habitat in three areas of Subunit 6B, because we had included areas that were disturbed by past activities and no longer meet the definition of critical habitat and had not included some areas that meet the definition of critical habitat for *Navarretia fossalis*. Following evaluation of this area in greater detail, we agreed with the peer reviewer and made changes to this subunit in the central portion on the east side, on the north end, and near the Hemet Airport. We are no longer proposing an area near the center on the east side that was developed and disturbed many years ago, has not supported *N. fossalis* since 1990, and therefore no longer meets the definition of critical habitat. Also, we are no longer proposing some land in the northern portion of the proposed subunit because it is dry, disturbed, and does not meet the definition of critical habitat for *N. fossalis*. Finally, we included vernal pool habitat on the eastern edge of our proposed subunit near the Hemet Airport that meets the definition of critical habitat for *N. fossalis*. The revised subunit consists of 943 ac (382 ha) of private land, a decrease of 111 ac (45 ha) from what we proposed in the June 10, 2009, proposed rule (74 FR 27588).

*Subunit 6C: Wickerd Road and Scott Road Pools*

We received information that we had not adequately captured the physical and biological features essential to the conservation of *Navarretia fossalis* in Subunit 6C. We received new information describing the Wickerd Road vernal pool (Roberts 2009, p. 1). We reviewed the new information, including the information about the vernal pool and newer aerial imagery for this area. As a result, we revised the subunit to include the upward sloping area between the Wickerd Road vernal pool and Scott Road that meets the definition of critical habitat for *N. fossalis* and contributes to the watershed of this vernal pool. The revised subunit consists of 235 ac (95 ha) of private land, an increase of 30 ac (12 ha) from what we proposed in the June 10, 2009, proposed rule (74 FR 27588).

*Additional Areas Currently Considered For Exclusion Under Section 4(b)(2) of the Act– The Ramona Grasslands Preserve*

In the proposed revised critical habitat designation published on June 10, 2009 (74 FR 27588), we identified lands in Subunit 4E as meeting the definition of critical habitat for *Navarretia fossalis*. Based on comments submitted during the initial public comment period from June 10, 2009, to August 10, 2009, we are also considering for exclusion from critical habitat under section 4(b)(2) of the Act the portion of Subunit 4E within the Ramona Grasslands Preserve. Of the 135 ac (55 ha) proposed in Subunit 4E, 51 ac (21 ha) are part of the Ramona Grasslands Preserve, which is owned by the Nature Conservancy and San Diego County, and managed by San Diego County Department of Parks and Recreation. The Ramona Grasslands Preserve is covered by a conservation easement and being managed and monitored according to the "Area Specific Management Directives for the Ramona Grasslands Preserve" drafted by San Diego County (2007). The management plan for the Ramona Grasslands Preserve provides for the conservation of *N. fossalis* and its habitat through vernal pool management goals, including: managing nonnative invasive plant species, maintaining the vernal pool hydrology, and managing grazing activities to benefit vernal pool habitat (Conservation Biology Institute 2007, pp. 26–27, 31–34). This area will be incorporated into the North County Multiple Species Conservation Plan (North County MSCP) upon completion of that plan (San Diego County 2009).

As we stated earlier, we request data and comments from the public on the DEA, on all aspects of the proposed revised critical habitat rule (including the changes to proposed critical habitat in Subunits 1A, 1B, 3B, 5C, 5I, 6A, 6B, and 6C), and our amended required determinations. The final revised rule may differ from the proposed revised rule based on new information we receive during the public comment periods. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as critical habitat, provided the exclusion will not result in the extinction of the species.

**Required Determinations——Amended**

In our proposed rule published in the **Federal Register** on June 10, 2009 (74 FR 27588), we indicated that we would defer our determination of compliance with several statutes and Executive Orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA to make these determinations.

In this document, we affirm the information in our June 10, 2009, proposed rule (74 FR 27588) concerning Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), E.O. 13132 (Federalism), E.O. 12988 (Civil Justice Reform), the Paperwork Reduction Act, the National Environmental Policy Act, and the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951). However, based on the DEA data, we are amending our required determinations concerning the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), E.O. 13211 (Energy Supply, Distribution, or Use), E.O. 12630 (Takings), and the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

*Regulatory Flexibility Act (5 U.S.C. 601 et seq.)*

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions), as described below. However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed revised designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of a final rulemaking.

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term significant economic impact is meant to apply to a typical small business firm's business operations.

To determine if the proposed revised designation of critical habitat for *Navarretia fossalis* would affect a substantial number of small entities, we consider the number of small entities affected within particular types of economic activities, such as residential and commercial development. In order to determine whether it is appropriate for our agency to certify that this rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat affects activities conducted, funded, permitted, or authorized by Federal agencies.

If we finalize this proposed revised critical habitat designation, Federal agencies must consult with us under section 7 of the Act if their activities may affect designated critical habitat. Consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process because *Navarretia fossalis* is listed as a threatened species under the Act. In the 2010 DEA, we evaluated the potential economic effects on small business entities resulting from implementation of conservation actions related to the proposed revision to critical habitat for *Navarretia fossalis*. The analysis was based on the estimated incremental impacts associated with the proposed rulemaking as described in sections 3 through 10 of the DEA. The SBREFA analysis evaluated the potential for economic impacts related to several categories, including: (1) Residential, commercial and industrial

development; (2) conservation lands management; (3) transportation; (4) pipeline projects; (5) flood control; (6) agriculture; and (7) fire management (Entrix, Inc. 2010, p. A-1). The DEA found that the only category of activity where the designation may impact small businesses is residential, commercial, and industrial development (Entrix, Inc. 2010, pp. A-1–A-4). For residential, commercial, and industrial development, the DEA estimated that there will be approximately 38 development projects in the areas proposed as critical habitat over the next 20 years. The total incremental impact to residential, commercial, and industrial development was estimated to be between $112,000 and $431,000 at a 7 percent discount rate over the next 20 years. On an annual basis this affects approximately two development related small businesses with a total annual impact ranging from $10,565 to $40,646 (Entrix, Inc. 2010, pp. A-3–A-4). In a regional context, there are approximately 500 small development related businesses in San Diego County and 303 in Riverside County. The 38 development related small businesses that may be impacted represent approximately 5 percent of the total number of development related small businesses in San Diego and Riverside Counties. We do not believe that this represents a substantial number of development-related small businesses or that an annual impact ranging from $10,565 to $40,646 is a significant economic impact; therefore, we do not find that the designation of critical habitat for *N. fossalis* will have a significant economic impact on a substantial number of small entities.

In summary, we considered whether the proposed revised designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if promulgated, the proposed revised critical habitat for *Navarretia fossalis* would not have a significant economic impact on a substantial number of small entities. Therefore, an initial regulatory flexibility analysis is not required.

*Executive Order 13211—Energy Supply, Distribution, and Use*

On May 18, 2001, the President issued E.O. 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. The OMB's guidance for implementing this Executive Order outlines nine outcomes that may constitute "a significant adverse effect" when compared to no regulatory action. As discussed in Appendix A, the DEA finds that none of these criteria are relevant to this analysis. The DEA concludes that no incremental impacts on the production, distribution, or use of energy are forecast associated specifically with this rulemaking. All forecast impacts are expected to occur associated with the listing of *Navarretia fossalis*, regardless of the designation of critical habitat. Therefore, designation of critical habitat is not expected to lead to any adverse outcomes (such as a reduction in electricity production or an increase in the cost of energy production or distribution), and a Statement of Energy Effects is not required.

*Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)*

In accordance with the Unfunded Mandates Reform Act, the Service makes the following findings:

(a) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both "Federal intergovernmental mandates" and "Federal private sector mandates." These terms are defined in 2 U.S.C. 658(5)-(7). "Federal intergovernmental mandate" includes a regulation that "would impose an enforceable duty upon State, local, or Tribal governments," with two exceptions. First, it excludes "a condition of federal assistance." Second, it also excludes "a duty arising from participation in a voluntary Federal program," unless the regulation "relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority," if the provision would "increase the stringency of conditions of assistance" or "place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding" and the State, local, or Tribal governments "lack authority" to adjust accordingly. "Federal private sector mandate" includes a regulation that "would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program."

Critical habitat designation does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. Designation of critical habitat may indirectly impact non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency. However, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) As discussed in the DEA of the proposed revised designation of critical habitat for *Navarretia fossalis*, we do not believe that this rule would significantly or uniquely affect small governments because it would not produce a Federal mandate of $100 million or greater in any year; that is, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The DEA concludes that incremental impacts may occur due to administrative costs of section 7 consultations for development, transportation, and flood control projects activities; however, these are not expected to affect small governments. Incremental impacts associated with these activities [jsc8]are expected to be borne by the Federal Government, California Department of Transportation, California Department of Fish and Game, Riverside County, Riverside County Flood Control and Water Conservation District, and City of Perris, which are not considered small governments. Consequently, we do not believe that the revised critical habitat designation would significantly or uniquely affect small government entities. As such, a Small Government Agency Plan is not required.

*Executive Order 12630 — Takings*

In accordance with E.O. 12630 ("Government Actions and Interference with Constitutionally Protected Private Property Rights"), we analyzed the potential takings implications of proposing revised critical habitat for *Navarretia fossalis* in a takings implications assessment. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits. The

proposed revised critical habitat for *N. fossalis* does not pose significant takings implications for the above reasons.

**References Cited**

A complete list of all references we cited in the proposed rule and in this document is available on the Internet at *http://www.regulations.gov* or by contacting the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

**Authors**

The primary authors of this notice are staff members of the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Proposed Regulation Promulgation**

Accordingly, we propose to further amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as proposed to be amended at 74 FR 27588, June 10, 2009, as set forth below.

## PART 17—[AMENDED]

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

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Critical habitat for *Navarretia fossalis* (spreading navarretia) in § 17.96(a), which was proposed for revision on June 10, 2009, at 74 FR 27620, is proposed to be further amended by:

a. Revising paragraph (5), including the index map of critical habitat units for *Navarretia fossalis* (spreading navarretia);

b. Revising paragraph (7)(ii), including the map of Subunits 1A (Cruzan Mesa) and 1B (Plum Canyon);

c. Revising paragraph (10)(ii), including the map of Subunit 3B (Carroll Canyon);

d. Redesignating paragraphs (19) through (27) as paragraphs (20) through (28);

e. Adding a new paragraph (19);

f. Revising newly designated paragraph (23)(ii), including the map of Subunit 5I (Eastern Otay Mesa Vernal Pool Complexes);

g. Revising newly designated paragraph (24)(ii), including the map of Subunit 6A (San Jacinto River);

h. Revising newly designated paragraph (25)(ii), including the map of Subunit 6B (Salt Creek Seasonally Flooded Alkali Plain); and

i. Revising newly designated paragraph (26)(ii), including the map of Subunit 6C (Wickerd and Scott Road Pools), to read as follows:

**§ 17.96 Critical habitat—plants.**

(a) Flowering plants.

* * * * *

Family Polemoniaceae: *Navarretia fossalis* (spreading navarretia)

* * * * *

(5) *Note:* Index Map of critical habitat units for *Navarretia fossalis* (spreading navarretia) follows:

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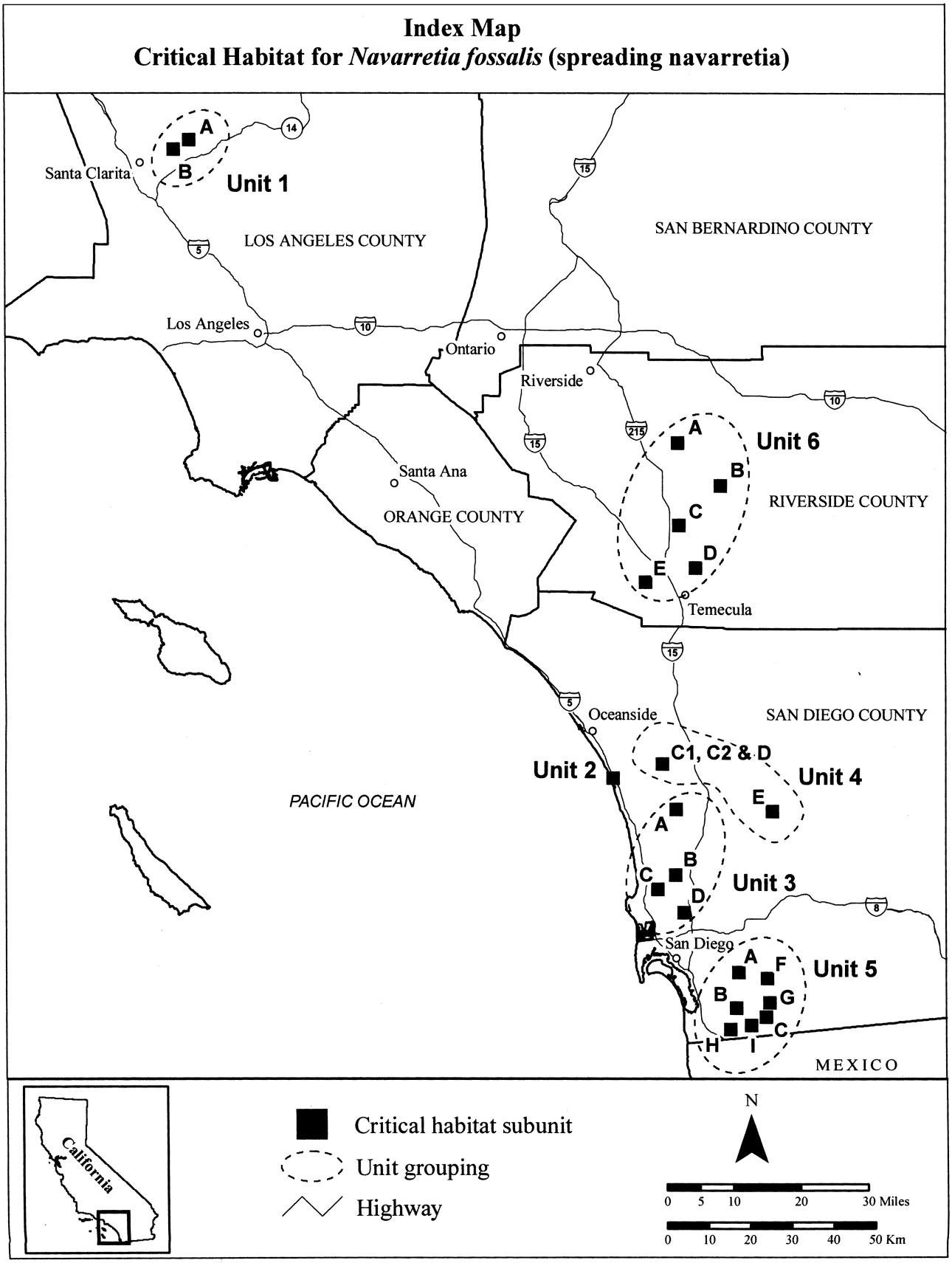
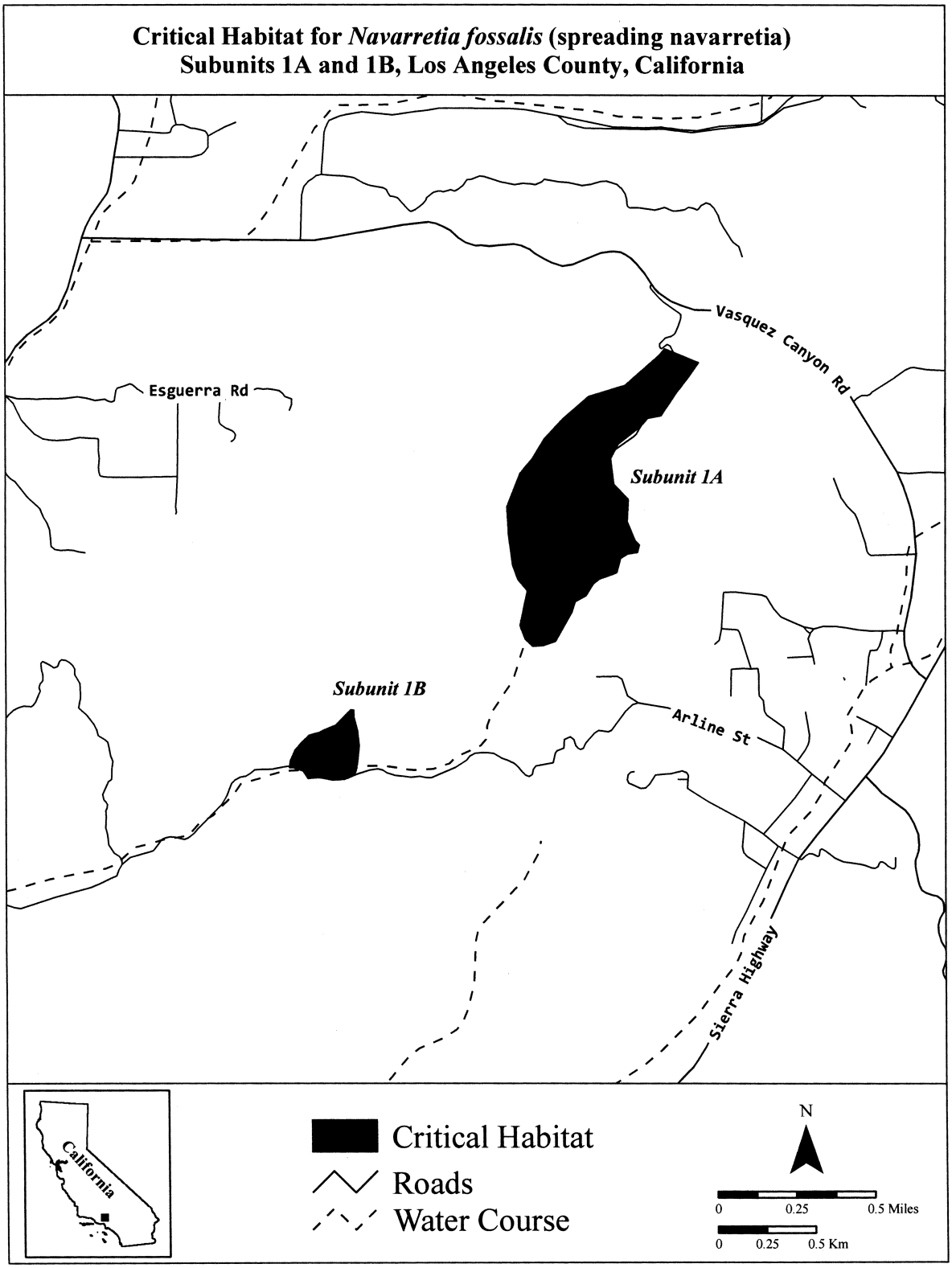

Index Map
Critical Habitat for *Navarretia fossalis* (spreading navarretia)
Unit 1
A
B
Santa Clarita
LOS ANGELES COUNTY
SAN BERNARDINO COUNTY
Los Angeles
Ontario
Riverside
Unit 6
A
B
C
D
E
RIVERSIDE COUNTY
Temecula
Santa Ana
ORANGE COUNTY
Oceanside
SAN DIEGO COUNTY
Unit 2
C1, C2 & D
Unit 4
E
PACIFIC OCEAN
A
B
C
D
Unit 3
San Diego
Unit 5
A
F
B
G
C
H
I
MEXICO
California
Critical habitat subunit
Unit grouping
Highway
N
0 5 10 20 30 Miles
0 10 20 30 40 50 Km

* * * * *

(7) * * *

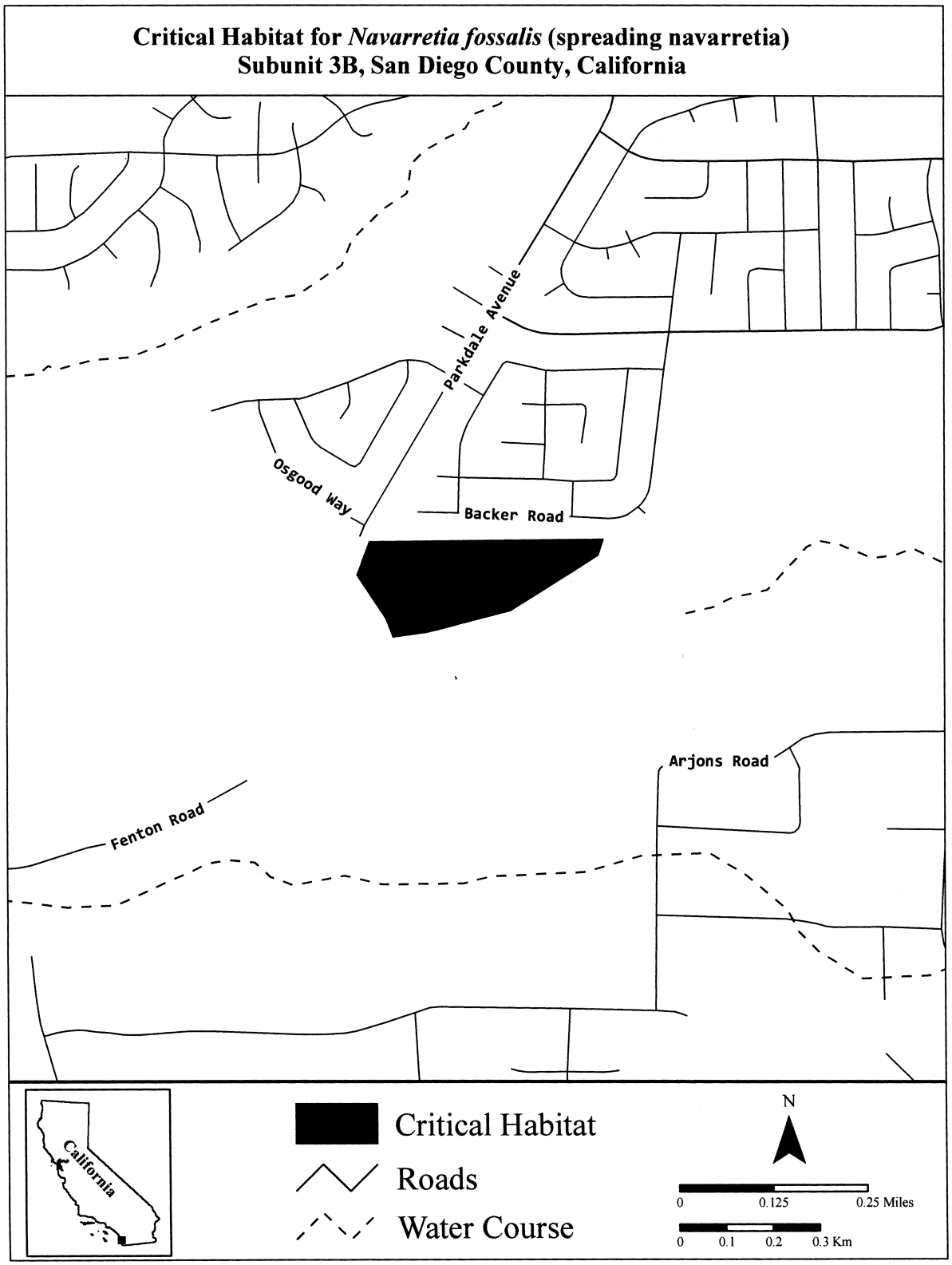
(ii) *Note*: Map of Los Angeles Basin–Orange Management Area Subunits 1A (Cruzan Mesa) and 1B (Plum Canyon) follows:



* * * * *

(10) * * *

(ii) *Note*: Map of Unit 3, Subunit 3B (Carroll Canyon) follows:

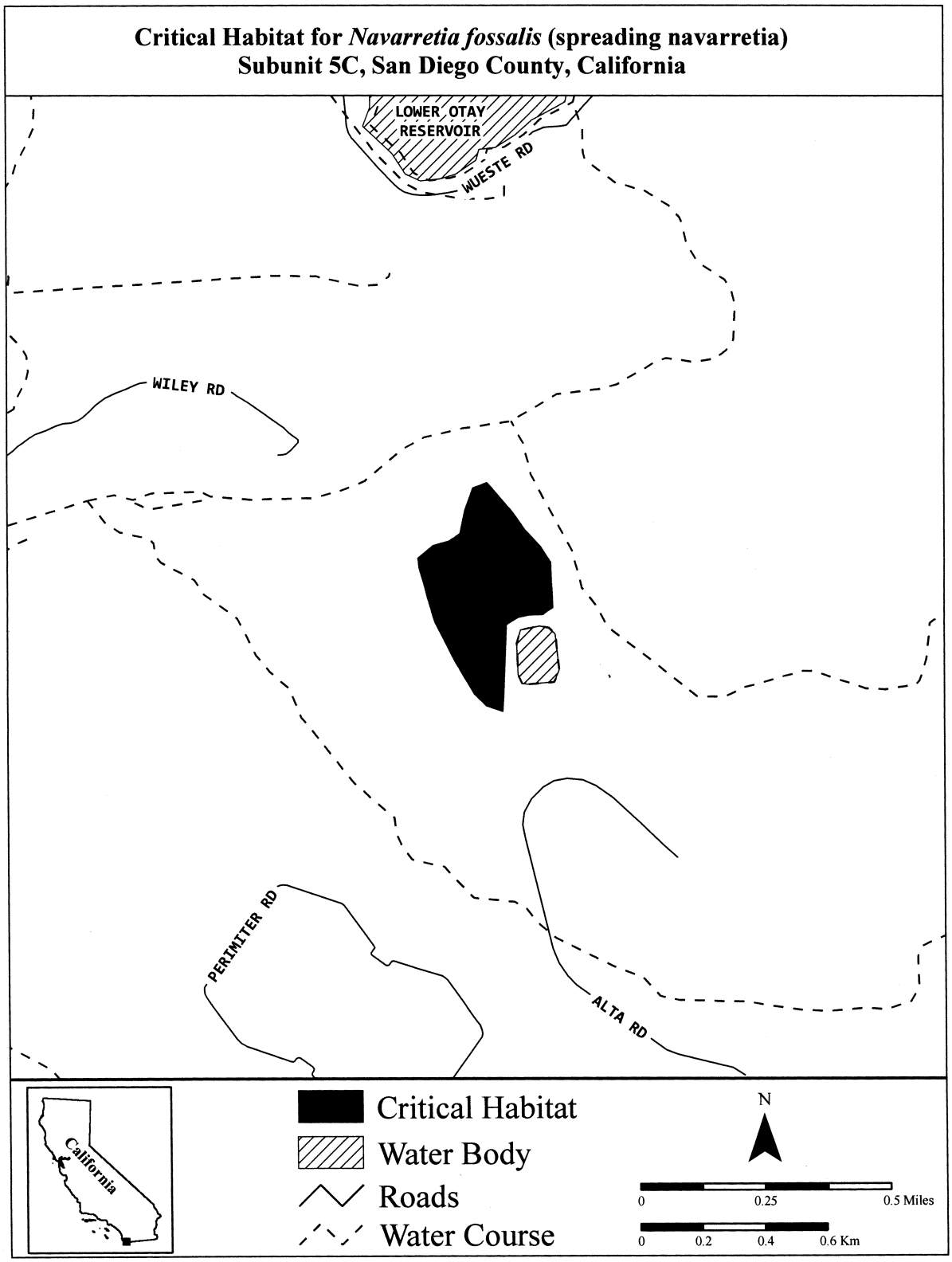


* * * * *

(19) Unit 5: San Diego: Southern Coastal Mesa Management Area, San Diego County, CA. Subunit 5C: J26 Vernal Pool Complex.

(i) [Reserved for textual description of Subunit 5C.]

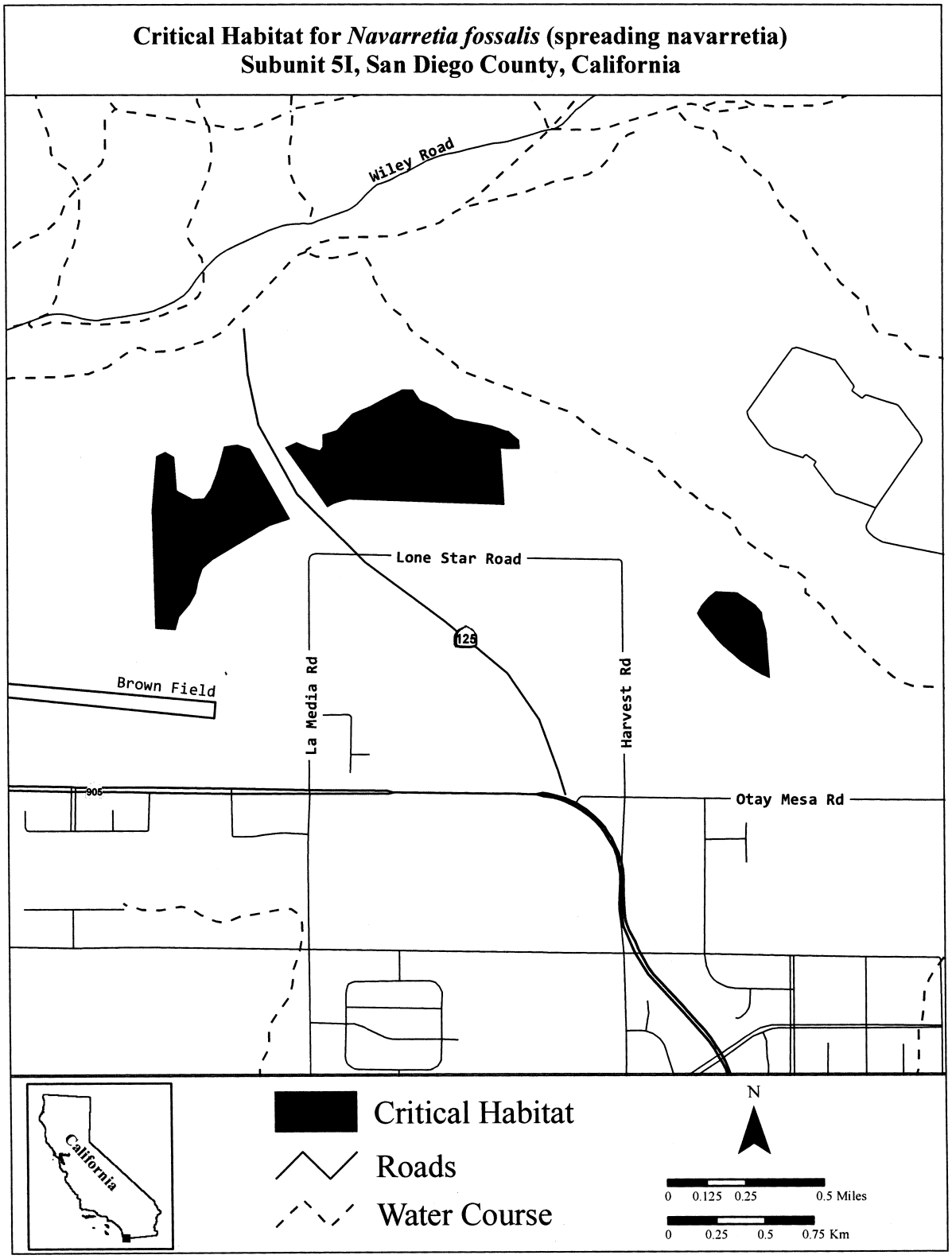
(ii) *Note*: Map of Unit 5, Subunit 5C (J26 Vernal Pool Complex) follows:



* * * * *

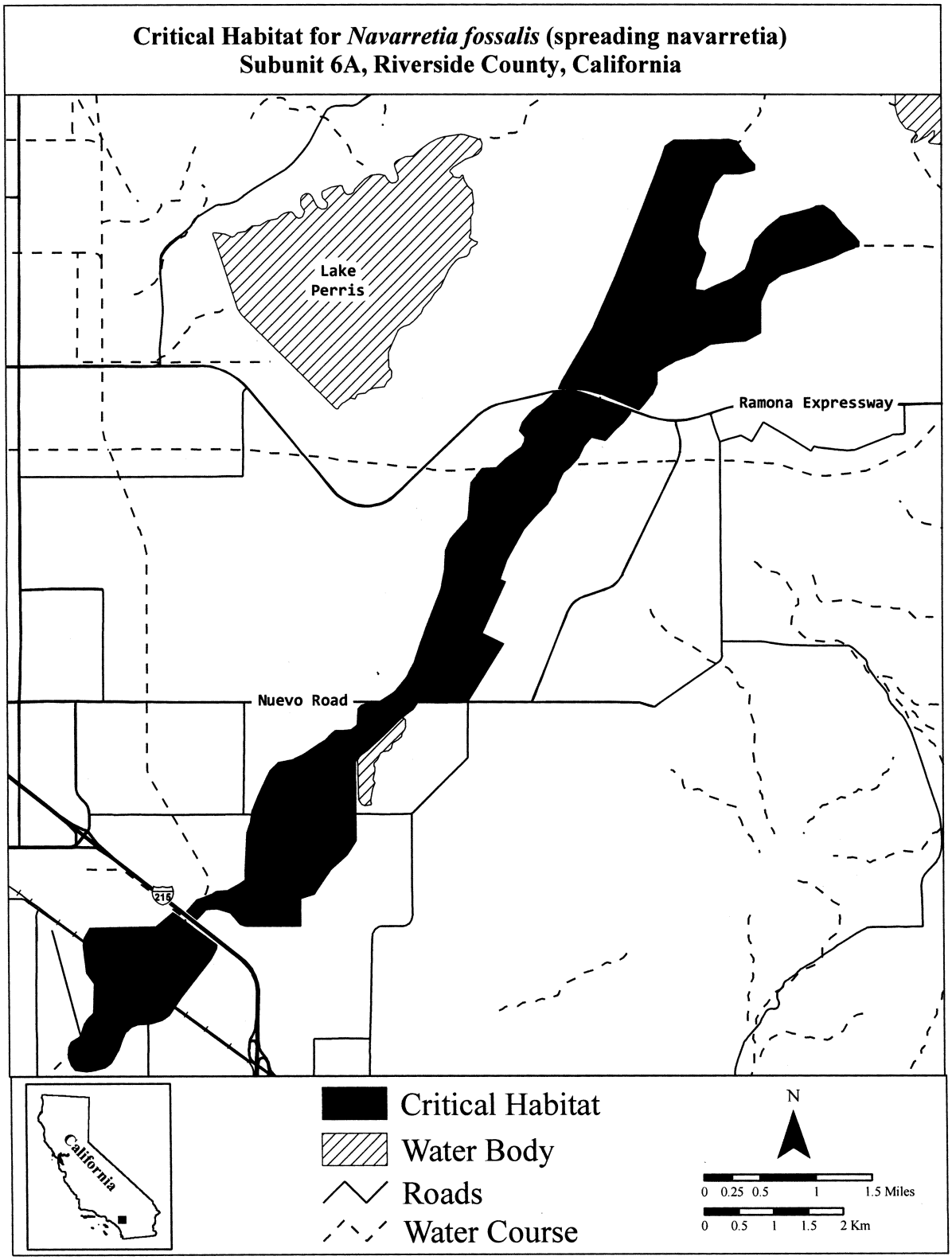
(23) * * *

(ii) *Note*: Map of Unit 5, Subunit 5I (Eastern Otay Mesa Vernal Pool Complexes) follows:



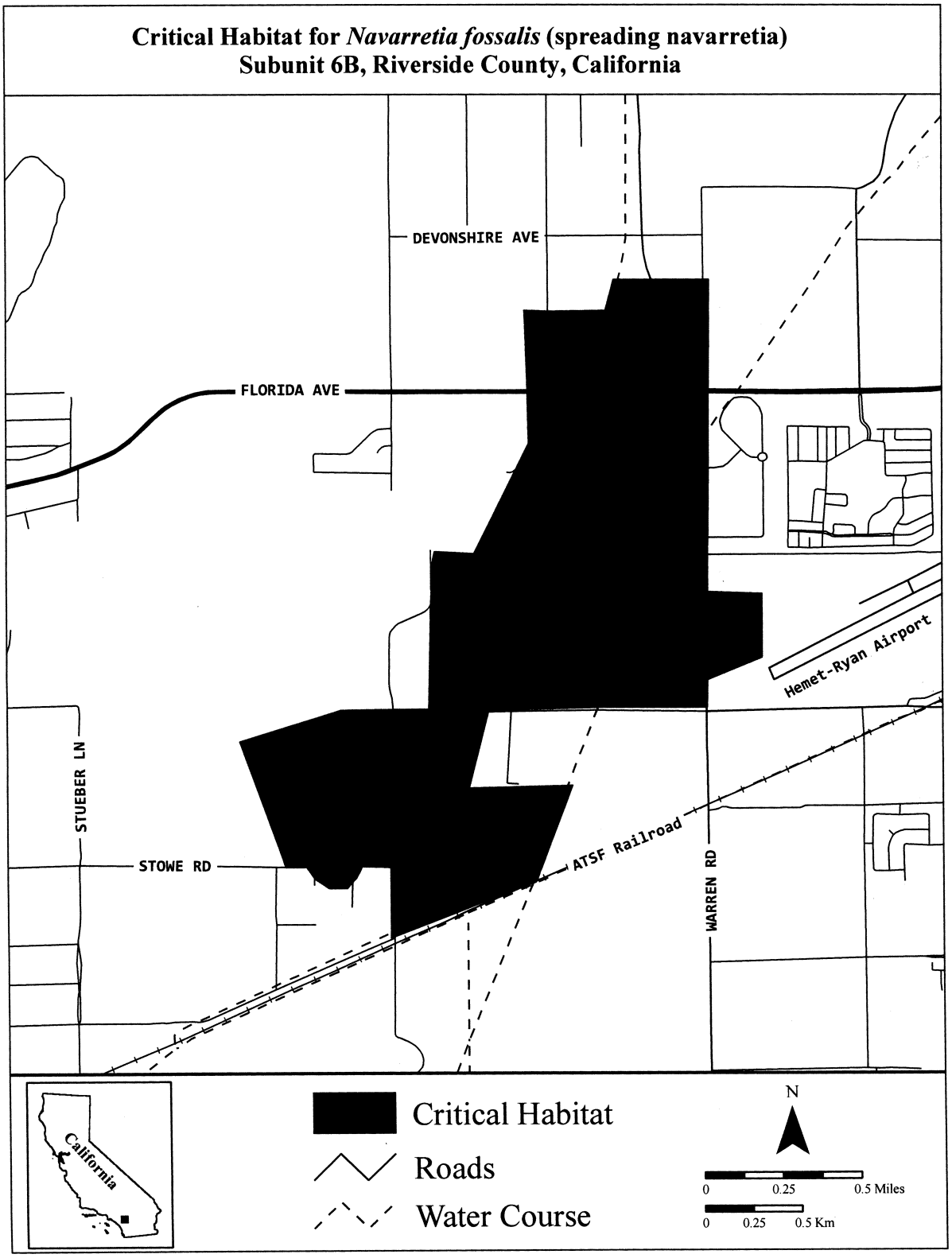
(24) * * *

(ii) *Note*: Map of Unit 6, Subunit 6A (San Jacinto River) follows:



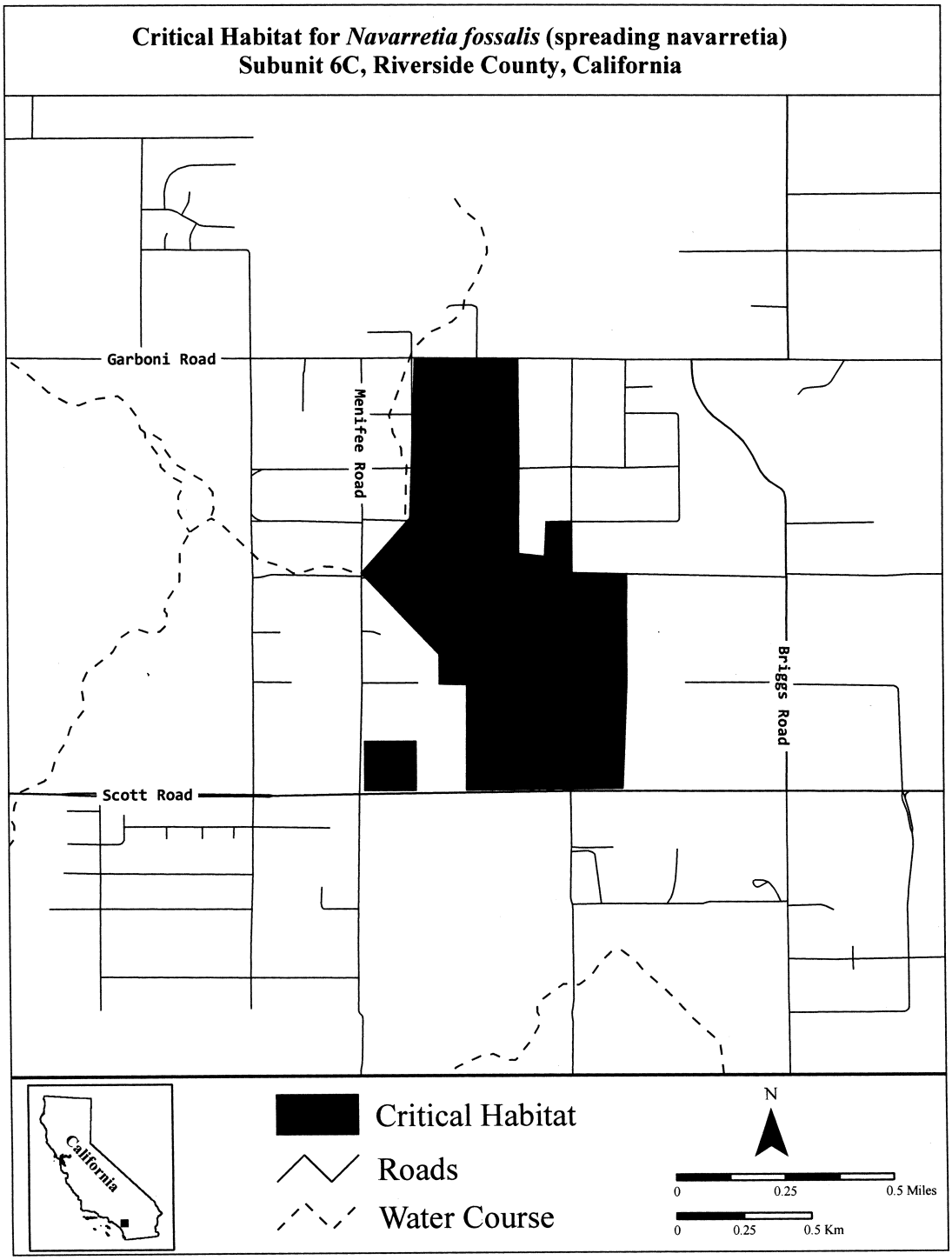
(25) * * *

(ii) *Note*: Map of Unit 6, Subunit 6B (Salt Creek Seasonally Flooded Alkali Plain) follows:



(26) * * *

(ii) *Note*: Map of Unit 6, Subunit 6C (Wickerd and Scott Road Pools) follows:




* * * * *

Dated: April 6, 2010

**Thomas L. Strickland,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2010–8453 Filed 4–14–10; 8:45 am]

**BILLING CODE 4310–55–C**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**[Docket No. FWS–R6–ES–2008–0029; MO 92210–0–008]**

## Endangered and Threatened Wildlife and Plants; Initiation of Status Review of the North American Wolverine in the Contiguous United States

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice; initiation of status review.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), under the authority of the Endangered Species Act of 1973, as amended (Act), announce the initiation of a status review of the North American wolverine (*Gulo gulo luscus*) in the contiguous United States. We conduct status reviews to determine whether the entity should be listed as endangered or threatened under the Act. Through this notice, we encourage all interested parties to provide us information regarding North American wolverines throughout their range and in the contiguous United States.

**DATES:** To allow us adequate time to conduct this review, we request that we receive information on or before May 17, 2010. After this date, you must submit information directly to the Field Office (*See* **FOR FURTHER INFORMATION CONTACT** section below). Please note that we may not be able to address or incorporate information that we receive after the above requested date.

**ADDRESSES:** You may submit information by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Search for docket FWS–R6–ES–2008–0029 and then follow the instructions for submitting comments.
- U.S. mail or hand-delivery: Public Comments Processing, Attn: FWS–R6–ES–2008–0029; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will post all information on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Request for Information section below for more information).

**FOR FURTHER INFORMATION CONTACT:** Mark Wilson, Field Supervisor, Montana Ecological Services Field Office, 585 Shepard Way, Helena, MT 59601; telephone (406) 449–5225; facsimile (406) 499–5339. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

### Request for Information

To ensure that the status review is complete and based on the best available scientific and commercial information, and to provide an opportunity to all interested parties to provide information for consideration during the status review, we are requesting information concerning North American wolverines rangewide and in the contiguous United States. We are seeking:

(1) General information concerning the taxonomy, biology, ecology, genetics, and status of North American wolverines rangewide and in the contiguous United States.

(2) Specific information relevant to the consideration of a potential distinct population segment (DPS) of North American wolverines in the contiguous United States. This consideration will be guided by our Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (16 U.S.C. 1531 *et seq.*) (61 FR 4722, February 7, 1996) (known as the DPS Policy), which specifically considers two elements: (i) The discreteness of the population segment in relation to the remainder of the species to which it belongs; and (ii) the significance of the population segment to the species to which it belongs.

(3) Specific information on the conservation status of North American wolverines rangewide and in the contiguous United States, including information on distribution, abundance, and population trends.

(4) Specific information on threats to North American wolverines rangewide and in the contiguous United States, including: (i) The present or threatened destruction, modification, or curtailment of its habitat or range; (ii) overutilization for commercial, recreational, scientific, or educational purposes; (iii) disease or predation; (iv) the inadequacy of existing regulatory mechanisms; and (v) other natural or manmade factors affecting its continued existence.

(5) Specific information on implemented or planned conservation actions to improve wolverine habitats or decrease threats to wolverines in the contiguous United States.

(6) Specific information on the potential effects of climate change on wolverines, their habitat, and their food sources in the contiguous United States.

(7) Information on the management of wolverines on both sides of the international boundary where populations occur and how this management may differ between Canada and the United states in how it affects the status of wolverines.

If you submit information, we request you support it with documentation, such as data, maps, bibliographic references, methods used to gather and analyze the data, or copies of any pertinent publications, reports, or letters by knowledgeable sources.

Submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made "solely on the basis of the best scientific and commercial data available."

You may submit your information concerning this status review by one of the methods listed in the **ADDRESSES** section. If you submit information via *http://www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the website. We will also post all hardcopy submissions on *http://www.regulations.gov.* If you include personal identifying information in your hardcopy submission, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so.

Information and supporting documentation that we receive and use in preparing a finding will be available for you to review by appointment during normal business hours at the U.S. Fish and Wildlife Service, Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

### Background

The North American wolverine (*Gulo gulo luscus*) is the largest terrestrial member of the family *Mustelidae.* Adult males weigh 12 to 18 kilograms (kg) (26 to 40 pounds (lb)), and adult females weigh 8 to 12 kg (17 to 26 lb) (Banci 1994, p. 99). The wolverine resembles a small bear with a bushy tail. It has a broad, rounded head; short, rounded ears; and small eyes. Each foot has five toes with curved, semi-retractile claws used for digging and climbing (Banci 1994, p. 99).

Wolverines exist in alpine and sub-alpine habitats, which in the contiguous

48 States occur at high elevations in the Rocky, North Cascade, and Sierra Nevada mountains (Aubry *et al.* 2007, p. 2153). Wolverines have recently been positively documented in the Sierra Nevada range in California and the southern Rocky Mountains of Colorado for the first time since the early 20th century.

Wolverines are opportunistic feeders and consume a variety of foods depending on availability. They primarily scavenge carrion, but also prey on small animals and birds, and eat fruits, berries, and insects (Hornocker and Hash 1981, p. 1290; Hash 1987, p. 579; Banci 1994, pp. 111–113).

Wolverines have delayed onset of reproduction in females and small litter sizes, and often reproduce only every other year.

Home ranges at the southern terminus of the current range are large for mammals of the size of wolverines, and may indicate that wolverines have high energetic requirements and at the same time occupy relatively unproductive niches (Inman *et al.* 2007a, p. 11). In addition, wolverines naturally occur in low densities that average about one wolverine per 150 $km^2$ (58 $mi^2$) (Hornocker and Hash 1981, pp. 1292–1295; Hash 1987, p. 578; Copeland 1996, pp. 31–32; Copeland and Yates 2006, p. 27; Inman *et al.* 2007a, p. 10; Squires *et al.* 2007, p. 2218).

## Previous Federal Actions

We received a petition dated August 3, 1994, from the Predator Project (now named the Predator Conservation Alliance) and Biodiversity Legal Foundation to list the North American wolverine in the contiguous United States as an endangered or threatened species under the Act and to designate critical habitat concurrent with listing. On April 19, 1995, we published a finding (60 FR 19567) that the petition did not present substantial information indicating that listing the North American wolverine in the contiguous United States may be warranted. We did not make a determination as to whether the contiguous U.S. population of the North American wolverine constituted a DPS or other listable entity.

On July 14, 2000, we received another petition dated July 11, 2000, submitted by the Biodiversity Legal Foundation, Predator Conservation Alliance, Defenders of Wildlife, Northwest Ecosystem Alliance, Friends of the Clearwater, and Superior Wilderness Action Network, to list the North American wolverine within the contiguous United States as an endangered or threatened species under the Act and to designate critical habitat for the species concurrent with the listing.

On October 21, 2003, we published a 90-day finding that the petition to list the North American wolverine in the contiguous United States did not present substantial scientific and commercial information indicating that listing as threatened or endangered may be warranted (68 FR 60112). We did not determine whether the contiguous U.S. population of the North American wolverine constituted a DPS (or other listable entity), because sufficient information was not available at the time.

On September 29, 2006, as a result of a complaint filed by Defenders of Wildlife and others alleging we used the wrong standards to assess the July 2000 wolverine petition, the U.S. District Court, Montana District, ruled that our 90-day petition finding was in error and ordered us to make a 12-month finding for the wolverine (*Defenders of Wildlife et al.* v. *Norton and Hogan* (9:05cv99 DWM; D. MT)). On April 6, 2007, the Court approved an unopposed motion to extend the deadline for this 12-month finding to February 28, 2008, so that we would be able to use information published in the September 2007 edition of the *Journal of Wildlife Management* containing a special section on North American wolverine biology. On June 5, 2007, we published a notice initiating a status review for the wolverine (72 FR 31048).

On March 11, 2008, we published a 12-month finding on the wolverine in the contiguous United States (73 FR 12929). In that finding, we determined that the wolverine in the contiguous United States did not constitute a DPS. Therefore, we determined that the wolverine in the contiguous United States was not a listable entity under the Act. On September 30, 2008, Defenders of Wildlife *et al.* filed a complaint challenging our 12-month finding on the basis of our application of the DPS Policy and the Act. On March 23, 2009, we settled the lawsuit with the plaintiffs and agreed to submit a new 12-month finding to the **Federal Register** by December 1, 2010.

## References Cited

A complete list of all references is available upon request from the Field Supervisor, Montana Ecological Services Field Office (*See* **FOR FURTHER INFORMATION CONTACT**).

## Author

The primary authors of this document are the staff members of the U.S. Fish and Wildlife Service, Montana Ecological Servies Field Office.

## Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 30, 2010.

**Daniel M. Ashe,**

*Deputy Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2010–8698 Filed 4–14–10; 8:45 am]

**BILLING CODE 4310–55–P**

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**[Docket No. FWS-R6-ES-2008-0127]**
**[MO 92210-0-0008-B2]**

# Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition to List the Wyoming Pocket Gopher as Endangered or Threatened with Critical Habitat

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of 12–month petition finding.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce a 12–month finding on a petition to list the Wyoming pocket gopher (*Thomomys clusius*) as endangered or threatened and to designate critical habitat under the Endangered Species Act of 1973, as amended. After review of all available scientific and commercial information, we find that listing the Wyoming pocket gopher as either endangered or threatened is not warranted at this time. We ask the public to continue to submit to us any new information that becomes available concerning the status of, or threats to, the Wyoming pocket gopher or its habitat.

**DATES:** The finding announced in this document was made on April 15, 2010.

**ADDRESSES:** This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS-R6-ES-2008-0127. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Wyoming Ecological Services Field Office, 5353 Yellowstone Road, Cheyenne, WY 82009. Please submit any new information, materials, comments, or questions concerning this finding to the above street address.

**FOR FURTHER INFORMATION CONTACT:** Brian Kelly, Field Supervisor, Wyoming

Ecological Services Field Office (see **ADDRESSES**); by telephone at 307-772-2374; or by facsimile at 307-772-2358. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

**SUPPLEMENTARY INFORMATION:**

## Background

Section 4(b)(3)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*) requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that presents substantial scientific or commercial information indicating that listing the species may be warranted, we make a finding within 12 months of the date of the receipt of the petition. In this 12–month finding, we may determine that the petitioned action is: (1) Not warranted, (2) warranted, or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12–month findings in the **Federal Register**.

### *Previous Federal Actions*

On August 9, 2007, we received a petition, dated August 7, 2007, from the Biodiversity Conservation Alliance and Center for Native Ecosystems requesting that we list the Wyoming pocket gopher (*Thomomys clusius*) within its known historic range, as threatened or endangered under the Act. Additionally, the petition requested that we designate critical habitat concurrent with listing. We acknowledged receipt of the petition in a letter dated September 6, 2007. In that letter, we advised the petitioners that we could not address their petition at that time because responding to existing court orders and settlement agreements for other listing actions required nearly all of our listing funding. We also concluded in that September 6, 2007, letter that emergency listing of the Wyoming pocket gopher was not warranted.

On July 11, 2008, we informed the petitioners that, due to progress on addressing other priority listing actions, funding had become available to allow us to address the petition in fiscal year 2008. On November 4, 2008, the petitioners filed a complaint with the U.S. District Court for the District of Colorado against us for failing to complete the 90–day finding (*Center for Native Ecosystems and Biodiversity Conservation Alliance* v. *U.S. Fish and Wildlife Service and Kempthorne* (1:08-cv-02394-JLK)).

On February 10, 2009, we published our finding that the petition to list the Wyoming pocket gopher presented substantial scientific or commercial information indicating that listing the species may be warranted (74 FR 6558). On March 20, 2009, the petitioners provided a notice of intent to sue on additional grounds for failure to complete the 12–month finding within 12 months of the petition. In a June 12, 2009, stipulated settlement, the Service agreed to complete the 12–month finding by April 10, 2010, which would allow us to include 2009 Wyoming pocket gopher survey data in our analysis. This notice constitutes our 12–month finding on the August 7, 2007, petition to list the Wyoming pocket gopher as endangered or threatened.

### *Species Information*

#### Life History

Pocket gophers are powerfully built mammals, characterized by a heavily muscled head without a noticeable neck, strong front limbs with long nails used for digging, small ears, small eyes, and fur-lined cheek pouches used to carry food (Verts and Carraway 1999, p. 3). They are highly fossorial (adapted to burrowing or digging), living, foraging, and reproducing in burrow systems and underground tunnels that provide protection from predators and from extreme environmental conditions (Clark and Stromberg 1987, p. 121).

Populations of pocket gophers generally tend to be small and patchily distributed across landscapes where they occur (Kennerly 1959, p. 251; Stinson 2005, p. 21). This distribution is thought to be primarily determined by the availability of soils appropriate for digging and foraging (Kennerly 1959, p. 249; Verts and Carraway 1999, p. 5). Specialization to local ecological conditions has resulted in a high degree of morphological variation across the range of each species (Patton and Brylski 1987, p. 493). For example, pocket gopher coat color is highly variable, strongly correlated with soil color, and thought to be an adaptive response to predation (Ingles 1950, p. 357; Wlasiuk and Nachman 2007, p. 567). Differences in abundance and nutritional content of forage can produce extreme variation in body size of individual pocket gophers and density of pocket gopher populations (Patton and Brylski 1987, p. 504).

Little is known about the Wyoming pocket gopher; assumptions about its distribution, ecology, and status are based on a few museum records, reports from more than 30 years ago, and research conducted in 2008 and 2009. This lack of knowledge has led to the recent efforts to obtain information on its distribution, status, and habitat use (Keinath and Griscom 2008, p. 1; Griscom *et al.* 2010, p. 3). Where specific life-history information is lacking, and where appropriate, we have provided information from other pocket gopher species, mainly in the *Thomomys* genus.

The Wyoming pocket gopher is differentiated from other pocket gophers in its geographical range by being smaller and paler, with a yellow cast to the coat, especially in younger animals. The dorsal coat is uniform in color, and the margins of the ears are fringed with whitish hairs (Thaeler and Hinesley 1979, p. 483; Clark and Stromberg 1987, p. 123; Keinath and Beauvais 2006, p. 8; Keinath and Griscom 2008, p. 2). This species does not display sexual dimorphism (differences in form between the sexes) (Clark and Stromberg 1987, p. 123; Keinath and Beauvais 2006, p. 8). Adult Wyoming pocket gophers typically have a body length of 112-134 millimeters (mm) (4.41-5.28 inches (in)), hind foot length of 20-22 mm (0.79-0.87 in), and a weight of 44-72 grams (g) (1.54-2.54 ounces (oz)) (Thaeler and Hinesley 1979, pp. 483-484; Clark and Stromberg 1987, p. 123). The measurements of specimens captured in 2008 and 2009 included body lengths of 86-128 mm (3.38-5.04 in), hind foot lengths of 15-23 mm (0.59-0.91 in), and weights of 43-66 g (1.52-2.33 oz) (Griscom *et al.* 2010, p. 23). These somewhat smaller measurements for 2008-2009 data can be partly explained by late summer captures that included juveniles, whereas older studies relied on captures prior to June 15 that would have included only adults (Griscom 2010a, pers. comm.).

The Wyoming pocket gopher occurs entirely within the range of the northern pocket gopher (*Thomomys talpoides*), but the two species likely occupy different habitats locally (Thaeler and Hinesley 1979, p. 486; Keinath and Beauvais 2006, p. 8; Griscom *et al.* 2010, p. 15). Approximately 50 percent of the known range of the species occurs on Bureau of Land Management (BLM) lands (Service 2009a, p. 1). A Wyoming Natural Diversity Database (WYNDD) predictive distribution model for the

Wyoming pocket gopher developed in January 2010 shows the species could occur in Sweetwater, Carbon, and Fremont Counties in Wyoming (Griscom *et al.* 2010, p. 32). The predicted range abuts Colorado's northern border, but Colorado was not included in the distribution analysis (Griscom *et al.* 2010, p. 32). Additional specimens are considered unlikely to be found south of current distribution points (Griscom *et al.* 2010, p. 12). To date, Wyoming pocket gophers have been located only in Sweetwater and Carbon Counties, which is consistent with historical records that show this area to be the extent of the species' range. Although the full historic range of the species has not been defined, we consider the capture points in Sweetwater and Carbon Counties presented by Thaeler and Hinesley (1979, pp. 482, 486-487) to present an approximation of historic range. This historic range includes the type specimen collected in 1857, two specimens collected in 1949 and 1951, and several specimens collected in the 1960s and 1970s (Thaeler and Hinesley 1979, p. 487). Very little information exists regarding the actual population size of the Wyoming pocket gopher (Keinath and Beauvais 2006, p. 21). The only population estimate we found was 10,000 (NatureServe 2009, unpaginated). However, we are unable to determine the basis for this estimate and thus have no way to determine its scientific validity.

Vegetation composition of a site may be more important in determining habitat for the Wyoming pocket gopher than soils or topography (Keinath and Griscom 2008, p. 2). The Wyoming pocket gopher occurs primarily in small "islands" of low vegetation within a sagebrush matrix. This matrix typically includes *Artemesia tridentada wyomingensis* (Wyoming big sagebrush), *Chrysothamnus* spp. (rabbitbrush), and other low shrubs, cushion plants, grasses, and forbs (Keinath and Griscom 2009, p. 1). In comparison to unoccupied control sites and northern pocket gopher capture sites, the Wyoming pocket gopher appears to prefer areas within this matrix with less perennial grass cover, less *Artemesia tridentata* (Big sagebrush), more *Krascheninnikovia lanata* (winterfat), more *Atriplex gardneri* (Gardner saltbush), more bare soil, less litter, and fewer surface rocks (Griscom *et al.* 2010, p. 15). Difference in habitat use would be expected, given that phenotype (observable physical characteristics) has been shown to correlate with habitat for pocket gophers (Ingles 1950, p. 357; Wlasiuk and Nachman 2007, p. 567).

Previously, the Wyoming pocket gopher was believed to exclusively occupy well-drained, gravelly ridges instead of the valley bottoms and riparian areas with deeper soils preferred by the northern pocket gopher (Thaeler and Hinesley 1979, p. 486). However, recent research showed Wyoming pocket gophers occupy sites with more varied topography (Keinath and Griscom 2008, p. 2). Compared to northern pocket gophers, Wyoming pocket gophers appear to prefer areas of lesser slopes (Griscom *et al.* 2010, p. 15). Wyoming pocket gophers appear to use a variety of soil types that can be more compacted than those used by northern pocket gophers (Griscom *et al.* 2010, p. 15). These soils often have a substantial gravel component, usually contain little clay (Keinath and Griscom 2008, p. 2), and tend to be more alkaline than the soils that northern pocket gophers prefer (Griscom 2009a, pers. comm.). In general, pocket gophers in the *Thomomys* genus are more specialized for tooth digging rather than claw digging, which allows for exploitation of a broader range of soil types (Lessa and Thaeler 1989, p. 696). Based on the characterization of the Wyoming pocket gopher's size and habitat, it appears to fit the island model of isolation displayed by other species of pocket gophers specifically adapted to the soils of an area (Miller 1964, pp. 259-260). The limited distribution of the Wyoming pocket gopher relative to other species of pocket gopher may be due to its specialized habitat requirements (Keinath and Beauvais 2006, pp. 12-15).

Pocket gophers construct extensive burrow systems. These systems consist of a main tunnel with side branches of shallow feeding tunnels (tunnels dug to forage on plant material). Additional feeding tunnels can be constructed when plant production is poor (Davis 1938, p. 338; Reichman *et al.* 1982, p. 691). The main tunnel also connects to a smaller system of chambers that serve as nest sites, food caches, and latrines (Miller 1964, p. 257; Keinath and Beauvais 2006, p. 16). Depths of the burrows vary from 6 to 12 inches below the ground surface. All aboveground entrances are plugged with soil (Clark and Stromberg 1987, p. 121). Burrow widths of the Wyoming pocket gopher are significantly smaller than those of the northern pocket gopher, likely reflecting their smaller body size (Griscom *et al.* 2010, p. 15). The extent of burrow systems can vary with the size of the individual, soil type, and plant production. The extensive tunneling and feeding activity of pocket gophers can have strong effects on soil formation, hydrology, nutrient flows, plant diversity, and competitive interactions of plants (Tilman 1983, pp. 290-292; Huntly and Inouye 1988, entire; Reichman and Seabloom 2002, entire; Sherrod *et al.* 2005, pp. 586-587; Kyle *et al.* 2008, p. 377). The effects of pocket gopher burrowing on physical and chemical soil properties vary based on the nature of the soil (Kerley *et al.* 2004, pp. 164-165).

The diet of pocket gophers consists of roots, stems, and leaves of forbs, with some consumption of grasses and shrubs (Aldous 1951, pp. 85-86; Ward and Keith 1962, p. 747). The average consumption of forbs by pocket gophers in west-central Colorado, as measured by stomach content, was highest in July and August at 96 percent, decreasing to 73 percent in October (Ward and Keith 1962, p. 747). Consumption of shrubs and roots of all types increased in late September and October, and consumption of grasses increased in June, September, and October (Ward and Keith 1962, p. 747). Pocket gophers in the *Thomomys* genus throughout the western United States generally prefer forb shoots during the growing season, and grass shoots, corms, and roots during periods of plant dormancy (Hunt 1992, pp. 47-48). Other species of the *Thomomys* genus (e.g., northern pocket gopher, Botta's (valley) pocket gopher (*T. bottae*), Townsend's pocket gopher (*T. townsendii*), Mazama (western) pocket gopher (*T. mazama*), and Camas pocket gopher (*T. bulbivorus*)) are not strict herbivores, in that they also seasonally consume the fungi associated with plant roots (i.e., are mycophagous) (Maser *et al.* 1978, p. 805; Taylor *et al.* 2009, p. 367). Pocket gophers may cut their food into small pieces and carry it in their cheek pouches back to the main burrow where it is consumed, stored for winter, used for nest building, or taken into tunnels and later pushed to the surface (Aldous 1951, p. 84; Verts and Carraway 1999, p. 6). Pocket gophers remain active all winter (Clark and Stromberg 1987, p. 121).

Based on the life histories of other pocket gophers, Wyoming pocket gophers presumably reproduce the calendar year following birth, have one litter with 4 to 6 young per year, and usually do not live more than two breeding seasons (Keinath and Beauvais 2006, p. 18). However, one northern pocket gopher is known to have survived for about 4 years (Hansen 1962, p. 153). Some species of pocket gophers have more than one litter per year in southern climates with longer breeding seasons (Miller 1946, pp. 335-336). Hansen (1960, p. 332) found no

evidence of more than one annual litter per female in the Rocky Mountain region.

Pocket gophers are solitary animals and are typically found together only during the breeding season, or when females have young. Variation in levels of tolerance between males and females ranges from being together only during mating to raising young of the year together (Hansen and Miller 1959, pp. 581-582). Pocket gophers are usually polygynous (Reichman *et al.* 1982, p. 693). However, some evidence of serial monogamy has been found in Botta's pocket gopher in Arizona (Reichman *et al.* 1982, p. 693). The sex ratio for Botta's pocket gopher was one male per one female; however, the effective sex ratio was one male per two females as some small males did not reproduce (Reichman *et al.* 1982, p. 693). Populations of Botta's pocket gopher in California showed a much more skewed sex ratio, ranging from 1.4 to 4.67 females per male (Patton and Feder 1981, p. 917). We do not have specific information regarding the Wyoming pocket gopher mating system or sex ratio.

Outside of the breeding season, pocket gophers are highly territorial, and males and females have exclusive territories. Generally, pocket gophers avoid each other (Reichman *et al.* 1982, p. 693). The infrequent interactions that occur are mostly agonistic, occasionally escalating to open combat and even death (Zinnel and Tester 1994, p. 96). This aggression appears to have evolved as a means to ensure adequate individual food supplies, but could also be related to reproductive behaviors like mate guarding (Zinnel and Tester 1994, pp. 99-100). Pocket gopher population density is likely to be primarily regulated through intraspecific aggression; the number of animals an area can hold appears to be determined by combative interactions (Zinnel and Tester 1994, p. 100).

Dispersal strategies of the Wyoming pocket gopher are unknown, but may be similar to other pocket gopher species. Although dispersal was common, 63 percent of individual Botta's pocket gophers set up their territory within 40 meters (m) (131.23 feet (ft)) of their natal home (Daly and Patton 1990, p. 1291). Average dispersal lengths for Botta's pocket gopher are estimated at 100-500 m (328.08-1,640.42 ft) per year (Hafner *et al.* 1998, p. 281). Individual Botta's pocket gophers that disperse are typically young, pre-reproductive, and more likely to be female (Daly and Patton 1990, p. 1287). Pre-reproductive juvenile females begin dispersing as early as the summer following their birth, while males typically delay dispersal for up to one year after birth (Daly and Patton 1990, p. 1287). Spring dispersal is common in reproductive adults of both sexes. Fifty percent of plains pocket gopher (*Geomys bursarius*) female adults relocate after raising a litter, leaving the site in possession of female young (Zinnel and Tester 1994, p. 99). Once pocket gophers establish territories and burrows, they may shift to other areas based on environmental conditions or interactions with other pocket gophers, but they generally do not move far from original territories (Miller 1964, p. 262; Reichman *et al.* 1982, pp. 687-688; Daly and Patton 1990, p. 1286).

Taxonomy

The Wyoming pocket gopher (*Thomomys clusius*) is a member of the Geomyidae (pocket gopher) family. Including the Wyoming pocket gopher, nine species are currently assigned to the genus *Thomomys*. The type specimen for Wyoming pocket gopher was collected in 1857 by Dr. W.A. Hammond near Rawlins, Wyoming, but was not described and given the name *Thomomys clusius* until 18 years later (Coues 1875, p. 138). The designation of the Wyoming pocket gopher within *Thomomys* has changed over time, with the name *clusius* being applied at both the species and subspecies level to various pocket gopher specimens collected in southern Wyoming (Keinath and Beauvais 2006, p. 11).

Thaeler and Hinesley (1979, entire) clarified the Wyoming pocket gopher taxonomy with karyotype (i.e., a count of the number of diploid chromosomes) and morphological analyses of pocket gopher specimens collected in Wyoming. Members of the pocket gopher genus *Thomomys* are the most karyotypically and morphologically diverse group of mammals known (Patton 1972, p. 574; Patton and Brylski 1987, p. 493). The Wyoming pocket gopher has a unique karyotype of 2n = 46, a yellowish coat, and a generally small size, which support the validity of Wyoming pocket gopher as a distinct species within *Thomomys* (Thaeler and Hinseley 1979, p. 483). These traits differed significantly from the northern pocket gopher, which occurs across the range of the Wyoming pocket gopher. Although northern pocket gophers are generally darker and larger, they share morphological similarities with Wyoming pocket gophers that had led to some misidentification of specimens in earlier publications (e.g., Bailey 1915 and Long 1965, cited in Keinath and Beauvais 2006, p. 11). Thus, karyotype analysis was previously thought necessary for positive identification. Northern pocket gophers differ from Wyoming pocket gophers in that they have a karyotype of 2n = 48 or 56, depending on the subspecies (Thaeler and Hinesley 1979, p. 483). However, based on the amplified fragment length polymorphism (AFLP) analysis completed on tail clippings during the 2008 field season, field assessment of phenotype was shown to be a reasonably reliable method for discerning the two species from each other (Hayden-Wing Associates 2008, p. 3; Beauvais 2009, p. 1; McDonald 2009a, pers. comm.). AFLP testing showed strong genetic signals that clearly differentiate the Wyoming pocket gopher from other species of pocket gophers (Beauvais 2009, p. 1; McDonald 2009a, pers. comm.). This recent genetic analysis has confirmed definitively what taxonomists had determined historically: the Wyoming pocket gopher is a unique species representing a monophyletic clade (i.e., descended from one common ancestor) (McDonald 2009a, pers. comm.).

**Summary of Information Pertaining to the Five Factors**

Section 4 of the Act, and its implementing regulations at 50 CFR 424, set forth the procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Under section 4(b)(1)(A), this determination should be made on the basis of the best scientific and commercial data available and after conducting a status review and taking into consideration State conservation efforts. In making our 12–month finding on a petition to list the Wyoming pocket gopher, we considered and evaluated the best available scientific and commercial information. Information pertaining to the status and threats to the Wyoming pocket gopher in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range*

Wyoming pocket gopher habitat is exposed to a number of influences that may affect the species, including energy exploration and development, road construction and use, climate change and drought, introduction of nonnative species, grazing, and urbanization. However, no studies have been conducted to determine the species' response to these influences, or to the potential changes in habitat that may result. Where information specific to the Wyoming pocket gopher is lacking, we have utilized information from other pocket gopher species, mainly in the *Thomomys* genus.

Literature describes both positive and negative effects to other species of pocket gophers resulting from various types of disturbance. Many pocket gopher species exhibit a positive response of increased rates of mound-building activities when vegetation has been disturbed (Mielke 1977, p. 175). Three species (Botta's pocket gopher, plains pocket gopher, and yellow-faced pocket gopher (*Cratogeomys castanops*)) are more common in disturbed areas, such as roadways and floodplains, in New Mexico (Best 1973, p. 1314). Similarly, pocket gopher (*Thomomys* spp.) burrows were frequently observed along roadways in Nevada, but not the adjacent creosote habitats, suggesting they were using areas where the habitat would have been unsuitable without the disturbance (Garland and Bradley 1984, p. 54). In contrast, plains pocket gophers and yellow-faced pocket gophers in southwestern Kansas are not present within areas of intensive agricultural operations involving annual plowing or disking (Hoffman *et al.* 2007, p. 300). Intensive residential and commercial development has reduced patch sizes of Mazama pocket gopher habitat in western Washington such that the species no longer occurs in many areas (Service 2009b, pp. 7-8; Flotlin 2010, pers. comm.). The response to disturbance may be dependent on the species, as the plains pocket gopher is more common in disturbed areas, such as roadsides and cultivated fields, while the yellow-faced pocket gopher is more common in native shortgrass prairie in southeastern Colorado (Moulton *et al.* 1983, p. 58).

In 2008 and 2009, WYNDD, with the assistance of several other groups, trapped Wyoming pocket gophers, northern pocket gophers, and Idaho pocket gophers (*T. idahoensis*) to better understand the species' range and distribution, habitat requirements and preferences, and the genetic and morphological differences between species (WYNDD 2009, p. 2; Hayden-Wing Associates 2008, p. 1; Keinath and Griscom 2008, p. 1; Griscom *et al.* 2010, pp. 5-7). This effort resulted in the successful trapping of 31 confirmed Wyoming pocket gophers distributed across the species' currently known range (Griscom *et al.* 2010, p. 5; Griscom 2010b, pers. comm.). Prior to 2008, a total of 16 confirmed Wyoming pocket gophers had been captured, and all of these confirmed specimens were collected by Charles Thaeler approximately 40 years ago (Griscom 2009b, pers. comm). This information provided both historic and recent locations for our use in creating a general assessment of Wyoming pocket gopher presence to ascertain if the known locations of the species have changed over time. Based on the limited number of collection sites, the species appears to be currently distributed throughout its known range in a pattern that approximates historic distribution (Figure 1). Therefore, we find no evidence that curtailment of the species' range is occurring.

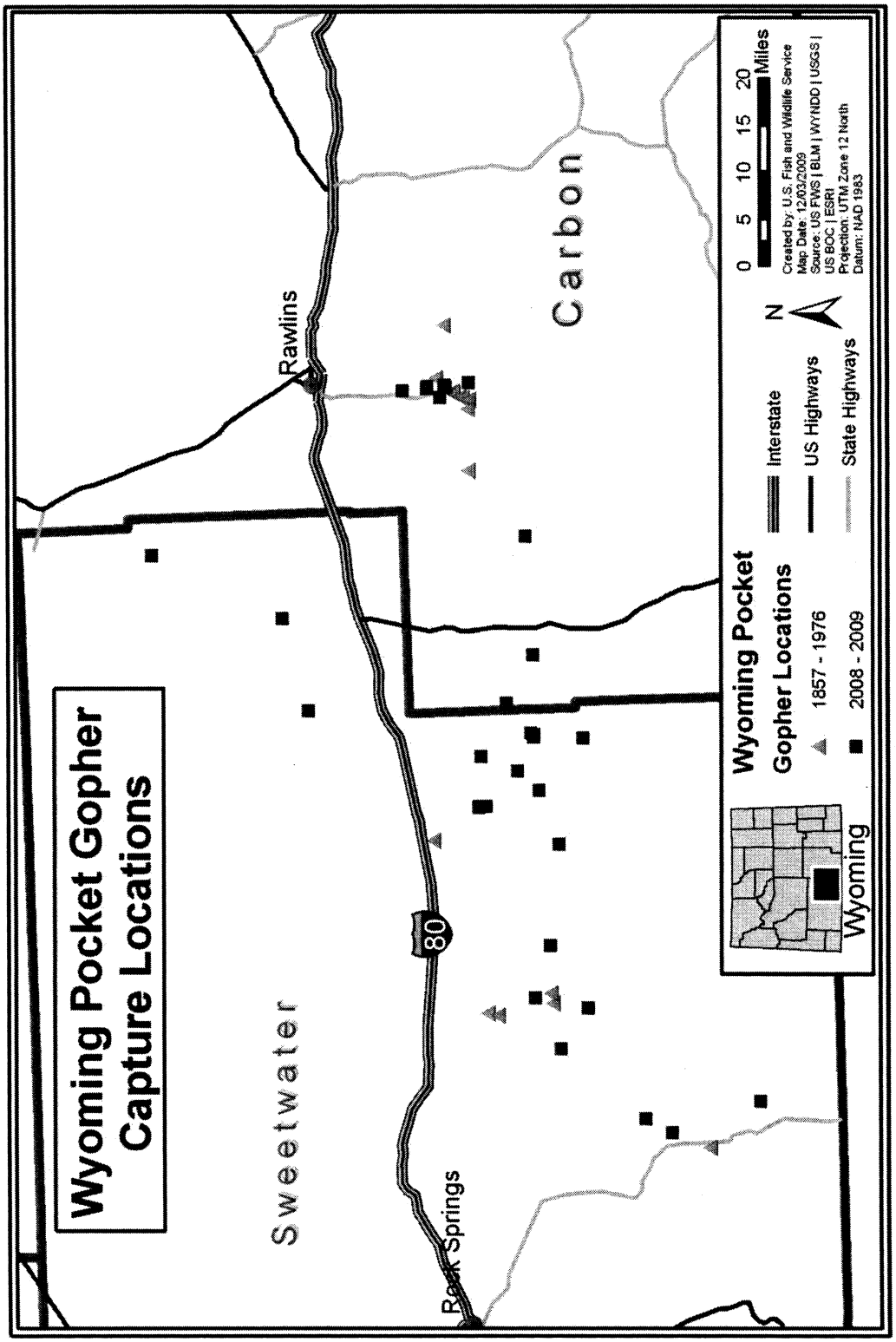


Figure 1: Historic and current capture locations of the Wyoming pocket gopher (Data compiled from Service, Bureau of Land Management, WYNDD, U.S. Geological Survey, U.S. Census Bureau, ESRI).

Although there is no evidence of curtailment of the species' range, habitat of the Wyoming pocket gopher is exposed to various influences that may affect the species, including energy exploration and development, road construction and use, introduction of nonnative species, climate change, drought, grazing, and urbanization. These variables that may affect the species' habitat are discussed below.

*Energy Exploration and Development*

The primary forms of existing and planned energy development in the range of the Wyoming pocket gopher are oil, gas, and wind. Based on existing

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) documents for major oil and gas developments, estimates of project life for major oil and gas developments within the Wyoming pocket gopher's range are between 10-50 years (Service 2010a, p. 3). Some non-renewable energy development is already occurring within the species' known occupied range. Renewable energy development is estimated to reach maximum development by 2030 (U.S. Department of Energy 2008, p. 10), and several developments are being considered within the species' range. Based on this information, we estimate the foreseeable future of energy development at a minimum of 10 years, but anticipate that energy development will be present for up to 50 years.

WYNDD is analyzing potential threats to Wyoming's 152 species of greatest conservation need related to energy development in its Assessment of Wildlife Vulnerability to Energy Development (AWVED). Preliminary conclusions from the AWVED analysis indicate that the Wyoming pocket gopher is Wyoming's species with the highest potential risk for energy-related effects based on its proximity to existing wells, the proportion of lands leased for oil and gas within its range, and the density of wells within that range (Keinath 2009, pp. 12-13). This potential risk is based on exposure to energy development across the species' range and is not based on any known effects to the species from energy development activities. Our February 10, 2009, 90–day finding (74 FR 6558) acknowledged that the likelihood of oil and gas development throughout the species' range is high based on the energy development potential and existing leases that cover much of the range. Approximately 4,000 actively producing oil and gas wells are within the range of the species (Service 2010b, p. 3), and an additional 10,000 oil and gas wells have been proposed in that area (Service 2010a, p. 1). In this finding, rather than what was done in our previous 90–day finding on the petition, we are determining whether the best available information indicates that the species meets the definition of a threatened or endangered species and therefore warrants listing under the Act, which is a more in-depth analysis than the one conducted for the 90–day finding.

Several different types of oil and gas exploration and development activities occur within the range of the Wyoming pocket gopher. Oil and gas geophysical exploration is conducted to generate a subsurface image of fluid minerals and usually involves either drilling holes and detonating explosives or using a vibrating pad that is driven across an area using heavy vehicles. The extent of impacts from either exploration method on pocket gophers is unknown. The vibrations and potential soil impacts would, at a minimum, temporarily alter habitat and may result in collapse of burrows. Pocket gophers in the immediate vicinity of operations would likely notice the activity, but the type of response is unknown. Pocket gopher communication likely occurs through seismic signals (Mason and Narins 2001, p. 1177), and frequent vibrations could disrupt signals used to attract mates, warn of intruders, or avoid predators. However, we have no information to support that energy exploration negatively impacts the species.

Oil and gas development involves staging a drilling rig and setting up additional equipment that is used during production. Generally, developers build roads to access each site and clear and level well pads. These soil-disturbing activities would affect the habitat that lies within and adjacent to the footprint of well pads and roads. Any soil that is moved could have a direct impact on pocket gophers that are present. Once a rig is in place, the drilling process creates vibrations that could affect habitat and any pocket gophers in the area. Once a well has been drilled and is producing, energy companies make regular trips to well pads to monitor production, conduct maintenance, or collect extracted resources. These regular trips may disturb, either directly or through the resulting noise, pocket gophers that are present at or near well pads and roads. In the past, the Wyoming pocket gopher has been considered potentially vulnerable to disturbance because the reasons for the species' limited distribution had not yet been explained (Keinath and Beauvais 2006, p. 21). However, as described above, certain types of disturbance can elicit a positive population response in some pocket gopher species.

Energy producers often try to maintain a clear work area by using herbicides on well pads and along roads. Herbicide use and the direct impacts of development would reduce the availability and quality of vegetation, creating negative effects to Wyoming pocket gopher habitat (Keith *et al.* 1959, pp. 142-144). In general, broadcast herbicide application is assumed to be minimal in southern Wyoming (Keinath and Beauvais 2006, p. 22). We do not have information on use of herbicides for oil and gas development, and we are unaware of monitoring for resulting vegetative shifts. Therefore, we are unable to assess how changes in the vegetation due to herbicide use may affect the Wyoming pocket gopher. The BLM does not use pesticides or rodenticides in Wyoming to protect reclamation areas (Abbott 2009a, pers. comm.), so we do not anticipate direct mortality from these substances in reclamation areas. Introduction and spread of nonnative plants may result from energy development activities, and the potential threat of nonnative vegetation to the Wyoming pocket gopher is discussed separately below.

We used information from Wyoming pocket gopher trapping and from known oil and gas development to assess the extent to which energy development may be affecting the species. By overlaying producing wells on a map with species capture sites, we found that the locations of capture sites in relation to new and existing development does not appear to reflect a pattern of either species avoidance of, or preference for, producing oil and gas wells. Some capture sites are as near as 95 m (312 ft) to a producing well site (Service 2010b, p. 2), while others are in areas that have no oil or gas wells. We recognize that this simple geospatial assessment has limitations in determining what effects oil and gas development has on the species. We also recognize dispersal is likely already difficult across portions of the range that do not currently have pocket gophers, and recolonization following local extirpation would be unlikely (Keinath *et al.* 2008, p. 7).

The amount of surface disturbance provides another approach to consider the impacts of natural gas development. The two largest natural gas developments not yet fully built in the Wyoming pocket gopher range are Atlantic Rim and Continental Divide-Creston (Service 2010a, p. 1). The scoping notice for the Continental-Divide Creston development states disturbances during initial development will be approximately 47,060 acres (ac) (19,045 hectares (ha)) of 1.1 million ac (445,154 ha), or 4.28 percent of the project area (BLM 2006a, p. 4). The impacted area will be reduced to 1.67 percent through interim reclamation (BLM 2006a, p. 4). As this proposal includes areas of infill, the amount of disturbance described in the scoping notice does not include existing development (BLM 2006a, p. 1). The proposed well density includes 8 wells per square mile, with a possibility of up to 16 wells per square mile in certain areas (BLM 2006a, p. 1). The Record of Decision for the Atlantic Rim development allows a total surface

disturbance of 2.8 percent of the project area at a given time, with well spacing of 8 wells per square mile (BLM 2007, p. 10). For comparison, the existing Continental Divide/Wamsutter II gas development has been mostly developed, with 22,400 ac (9,065 ha) of surface disturbance across 1,061,200 ac (429,452 ha) (2.11 percent of the project area) and well densities of 1 to 8 wells per square mile (BLM 2000, section 2.0). All of these surface disturbance percentages are small. Although we do not know how the Wyoming pocket gopher is likely to respond to any proposed increases in well numbers, the level of development indicates that large interstitial spaces will continue to be available for Wyoming pocket gopher use. We know from our analysis that the Wyoming pocket gopher does occur near developed areas (Service 2010b, p. 2).

The BLM administers approximately half of the lands within the Wyoming pocket gopher range (Service 2009a, p. 1). Throughout the range, the BLM has leased 41.23 percent of the Wyoming pocket gopher range for oil and gas development, and 11.23 percent of the range on BLM lands has producing oil and gas leases (Service 2010c, p. 2). We are unable to determine whether development will occur on all leases.

Given limited knowledge of pocket gopher response to oil and gas development, and both the positive and negative observed impacts of disturbance to other species of pocket gophers, we do not consider producing wells at current or projected levels to be a threat to the Wyoming pocket gopher.

Although little wind development has occurred within the range of the species, projections for future wind energy are significant. One major proposal, the Chokecherry and Sierra Madre Wind Energy Project, includes 1,000 wind turbines across 98,500 ac (39.66 ha) within the range of the Wyoming pocket gopher (AECOM 2009, p. 1). Wind development may cause effects to habitat that are similar to oil and gas development. Wind development also results in a network of pads connected by roads. Soils are disturbed during development, and frequent maintenance trips are necessary. The Wyoming pocket gopher's response to wind development within its habitat is not known. For the Botta's pocket gopher, researchers mapping prey base to better understand raptor mortalities at a wind farm in California observed that pocket gophers were clustered near the wind turbines (Thelander *et al.* 2003, p. 23). They attributed this to the pocket gophers' attraction to the vertical and lateral edges formed by access roads and the area around wind towers (Thelander *et al.* 2003, p. 24). We anticipate that the response of the Wyoming pocket gopher may be similar, but we lack species-specific information. Therefore, the best available information does not indicate whether current or future wind development will have positive or negative effects on the Wyoming pocket gopher.

Summary of Energy Exploration and Development

Little information exists to indicate whether the Wyoming pocket gopher will be affected by an increased density of wells or by an expansion of oil, gas, and wind development into currently undeveloped areas. The response to disturbance in pocket gophers appears to be species-specific. For example, in southeastern Colorado, the plains pocket gopher is more common in disturbed areas, but the yellow-faced pocket gopher is more common in native versus disturbed habitats (Moulton *et al.* 1983, p. 58). Based on our current understanding of the Wyoming pocket gopher, energy development, at levels that we can detect or anticipate, is as likely to benefit Wyoming pocket gophers as it is to harm them.

We have no information that additional energy development activity will fragment habitat in a way that will significantly limit dispersal, movement, or genetic interchange. Using the best available information, we conclude that these habitat alterations do not constitute a threat to the Wyoming pocket gopher now, or in the foreseeable future.

*Road Construction and Use*

Roads are built to create access for oil, gas, and wind developments, as well as for other activities that occur on the landscape, including recreation, grazing, and land management. Much of the recent expansion of road networks in Wyoming pocket gopher habitat is related to energy development, but some areas have also likely experienced an increase in access by recreational vehicles. Expansion of road networks may fragment the species' habitat, create barriers to movement of the species, isolate individual populations, and increase opportunities for invasive species (Keinath and Beauvais 2006, pp. 22-23). Roads may increase direct mortality from vehicles, but this source of mortality is not always significant to populations (Garland and Bradley 1984, p. 52). Roads also may improve habitat for pocket gophers in some ways by providing looser soil and increasing vegetation in rights-of-way from precipitation run-off. As described above, roads can have a positive effect on other pocket gopher species (Best 1973, p. 1314; Moulton *et al.* 1983, p. 58; Garland and Bradley 1984, p. 54). The effects of roads on Wyoming pocket gopher populations are not known; however, we have limited anecdotal observations of individual gopher occupancy near roads. In 2009, one Wyoming pocket gopher specimen was captured 7 m (23 ft) from a graded dirt road, and northern pocket gophers were captured as close as 2 m (6.5 ft) to a graded dirt road (Griscom 2009b, pers. comm.). Small mammals may avoid roads due to noise and other factors, but roads may also provide additional habitat or movement corridors (Garland and Bradley 1984, entire; U.S. Department of Transportation 2009, unpaginated). Northern pocket gophers have been observed digging tunnels underneath a right-of-way road (Richens 1966, p. 532).

Depending upon the size of the road and the associated degree of soil compaction, a road may impact the dispersal of Wyoming pocket gophers. For example, distribution of the Shelton pocket gopher (*T. mazama couchi*) was impacted by soil compaction around an airport runway, and no pocket gopher activity was observed in graded areas that appeared to be highly compacted (GeoEngineers 2003, p. 15). The Wyoming pocket gopher apparently can use more compacted soils than the northern pocket gopher (Griscom *et al.* 2010, p. 15), but we are unsure what amount of soil compaction would begin to limit habitat use by the Wyoming pocket gopher.

Many roads in the range of the Wyoming pocket gopher have been on the landscape for decades or for more than a century, while others have been developed within the past few years. Evidence suggests some historic wagon trails (a type of road) have lasted for well over 100 years (BLM 2009, unpaginated), even when use of the road is discontinued. Other roads are reclaimed and do not have such a lasting effect. We anticipate that the existing roads within the range of the Wyoming pocket gopher will persist for at least 10 to 50 years in support of energy development activities. Additional roads may also be constructed to support that development, while others are reclaimed when no longer necessary. We anticipate that county roads providing access to livestock management facilities, homes, and recreational opportunities will persist indefinitely.

We conclude the effects of roads on the Wyoming pocket gopher may be positive and negative. Although we remain concerned about the potential impacts of roads, the best available information does not indicate that road construction and use poses a threat to the Wyoming pocket gopher now, or in the foreseeable future.

*Nonnative Species*

The introduction of nonnative species may affect the Wyoming pocket gopher, but the degree of impact from these species is not clear. A review of Wyoming pocket gopher information resulted in no information indicating a likelihood that nonnative vegetation alters or restricts pocket gopher populations; nonnative species were viewed as a potential threat, but not a current threat (Keinath and Beauvais 2006, p. 23). We do not fully understand the extent to which nonnative species will spread throughout the species' range into the future. Nonnative vegetation is considered a threat to the Mazama pocket gopher in western Washington (Service 2009b, pp. 7-8). The Mazama pocket gopher is adapting to the presence of many types of nonnative vegetation; however, the presence of *Cytisus scoparius* (Scotch broom), which has large root masses, restricts pocket gopher dispersal. The loss of prairie habitat to conifer encroachment is also a threat to the Mazama pocket gopher (Flotlin 2010, pers. comm.). *Cytisus scoparius* does not occur within the range of the Wyoming pocket gopher, and conifer encroachment is limited.

To inform our evaluation of the potential threat from nonnative species, we looked at the potential for *Bromus tectorum* (cheatgrass) to impact Wyoming pocket gopher populations. The conversion from *A. tridentata* spp. to *B. tectorum* has been shown to negatively impact other small mammals (Yensen *et al.* 1992, p. 309). The spread of *B. tectorum* has the potential to change vegetative communities in a way that could affect the Wyoming pocket gopher. As discussed previously, forbs are an important component of pocket gopher diets, and high densities of *B. tectorum* reduce the biomass and growth rates of forbs, as well as seedling survival for some forb species (Parkinson 2008, pp. 37-46). Further, when chemical treatments were used to experimentally reduce the abundance of weedy forbs in favor of grasses, a northern pocket gopher population declined roughly in proportion to the loss of forbs (Keith *et al.* 1959, p. 231).

Pocket gophers that eat grass species have reduced body weights (Tietjen *et al.* 1967, pp. 642-643). Grasses, when not consumed with other vegetation, do not seem to provide an adequate diet for *Thomomys* species (Cox 1989, p. 80). While *Bromus tectorum* may impact the abundance of forbs in the species' habitat, *B. tectorum* may also be used by Wyoming pocket gophers. Small quantities of the seeds of *B. tectorum* have been occasionally found in tunnels of northern pocket gophers, although seed heads of *B. tectorum* were not preferred as forage (Cox 1989, pp. 78-80). Northern pocket gophers also occur at locations where *B. tectorum* was considered to be a prevalent plant species (Ostrow *et al.* 2002, p. 992). During their breeding season, Botta's pocket gophers have been found to consume substantial quantities of species related to *B. tectorum, B. mollis* (soft brome) and *B. rubens* (red brome), when the nutrient content of the plants was highest (Hunt 1992, p. 49).

While *Bromus tectorum* appears to have the potential to impact Wyoming pocket gopher habitat, the spread of *B. tectorum* throughout the habitat of the Wyoming pocket gopher is not a foregone conclusion. In Wyoming, *B. tectorum* can be locally abundant, but precipitation and elevation differences influence where *B. tectorum* occurs (Smith and Enloe 2006, p. 1). In southern Wyoming counties, the fall precipitation prior to cold weather needed for *B. tectorum* germination is generally rare in zones where 14 inches or less of precipitation is received annually (Smith and Enloe 2006, p. 1). The annual precipitation within the range of the Wyoming pocket gopher is generally less than 14 inches of precipitation annually (National Atlas 2005, unpaginated).

In approximately the last 100 years, no broad-scale *B. tectorum* eradication method has been developed. Given the history of invasive plants on the landscape, the continued challenges in controlling such species, and the current infestation of invasive plants across the Wyoming pocket gopher's range, we anticipate that invasive plants will be on the landscape for the next 100 years or longer. However, studies indicate *B. tectorum* germination may be generally rare in Wyoming pocket gopher habitat, possibly inhibiting the future spread and impact of this invasive species in Wyoming pocket gopher habitat. In summary, we could find no information suggesting that nonnative species or *B. tectorum*, where it occurs within the occupied range of the Wyoming pocket gopher, represent a threat to the species now, or in the foreseeable future.

*Climate Change*

The Intergovernmental Panel on Climate Change (IPCC) has concluded that warming of the climate is unequivocal and that continued greenhouse gas emissions at or above current rates will cause further warming (IPCC 2007, p. 30). Eleven of the 12 years from 1995 through 2006 rank among the 12 warmest years in the instrumental record of global surface temperature since 1850 (Independent Scientific Advisory Board 2007, p. 6). Climate-change scenarios estimate that the mean air temperature could increase by more than 3 degrees Celsius (5.4 degrees Fahrenheit) by 2100 (IPCC 2007, p. 46). The IPCC also projects that there will very likely be regional increases in the frequency of hot extremes, heat waves, and heavy precipitation (IPCC 2007, p. 46), as well as increases in atmospheric carbon dioxide (IPCC 2007, p. 36).

Plant species provide habitat and forage that affect the ability of mammal species, such as the Wyoming pocket gopher, to persist over time. A variety of plant-related factors are not included in climate space models, including the effect of elevated carbon dioxide on plant water-use efficiency, the physiological effect to the species of exceeding the assumed (modeled) bioclimatic limit, the life stage at which the limit affects the species (seedling versus adult), the life span of the species, and the movement of other organisms into the species' range (Shafer *et al.* 2001, p. 207). These factors would likely help determine how climate change would affect plant species distributions. While more empirical studies are needed on what determines species and multi-species distributions, those data are often lacking; in their absence, climatic space models can play an important role in characterizing the types of changes that may occur so that the potential impacts on natural systems can be assessed (Shafer *et al.* 2001, p. 213).

One study modeled potential climate change impacts to *A. tridentata* spp., which are representative of the ecosystem currently known to be occupied Wyoming pocket gopher habitat (Shafer *et al.* 2001, pp. 200-215). Each scenario in the study predicted a reduction in the size of the overall range of sagebrush and shift where sagebrush may occur. These simulated changes were the result of increases in the mean temperature of the coldest month, which the authors speculated may interact with soil moisture levels to produce the simulated impact. Each model predicted that climate suitability

for big sagebrush would shift north into Canada. Other areas within big sagebrush distributions would become less suitable climatically and would potentially cause a significant contraction in sagebrush range. Since the Wyoming pocket gopher is associated with sagebrush in the matrix that forms Wyoming pocket gopher habitat, contractions of sagebrush could result in negative effects to the species. However, although the Wyoming pocket gopher occurs within sagebrush habitats, the species prefers vegetation other than sagebrush at a finer scale within that matrix (Griscom *et al.* 2010, p. 15).

In some cases, effects of climate change can be demonstrated (e.g., McLaughlin *et al.* 2002, p. 6073). Where it can be, we rely on that empirical evidence, such as increased stream temperatures (see Rio Grande cutthroat trout, 73 FR 27900, May 14, 2008) or loss of sea ice (see polar bear, 73 FR 28212, May 15, 2008), and treat it as a threat that can be analyzed. The degree to which climate change will interact with ecological processes important to Wyoming pocket gophers is not currently known.

Based on the evolutionary and ecological response of pocket gopher species to past global warming and cooling events, changes in temperature and precipitation may result in phenotypic and density changes in Wyoming pocket gopher populations (Hadly 1997, p. 292; Hadly *et al.* 1998, p. 6896; Barnosky *et al.* 2003, pp. 360-361), but we have no information specific to the Wyoming pocket gopher. If the Wyoming pocket gopher's range experiences increased temperatures and reduced precipitation in the future, these changes could include reduced body size and population abundance (Hadly 1997, p. 292). Past climate-induced, population-level, phenotypic change in pocket gophers was likely the result primarily of developmental plasticity within populations and not large-scale migration (Hadly *et al.* 1998, p. 6896; Barnosky *et al.* 2003, p. 362). Measured changes in phenotype and population size appeared to be an initial response to global warming episodes, with the extent of change being dependent upon the magnitude and duration of climatic change (Barnosky *et al.* 2003, pp. 364-365).

Smaller body size and reduced abundance experienced by historical pocket gopher populations during global hot, dry periods is likely a response to reduced food availability during those periods (Hadly 1997, p. 290). Projected climate change has the potential to significantly alter the distribution of forage important to pocket gophers through shifts in timing and amount of precipitation, or through changes in seasonal high, low, or average temperatures (Bachelet *et al.* 2001, p. 174). For example, warmer temperatures and greater concentrations of atmospheric carbon dioxide create conditions favorable to *Bromus tectorum*, which outcompetes native vegetation and greatly accelerates the natural fire cycle in areas where it becomes established (Chambers and Pellant 2008, p. 31; Global Climate Change Impacts in the United States 2009, p. 83). Future carbon dioxide emissions from energy use are projected to increase by 40 to 110 percent between 2000 and 2030 (IPCC 2007, p. 44). If a resulting shift in the vegetative communities occurs within the range of the Wyoming pocket gopher, the displacement of native forbs and grasses could significantly alter the availability of sufficient forage resources. This could then be exacerbated by the continued loss of those resources as a result of the shortened fire cycle.

Application of continental-scale climate change models to regional landscapes and even more local or "step-down" models projecting habitat potential based on climatic factors is informative, but contains a high level of uncertainty when predicting future effects to the Wyoming pocket gopher and its habitat due to a variety of factors, including regional weather patterns, local physiographic conditions, life stages of individual species, generation time of species, and species' reactions to changing carbon dioxide levels. The models summarized above are limited by these types of factors; therefore, their usefulness in assessing the threat of climate change on the Wyoming pocket gopher into the future is also limited.

*Drought*

Drought conditions occur within the range of the Wyoming pocket gopher and are a natural process that has historically occurred separately from climate change. We anticipate natural drought cycles to occur periodically within the range of the Wyoming pocket gopher into the future. We could find no specific information regarding the effects of drought on the Wyoming pocket gopher. Presumably drought would likely affect forage growth and potentially limit food availability. While this may have temporary effects on population numbers and the reproductive ability of the Wyoming pocket gopher, the species continues to occupy its known range despite historic periods of natural drought.

Summary of Climate Change and Drought

The direct, long-term impact from climate change to the Wyoming pocket gopher is not known. Shifts in the vegetative community may affect the species' ability to forage. However, given our lack of knowledge of important food resources for the Wyoming pocket gopher, our resulting lack of understanding about how changes in the forage base may affect the species, and our uncertainty regarding the effects of climate change on those food resources, we cannot consider climate change to be a threat to the species now, or in the foreseeable future. A reduction in forage availability may also occur during periods of drought. However, we have no data to facilitate our understanding of what impacts this may have on the species. Additionally, the Wyoming pocket gopher has persisted within its known range since at least 1857 (Thaeler and Hinesley 1979, p. 480) despite periods of natural drought. Therefore, while there may be population variation as a result of drought, we do not have any data indicating that drought creates a threat to the Wyoming pocket gopher now, or in the foreseeable future.

*Grazing*

Currently, livestock grazing is the most widespread type of land use across the sagebrush biome, which includes the known range of the Wyoming pocket gopher (Knick *et al.* 2003, p. 616; Connelly *et al.* 2004, pp. 7-29; Knick *et al.*, in press, p. 27). Several studies have shown that livestock grazing can result in reduced pocket gopher abundance and in some cases complete exclusion (Phillips 1936, p. 676; Hunter 1991, p. 117; Stromberg and Griffin 1996, p. 1205; Eviner and Chapin 2003, p. 125). Livestock grazing has the potential to negatively affect pocket gophers through a variety of mechanisms, such as soil compaction (Phillips 1936, pp. 677-678). However, direct competition for forage likely has the largest negative effect on pocket gopher populations (Phillips 1936, p. 677). Wild ungulate grazing has been found to have similar competitive effects to other small mammals (Coäte *et al.* 2004, p. 129), and this interaction may impact pocket gophers. However, we have no information to suggest that this competition is occurring with the Wyoming pocket gopher.

Historically, pocket gophers have been recognized by livestock producers as competitors with livestock for limited rangeland forage (Richens 1965, p. 424; Julander *et al.* 1969, p. 325; Turner

1969, p. 377; Laycock and Richardson 1975, p. 458). Pocket gophers primarily feed on forbs; however, diet composition can shift seasonally to include varying percentages of grasses and shrubs (see discussion above under Life History; Aldous 1951, pp. 85-86; Ward and Keith 1962, p. 747). Cattle are grazers, feeding mostly on grasses, but they will make seasonal use of forbs and shrub species (Vallentine 1990, p. 226). Domestic sheep are intermediate feeders, making high use of forbs but also using a large volume of grass and shrub species (Vallentine 1990, pp. 240-241). Horses are generalists, but seasonally their diets can be almost wholly comprised of grasses (Wagner 1983, pp. 119-120). The degree of competition between pocket gophers and livestock due to diet varies with local conditions that affect type and abundance of vegetation, stocking rates, and types of livestock (Phillips 1936, p. 676; Eviner and Chapin 2003, p. 125). We are unable to assess the levels of competition that are occurring, but competition has likely remained constant since grazing levels on BLM lands have generally been stable since 1978 (Laycock *et al.* 1996, p. 50). We anticipate future levels of competition from grazing to remain constant, as the recently renewed BLM Resource Management Plan for much of the range of the Wyoming pocket gopher does not include a change in past livestock stocking rates (BLM 2008, pp. 2-19).

Domestic livestock grazing will continue at present levels within the range of the Wyoming pocket gopher (BLM 2008, pp. 2-19). The current amounts, kinds, and seasons of livestock grazing use will be authorized until monitoring, field observations, ecological site inventory, or other data acceptable to the BLM indicates an adjustment to grazing use is necessary (BLM 2008, pp. 2-19). While we cannot provide an exact estimate of the foreseeable future for grazing, we expect this use to be persistent across the Wyoming pocket gopher's range for several decades.

We recognize the potential for negative impacts to Wyoming pocket gopher populations due to direct competition with livestock, but have no information about the impacts of grazing practices or grazing intensity to the species. Livestock grazing has remained consistent over time, and the Wyoming pocket gopher has continued to occupy its known range. Additionally, we are unaware of any studies linking grazing practices to population levels of the Wyoming pocket gopher. Therefore, we have no information to indicate that grazing poses a threat to the Wyoming pocket gopher now, or in the foreseeable future.

*Urbanization*

Urbanization is considered a significant threat to other species of pocket gopher, such as the Mazama pocket gopher (Service 2009b, p. 8); however, urbanization is limited within the range of the Wyoming pocket gopher. This area is largely rural, with approximately 55,000 people residing in Carbon and Sweetwater Counties in 2008 (U.S. Census Bureau 2009, p. 94), which is an average of 3 people per square mile (2.6 square kilometers). However, most of this population is concentrated in the population centers of Rock Springs, Green River, and Rawlins, which are at the edges of the potential Wyoming pocket gopher range. The BLM administers approximately half of the land in the range of the species, so urban development is precluded from those areas. Limited housing development is occurring near Wyoming pocket gopher collection sites, primarily to support gas field workers. These areas provide concentrated areas of disturbance, which create fewer impacts to the overall range of the species. The limited amount of housing across the range of the species also restricts the opportunities for domestic pet predation on Wyoming pocket gophers. We are unable to quantify a foreseeable future, but anticipate that additional urbanization will be limited based on the isolated nature of the area and the harsh environment that has not historically attracted many people. Based on the limited amount of urbanization, we do not consider it to be a significant threat to the Wyoming pocket gopher now, or in the foreseeable future.

**Summary of Factor A**

We conclude that the range of the Wyoming pocket gopher has experienced and will continue to experience significant changes, primarily related to oil, gas, and wind development. The range is also likely to experience some changes related to climate change. Changes from other sources, including nonnative vegetation, grazing, and urbanization, may occur to a lesser degree. However, we are unable to demonstrate that these alterations to habitat will result in negative effects to the species. Examining data from studies on other species of pocket gophers' responses to similar disturbances did not provide clarity as the response appeared to vary by species. For example, the invasive *Bromus tectorum* may negatively affect pocket gophers, but northern pocket gophers can occur where *B. tectorum* is a prevalent plant species (Ostrow *et al.* 2002, p. 992), and the seeds of *B. tectorum* were occasionally found in their burrows (Cox 1989, pp. 78-80). Many species of pocket gophers increase rates of mound building in areas of disturbed vegetation, while others are not found in areas of disturbance (Moulton *et al.* 1983, p. 58). Therefore, predicting the potential effects of habitat disturbances or alteration on the Wyoming pocket gopher based on the responses of other pocket gophers is not possible. The species continues to occupy its known historic range despite habitat alterations that have occurred within that range, and we have no evidence of population declines.

We conclude that the best scientific and commercial information available indicates that the Wyoming pocket gopher is not now, or in the foreseeable future, threatened by the present or threatened destruction, modification, or curtailment of its habitat or range to the extent that listing under the Act as an endangered or threatened species is warranted at this time.

*Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes*

Overutilization is the consumptive use of an organism, where individuals are intentionally captured or taken for a variety of purposes. Examples include take for human consumption, use of feathers or fur to create garments, and capture and removal of individuals for scientific or educational examinations or study. We have no data indicating that the Wyoming pocket gopher has been, is currently being, or will be in the future, used for commercial, recreational, or educational purposes.

In the late 1970s, in Wyoming and Colorado, 228 pocket gophers of three different species were collected and euthanized to collect tissue for taxonomic delineation (Thaeler and Hinesley 1979, p. 480). Forty of the animals collected were identified as Wyoming pocket gophers, although the authors note that tissue preparation on 83 individuals was insufficient to do genetic analyses. Therefore, more Wyoming pocket gophers may have been collected but not identified. No further documented captures of the Wyoming pocket gopher occurred until 2008, when 12 individuals were trapped to collect genetic and morphological information for species determination (Griscom *et al.* 2010, p. 5). Two of those pocket gophers were euthanized to obtain the tissue necessary for karyotyping procedures (McDonald 2009b, pers. comm.). Trapping

continued in 2009 to collect distribution and habitat information. A total of 19 individuals were captured in 2009 (Griscom 2010b, pers. comm.), with 2 individuals found dead in the traps (Griscom *et al.* 2010, p. 9). No other Wyoming pocket gopher mortalities from these trapping efforts were reported. Tissue samples (removing the tip of the tail) were collected from 5 individuals in 2008 and 15 individuals in 2009 prior to their subsequent release at the capture location (Griscom 2009c, pers. comm.; Griscom *et al.* 2010, p. 22). Some individuals may have died after release at the capture location; however, one Wyoming pocket gopher (Griscom 2009c, pers. comm.) and a pocket gopher of another species were recaptured a day or two after the tip of the tail was removed (Griscom *et al.* 2010, p. 11). The wounds were healing, and the pocket gophers did not appear to show any ill effects (Griscom *et al.* 2010, p. 11). Northern pocket gophers survived in a lab environment for several weeks after having their tails clipped (McDonald 2009a, pers. comm.). This limited evidence suggests that this tissue collection does not result in mortality.

The Wyoming Game and Fish Department (WGFD) issued collection permits for Wyoming pocket gophers for the scientific work that occurred in 2008 and 2009 (Emmerich 2009, p. 2). The review associated with the permitting process provided a protective measure to the species by limiting take to those individuals authorized to perform the work (Wyoming Game and Fish Commission (WGFC) 1998, pp. 52-8–52-9). Based on recent interest in the Wyoming pocket gopher, we anticipate that some utilization of the species related to scientific research will occur in 2010 and possibly in future years.

We could find no other information on research or scientific use of the Wyoming pocket gopher. The lack of population data for this species results in difficulties in determining whether the Wyoming pocket gopher is adversely impacted by scientific purposes. However, we do not believe overutilization to be a current or future threat because relatively few individuals have been affected by scientific research, research methodologies generally involve live captures, and available information indicates captured individuals can survive without noticeable effects.

**Summary of Factor B**

We conclude that the best scientific and commercial information available indicates that the Wyoming pocket gopher is not now, or in the foreseeable future, threatened by overutilization for commercial, recreational, scientific, or educational purposes to the extent that listing under the Act as an endangered or threatened species is warranted at this time.

*Factor C. Disease or Predation*

Disease and parasites have not been demonstrated to limit populations of pocket gophers (Keinath and Beauvais 2006, p. 20). In general, pocket gophers host some endo- and exo-parasites, most of which have been identified incidentally to other research (Keinath and Beauvais 2006, p. 21). In some cases, northern pocket gophers have been found with sufficient levels of botfly larvae to result in mortality, with up to 25 to 37 percent of local gopher populations affected (Keinath and Beauvais 2006, p. 21 and references therein). However, the effects of these infestations on population persistence were not provided. No research has been conducted on diseases and parasites of the Wyoming pocket gopher. Therefore, combined with the lack of population data, we have no way of assessing the current or future impact of this factor on this species. We recognize that lower levels of genetic diversity may allow a population to have greater susceptibility to diseases (Sanjayan *et al.* 1996, p. 1525), but we do not have information indicating that disease poses a threat to the Wyoming pocket gopher, and we do not have sufficient information to describe genetic diversity of the species. Additionally, we do not have information indicating that human activities in the area increase the susceptibility of the Wyoming pocket gopher to disease or parasites due to increased physiological stress.

Pocket gophers are subject to predation from gopher snakes (*Pituophis catenifer*), rattlesnakes (*Crotalus viridis*), long-tailed weasels (*Mustela frenata*), coyotes (*Canis latrans*), bobcats (*Lynx rufus*), badgers (*Taxidea taxus*), foxes (*Vulpes* spp.), skunks (*Mephitis* spp.), numerous owls (Keinath and Beauvais 2006, p. 20), and domestic pets (Stinson 2005, p. 51). However, we have no data indicating that predation limits Wyoming pocket gopher populations. Ravens (*Corvus corax*) use road networks associated with oil fields in southwestern Wyoming for foraging activities (Bui 2009, p. 31), and common raven abundance increases in association with oil and gas development in southwestern Wyoming (Holmes 2009, p. 1). However, we could find no information that ravens prey upon pocket gophers. Therefore, if raven abundance is increasing within the range of the Wyoming pocket gopher as a result of energy development activities, there is likely no effect on Wyoming pocket gophers. We were unable to find any other information to suggest that the predator-prey balance for the Wyoming pocket gopher has been affected by any anthropogenic activity, or may be affected within the forseeable future.

Based on our understanding of past and current effects, we do not anticipate the effects of disease, parasites, or predation to change for the foreseeable future.

**Summary of Factor C**

We conclude that the best scientific and commercial information available indicates that the Wyoming pocket gopher is not now, or in the foreseeable future, threatened by disease or predation to the extent that listing under the Act as an endangered or threatened species is warranted at this time.

*Factor D: The Inadequacy of Existing Regulatory Mechanisms*

Under this factor, we examine whether identified threats to the Wyoming pocket gopher are adequately addressed by existing regulatory mechanisms. These mechanisms could include: (1) Local land use laws, processes, and ordinances; (2) State laws and regulations; and (3) federal laws and regulations. Regulatory mechanisms, if they exist, may preclude listing if such mechanisms are judged to adequately address the threat to the species such that listing is not warranted.

We could find no local land use laws, processes, or ordinances that provide a regulatory mechanism for the Wyoming pocket gopher. The State of Wyoming has identified the Wyoming pocket gopher as a Native Species Status 4, meaning that while populations are restricted in distribution, the species' habitat does not appear to be declining, and there are no known sensitivities to human disturbance (Oakleaf *et al.* 2002, p. 263). Important conservation efforts for this species identified by the WGFD are to collect more information on the species' status, trends, and habitat use. The Wyoming pocket gopher is identified in the WGFD Comprehensive Wildlife Conservation Strategy (WGFD 2005, pp. 250-251) as a species of concern, which signifies a decline or restriction to the population or its habitat or both, but confers no State protection to the species. The Wyoming pocket gopher received this designation based on restricted habitat and limited available information on the species (Emmerich 2009, p. 1). The WGFD does

restrict the take of the Wyoming pocket gopher under Chapter 52 of the WGFC regulations (WGFC 1998, p. 52-9; Emmerich 2009, p. 1). This designation protects individuals of the species from take unless take is authorized by regulations or is necessary to address human health or safety (WGFC 1998, pp. 52-58). No state regulatory mechanisms provide for protection of the species' habitat.

The Wyoming pocket gopher has been identified as a sensitive species by Region 2 of the U.S. Forest Service (USFS) based on the species' rarity and potential sensitivity to disturbance (Keinath and Beauvais 2006, p. 6; USFS 2006, p. 10), although we are unaware of any occurrence of this species on USFS lands (Keinath and Beauvais 2006, p. 7). The USFS does not confer any protective regulations to identified sensitive species. The BLM in Wyoming also identifies the Wyoming pocket gopher as a sensitive species (Abbott 2009b, pers. comm.), which requires the agency to consider the welfare of these species when evaluating any action on public lands (BLM 2001, pp. 21J-22D3c(2)). The BLM has identified the Wyoming pocket gopher in NEPA documents in the areas of the Wyoming pocket gopher's distribution, such as the 2006 Atlantic Rim Final Environmental Impact Statement (BLM 2006b, p. 4-89). Project proponents for future projects on BLM lands were instrumental in collecting distributional data in 2008 and 2009 (Beauvais 2009, p. 4; Griscom *et al.* 2010, p. 6). However, species-specific management actions have not been developed by the BLM (Keinath and Beauvais 2006, pp. 6-8; Abbott 2010, pers. comm.). Despite the lack of regulatory mechanisms, this species continues to occupy its known range.

We anticipate no changes in the current regulatory mechanisms for the foreseeable future, unless research on the Wyoming pocket gopher indicates that regulatory mechanisms are necessary and can help prescribe specific effective protections.

**Summary of Factor D**

We conclude that the best scientific and commercial information available indicates that the Wyoming pocket gopher is not now, or in the foreseeable future, threatened by the inadequacy of existing regulatory mechanisms to the extent that listing under the Act as an endangered or threatened species is warranted at this time. It is unclear that regulatory mechanisms in addition to those described are needed for the species based on the current understanding of threats.

*Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence*

Other natural or manmade factors affecting the continued existence of the Wyoming pocket gopher that we analyzed include vulnerability of small populations, use of poisons to target the species, and recreational activities. We are unaware of other factors that may affect the continued existence of the species.

*Vulnerability of Small Populations*

The Wyoming pocket gopher is a narrow endemic species (i.e., a species whose natural occurrence is confined to a certain region and whose distribution is relatively limited). The best available scientific data suggest that this species occurs in just two counties in southwest Wyoming. Small geographic range has been identified as the most important single indicator of elevated extinction risk in mammals (Purvis *et al.* 2000, p. 1949; Oborny *et al.* 2005, p. 291; Cardillo *et al.* 2006, pp. 4157-4158; Cardillo *et al.* 2008, p. 1445; Davies *et al.* 2008, p. 11559). The inherent vulnerability associated with small geographic range is due to the fact that a single localized threat, whether it is manmade (e.g., development) or environmental (e.g., disease), can potentially impact the entire distribution of the species, resulting in an increased probability of extinction (Davies *et al.* 2008, p. 11559).

Small population size has also been identified as an important predictor of extinction vulnerability (O'Grady *et al.* 2004, p. 517). Although we have no information on Wyoming pocket gopher abundance, restricted geographic range frequently correlates with small population size (Purvis *et al.* 2000, p. 1947). Thus, it is reasonable to assume that abundance is low relative to other pocket gopher species with larger geographic ranges (e.g., northern pocket gopher). Given their restricted distribution and presumably relatively small population size, Wyoming pocket gophers are more vulnerable to demographic, environmental, and genetic stochasticity than larger, more widely distributed species, which could affect the Wyoming pocket gopher's likelihood for long-term persistence.

Wyoming pocket gopher distribution appears to be discontinuous, and it remains undetermined if a metapopulation structure (a group of spatially separated populations which interact at some level) exists for this species (Keinath and Beauvais 2006, p. 19). Based on the abilities of other pocket gophers, which is consistent in the scientific literature for all species, Wyoming pocket gophers are not thought capable of dispersing long distances and may be restricted by the energetic demands of tunneling (Hansen 1962, p. 152; Vaughan 1963, p. 371; Keinath and Beauvais 2006, p. 16). There may be some above-ground dispersal at night (Griscom 2009a, pers. comm.) or when there is snow cover (Vaughan 1963, p. 369). The patchy distribution and low dispersal capability result in a low probability for recolonization following local population extinctions (Keinath *et al.* 2008, p. 7). When the area over which a colonization-extinction process operates is geographically small, as is the case with Wyoming pocket gopher, a single local extinction that is not followed by recolonization can have a large impact on the occupancy of the total area (Oborny *et al.* 2005, p. 291).

The Wyoming pocket gopher has persisted since at least 1857 (Coues 1875, p. 138) and may never have had a large population size. The species appears to be currently distributed throughout its known range in a pattern that approximates historic distribution (see Figure 1 above). However, it appears to have several characteristics, such as small geographic range, isolated populations, and low dispersal ability, which increase the species' vulnerability to extinction from stochastic events and other threats on the landscape. Currently, we do not have information on these threats to an extent that allows us to know whether small population size allows for other manmade or environmental factors to create a threat to the Wyoming pocket gopher. Further, the historic range and persistence of the species' population size indicate the species occurs in normally low population densities. We are unable to quantify a foreseeable future for stochastic events that may have disproportionate negative effects on small population sizes. We do not anticipate the effects of these events on small population size to change, but our understanding of these effects may improve over time.

*Lethal Control of Pocket Gophers*

Campaigns to eliminate other species of pocket gophers are often pursued in association with development, farmlands, and ranchlands. We have no information that indicates that pocket gophers are the target of lethal control campaigns within the range of the Wyoming pocket gopher. Strychnine and Rozol are both rodenticides approved by the U.S. Environmental Protection Agency for control of pocket gophers, and these substances may

create a threat to the Wyoming pocket gopher through targeted application or non-target poisonings of another species (Dickerson 2009a, pers. comm.). We are unable to show the extent to which these and similar substances are used on private lands in the area; however, rangelands, which form the majority of Wyoming pocket gopher habitat, are not typically the target of pocket gopher control measures (Dickerson 2009b, pers. comm.). Additionally, the BLM does not use pesticides or rodenticides in Wyoming to protect reclamation areas (Abbott 2009a, pers. comm.). We are unable to determine if the Wyoming pocket gopher may be targeted by, or exposed to, substances used for lethal control in the future. We are unaware of other methods that are commonly used for lethal control of pocket gopher populations. We currently do not have any information that would lead us to anticipate an increase in lethal control of the Wyoming pocket gopher for the foreseeable future.

*Recreational Activities*

Recreational activities within the range of the Wyoming pocket gopher include hunting, camping, hiking, horse riding, use of all-terrain vehicles, and visiting historic sites. These activities may cause elevated levels of human presence on the landscape and resultant disturbances to habitat, which were discussed in Factor A. We have no information to indicate that increased human presence related to recreation poses a threat to the Wyoming pocket gopher. We anticipate that recreational activities will continue at current or slightly increased levels within the range of the Wyoming pocket gopher for the foreseeable future.

**Summary of Factor E**

Based on the best available information, we have no indication that other natural or manmade factors are likely to significantly threaten the existence of the species. We recognize the inherent vulnerabilities of small populations and restricted geographic range, which appear to be exhibited by the Wyoming pocket gopher. The impacts of various potential threats can be more pronounced on small or isolated populations, and we have identified numerous activities occurring on the landscape within the range of the Wyoming pocket gopher (see Factor A discussion). However, at this time, we do not have information to indicate that these activities pose a threat to the Wyoming pocket gopher. Additionally, we do not consider a small population alone to be a threat to species; rather, it can be a vulnerability that can make it more susceptible to threat factors, if they are present. Many naturally rare species have persisted for long periods within small geographic areas, and many naturally rare species exhibit traits that allow them to persist despite their small population sizes (Nevo *et al.* 1997, p. 388; Rubinoff and Powell 2004, p. 2547; Lawson *et al.* 2008, p. 927; Abeli *et al.* 2009, p. 3887). The Wyoming pocket gopher is one of these species, existing in a limited range since its discovery in 1857. We have no information that this rarity is working in combination with any threat factors that would cause the species to be likely to become in danger of extinction in all or a significant portion of its range in the foreseeable future. We have identified lethal control of pocket gophers and recreational activities as other manmade factors that may impact the species, but we have no information that these factors are negatively impacting the species at this time.

We conclude that the best scientific and commercial information available indicates that the Wyoming pocket gopher is not now, or in the foreseeable future, threatened by other natural or manmade factors affecting its continued existence to the extent that listing under the Act as an endangered or threatened species is warranted at this time.

**Finding**

As required by the Act, we considered the five factors in assessing whether the Wyoming pocket gopher is endangered or threatened throughout all or a significant portion of its range. We have carefully examined the best scientific and commercial information available regarding the status and the past, present, and future threats faced by the Wyoming pocket gopher. We reviewed the petition, information available in our files, and other published and unpublished information submitted to us by the public following our 90–day petition finding. We also consulted with Wyoming pocket gopher experts and other Federal and State resource agencies. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species warrants listing as threatened or endangered as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of threatened or endangered under the Act. We were able to quantify the foreseeable future only for energy development and scientific utilization of the species, but discussed how we anticipate each factor to change over time. We were unable to project changes to the species into the future because we do not have sufficient data to know if these factors will result in positive or negative effects to the species.

Our review of the best available scientific and commercial information pertaining to the five factors does not support the assertion that there are threats of sufficient imminence, intensity, or magnitude to indicate the Wyoming pocket gopher is in danger of extinction (endangered), or is likely to become endangered within the foreseeable future (threatened), throughout all or a significant portion of its range. Therefore, we find that listing the Wyoming pocket gopher throughout all or a significant portion of its range is not warranted at this time.

In making this finding, we recognize that the Wyoming pocket gopher, despite not being warranted for listing as endangered or threatened, may benefit from increased management emphasis due to its limited distribution and range. In particular, future oil, gas, and wind development may have positive or negative impacts to the species and should be carefully considered and monitored. We recommend precautionary measures be taken to protect the species, and that additional research be pursued to improve the understanding of the species so that the responses to future potential threats can be better understood.

**Distinct Vertebrate Population Segments**

After assessing whether the species is endangered or threatened throughout its range, we next consider whether a distinct vertebrate population segment (DPS) of the Wyoming pocket gopher meets the definition of endangered or is likely to become endangered in the foreseeable future (threatened).

Under the Service's Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722, February 7, 1996), three elements are considered in the decision concerning the establishment and classification of a possible DPS. These are applied similarly for additions to or removals from the Federal List of Endangered and Threatened Wildlife. These elements include: (1) The discreteness of a population in relation to the remainder of the taxon to which it belongs; (2) the significance of the population segment to the taxon to which it belongs; and (3) the population segment's conservation status in relation to the Act's standards for listing, delisting (removal from the list), or reclassification (i.e., is the population segment endangered or threatened).

As stated above, the Wyoming pocket gopher is a narrow endemic species, historically and currently found in only two counties in south-central Wyoming. Only 47 confirmed Wyoming pocket gophers have been trapped over approximately the past 40 years, and the species appears to be currently distributed throughout its known range in a pattern that approximates historic distribution (see Figure 1 above). Dispersal strategies of the Wyoming pocket gopher are unknown (see discussion under Life History above). However, in other species of pocket gophers, dispersal has been well documented (e.g., Daly and Patton 1990, p. 1291; Hafner *et al.* 1998, p. 281), and we have no evidence to suggest that the Wyoming pocket gopher does not disperse within its known range. Therefore, we have no evidence suggesting that the Wyoming pocket gopher is isolated in any part of its range. We determine, based on a review of the best available information, that no portion of the Wyoming pocket gopher range meets the discreteness conditions of the 1996 DPS policy. The DPS policy is clear that significance is analyzed only when a population segment has been identified as discrete. Since we found that no population segment meets the discreteness element, and therefore no population segment qualifies as a DPS under the Service's DPS policy, we will not conduct an evaluation of significance.

*Significant Portion of the Range*

Having determined that the Wyoming pocket gopher does not meet the definition of an endangered or threatened species throughout its entire region, we must next consider whether there are any significant portions of the range where the Wyoming pocket gopher is in danger of extinction or is likely to become endangered in the foreseeable future.

On March 16, 2007, a formal opinion was issued by the Solicitor of the Department of the Interior (USDI), "The Meaning of 'In Danger of Extinction Throughout All or a Significant Portion of Its Range'" (USDI 2007, entire). We have summarized our interpretation of that opinion and the underlying statutory language below. A portion of a species' range is significant if it is part of the current range of the species and it contributes substantially to the representation, resiliency, or redundancy of the species. The contribution must be at a level such that its loss would result in a decrease in the ability to conserve the species.

In determining whether a species is endangered or threatened in a significant portion of its range, we first identify any portions of the range of the species that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be significant, and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that are not significant, such portions will not warrant further consideration.

If we identify portions that warrant further consideration, we then determine whether the species is endangered or threatened in these portions of its range. Depending on the biology of the species, its range, and the threats it faces, the Service may address either the significance question or the status question first. Thus, if the Service considers significance first and determines that a portion of the range is not significant, the Service need not determine whether the species is endangered or threatened there. Likewise, if the Service considers status first and determines that the species is not endangered or threatened in a portion of its range, the Service need not determine if that portion is significant. However, if the Service determines both that a portion of the range of a species is significant and that the species is endangered or threatened there, the Service will specify that portion of the range as endangered or threatened under section 4(c)(1) of the Act.

The terms "resiliency," "redundancy," and "representation" are intended to be indicators of the conservation value of portions of the range. Resiliency of a species allows the species to recover from periodic disturbance. A species will likely be more resilient if large populations exist in high-quality habitat that is distributed throughout the range of the species in such a way as to capture the environmental variability found within the range of the species. A portion of the range of a species may make a meaningful contribution to the resiliency of the species if the area is relatively large and contains particularly high-quality habitat, or if its location or characteristics make it less susceptible to certain threats than other portions of the range. When evaluating whether or how a portion of the range contributes to resiliency of the species, we evaluate the historical value of the portion and how frequently the portion is used by the species, if possible. In addition, the portion may contribute to resiliency for other reasons—for instance, it may contain an important concentration of certain types of habitat that are necessary for the species to carry out its life-history functions, such as breeding, feeding, migration, dispersal, or wintering.

Redundancy of populations may be needed to provide a margin of safety for the species to withstand catastrophic events. This does not mean that any portion that provides redundancy is necessarily a significant portion of the range of a species. The idea is to conserve enough areas of the range such that random perturbations in the system act on only a few populations. Therefore, each area must be examined based on whether that area provides an increment of redundancy that is important to the conservation of the species.

Adequate representation ensures that the species' adaptive capabilities are conserved. Specifically, the portion should be evaluated to see how it contributes to the genetic diversity of the species. The loss of genetically based diversity may substantially reduce the ability of the species to respond and adapt to future environmental changes. A peripheral population may contribute meaningfully to representation if there is evidence that it provides genetic diversity due to

its location on the margin of the species' habitat requirements.

Section 4(c)(1) of the Act requires the Service to determine whether a portion of a species' range, if not all, meets the definition of endangered or threatened. As stated above, based on the best scientific information, we find listing the Wyoming pocket gopher across its entire range is not warranted. We were unable to identify any significant portion of the range that merits additional analysis. The 31 Wyoming pocket gopher captures that occurred in 2008 and 2009 indicate that the species is currently distributed throughout its known historic range (see Figure 1 above). The limited information available on the Wyoming pocket gopher, such as the lack of population numbers and dynamics, does not allow us to determine what portion of the range, if any, contributes substantially and differentially to the long-term persistence of the species. As discussed previously, we do not know how the species is likely to respond to many potential threats (e.g., wind energy), and therefore we cannot determine if the potential threats imperil a significant portion of the species' range. Further, for those potential threats with more well-understood impacts to the species (e.g., poisoning), we could find no portion of the range in which threats are concentrated or otherwise likely to impact a significant portion of the species' range.

## Conclusion

We do not find that the Wyoming pocket gopher is in danger of extinction now, nor is it likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing the species as endangered or threatened under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the Wyoming pocket gopher to our Wyoming Ecological Services Field Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor this species and encourage its conservation. If an emergency situation develops for the Wyoming pocket gopher or any other species, we will act to provide immediate protection.

## References Cited

A complete list of all references cited in this document is available on the Internet at *http://www.regulations.gov* and upon request from the Wyoming Ecological Services Field Office (see **ADDRESSES** section).

## Author

The primary authors of this document are staff members of the Wyoming Ecological Services Field Office (see **ADDRESSES** section).

## Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 30, 2010.

**Daniel M. Ashe,**

*Acting Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2010–8578 Filed 4–14–10; 8:45 am]

**BILLING CODE 4310–55–S**

# Notices

Federal Register

Vol. 75, No. 72

Thursday, April 15, 2010

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

### Forest Service

### Recreation Resource Advisory Committees

**AGENCY:** Forest Service, USDA.

**ACTION:** Call for nominations for the Pacific Northwest Recreation Resource Advisory Committees.

**SUMMARY:** The Secretary of Agriculture has established the Pacific Northwest Recreation Resource Advisory Committees (Recreation RACs) pursuant to section 4 of the Federal Lands Recreation Enhancement Act (REA) that was passed into law as part of the 2005 Consolidated Appropriations Act (Pub. L. 108–447) on December 8, 2004. The purpose of this Recreation RAC is to provide recommendations regarding recreation fees to both the Forest Service and the Bureau of Land Management (BLM) as appropriate. There are currently three vacancies on the Recreation RAC: Summer Motorized Recreation, Summer Motorized Outfitter and Guide Recreation, and Tribal. The public is invited to submit nominations for membership on the Recreation RACs.

**DATES:** All nominations should be received by the appropriate Regional Office by May 5, 2010. If necessary, manager may continue accepting applications beyond this date to ensure broad and balanced representation on the Recreation RAC. Nominations must contain a completed application packet that includes background information and other information that addresses a nominee's qualifications. Application packets for Recreation RACs can be obtained from the Forest Service Regional Office listed below or on the Web at *http://www.fs.fed.us/passespermits/rrac-application.shtml.*

**ADDRESSES:**

**Regional Contacts for Recreation RACs**

1. *Pacific Northwest Regional Office:* Shandra Terry, Regional Public Involvement Coordinator, Public Affairs, 333 SW 1st Ave., Portland, OR 97208, (503) 808–2242.

**FOR FURTHER INFORMATION CONTACT:** Julie Cox, National Recreation RAC Coordinator, 333 SW 1st Avenue, Portland, OR 97208, (503) 808–2984.

**SUPPLEMENTARY INFORMATION:**

**Nomination and Application Information for Recreation RACs**

Each Forest Service Recreation RAC shall consist of 11 members appointed by the Secretary of Agriculture. These members shall provide a broad and balanced representation from the recreation community as follows:

1. Five persons who represent recreation users and that include, as appropriate, the following:

a. Winter motorized recreation, such as snowmobiling;

b. Winter nonmotorized recreation, such as snowshoeing, cross country and downhill skiing, and snowboarding;

c. Summer motorized recreation, such as motorcycles, boaters, and off-highway vehicles;

d. Summer nonmotorized recreation, such as backpacking, horseback riding, mountain biking, canoeing, and rafting; and

e. Hunting and fishing.

2. Three persons who represent interest groups that include, as appropriate, the following:

a. Motorized outfitters and guides;

b. Nonmotorized outfitters and guides; and

c. Local environmental groups.

3. Three persons, as follows:

a. A State tourism official to represent the State;

b. A person who represents affected Indian tribes; and

c. A person who represents affected local government interests.

Any individual or organization may nominate one or more qualified persons to represent the interests listed above to serve on the Recreation RAC. To be considered for membership, nominees must—

1. Identify what interest group they would represent and how they are qualified to represent that group;

2. State why they want to serve on the committee and what they can contribute;

3. Show their past experience in working successfully as part of a collaborative group; and

4. Complete Form AD–755, Advisory Committee or Research and Promotion Background Information.

Letters of recommendation are welcome. Individuals may also nominate themselves. Nominees do not need to live in a State within a particular Recreation RAC area of jurisdiction nor live in a State in which Forest Service-managed lands are located.

Application packets, including evaluation criteria and the AD–755 form, are available at *http://www.fs.fed.us/passespermits/rrac* or by contacting the respective regions identified in this notice. Nominees must submit all documents to the appropriate regional contact. Additional information about recreation fees and REA is available at *http://www.fs.fed.us/passespermits/about-rec-fees.shtml.*

The Agency will also work with Governors and county officials to identify potential nominees.

The Agency will review the applications and prepare a list of qualified applicants from which the Secretary of Agriculture shall appoint both committee members and alternates. An alternate will become a participating member of the Recreation RACs only if the member for whom the alternate is appointed to replace leaves the committee permanently.

Recreation RAC members serve without pay but are reimbursed for travel and per diem expenses for regularly scheduled committee meetings. All Recreation RAC meetings are open to the public and an open public forum is part of each meeting. Meeting dates and times will be determined by Agency officials in consultation with the Recreation RAC members, when the committee is formed.

Dated: April 8, 2010.

**J. Lenise Lago,**

*Deputy Regional Forester.*

[FR Doc. 2010–8487 Filed 4–14–10; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Newspapers Used for Publication of Legal Notices in the Southwestern Region, Which Includes Arizona, New Mexico, and Parts of Oklahoma and Texas

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice.

**SUMMARY:** This notice lists the newspapers that will be used by all Ranger Districts, Grasslands, Forests, and the Regional Office of the Southwestern Region to give legal notice for the availability for comments on projects under 36 CFR 215, notice of decisions that may be subject to administrative appeal under 36 CFR part 215 or Optional Appeal Procedures Available During the Planning Rule Transition Period (formerly 36 CFR part 217), and for opportunities to object to proposed authorized hazardous fuel reduction projects under 36 CFR 218.4. This notice also lists newspapers of record for notices pertaining to plan amendments and revisions under 36 CFR 219. Newspaper publication is in addition to mailings and direct notice made to those who have participated in the planning of projects or plan revisions and amendments by submitting comments and/or requesting notice.

**DATES:** Use of these newspapers for the purpose of publishing legal notice for a plan amendment decision that is subject to appeal under "Optional Appeal Procedures Available During the Planning Rule Transition Period" (formerly 36 CFR Part 217), for a comment and project decision that may be subject to appeal under 36 CFR part 215, for opportunity to object under 36 CFR 218, and for planning notices on a plan revision or plan amendment under 36 CFR part 219 shall begin on the date of this publication and continue until further notice.

**ADDRESSES:** Southwestern Region, ATTN: Regional Appeals Assistant, 333 Broadway SE., Albuquerque, NM 87102–3498.

**FOR FURTHER INFORMATION CONTACT:** Connie Smith, 505–842–3223.

**SUPPLEMENTARY INFORMATION:** Where more than one newspaper is listed for any unit, the first newspaper listed is the primary newspaper of record of which publication date shall be used for calculating the time period to file comment, appeal or an objection.

**Southwestern Regional Office**

*Regional Forester*

Notices of Availability for Comment and Decisions and Objections affecting New Mexico Forests:— "Albuquerque Journal", Albuquerque, New Mexico, for National Forest System Lands in the State of New Mexico and for any projects of Region-wide impact. Regional Forester Notices of Availability for Comment and Decisions and Objections affecting Arizona Forests:— "The Arizona Republic", Phoenix, Arizona, for National Forest System lands in the State of Arizona and for any projects of Region-wide impact. Regional Forester Notices of Availability for Comment and Decisions and Objections affecting National Grasslands in New Mexico, Oklahoma, and Texas are listed by Grassland and location as follows: Kiowa National Grassland Notices published in:—"Union County Leader", Clayton, New Mexico. Rita Blanca National Grassland in Cimarron County, Oklahoma Notices published in:— "Boise City News", Boise City, Oklahoma. Rita Blanca National Grassland in Dallam County, Texas Notices published in:— "The Daihart Texan", Daihart, Texas. Black Kettle National Grassland in Roger Mills County, Oklahoma Notices published in:— "Cheyenne Star", Cheyenne, Oklahoma. Black Kettle National Grassland in Hemphill County, Texas notices published in:—"The Canadian Record", Canadian, Texas. McClellan Creek National Grassland in Gray County, Texas Notices published in:— "The Pampa News", Pampa, Texas.

**Arizona National Forests**

*Apache-Sitgreaves National Forests*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Alpine Ranger District, Black Mesa Ranger District, Lakeside Ranger District, and Springerville Ranger District are published in:—"The White Mountain Independent", Show Low and Navajo County, Arizona.

Clifton Ranger District Notices are published in:—"Copper Era", Clifton, Arizona.

*Coconino National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Mogollon Rim Ranger District, Mormon Lake Ranger District, and Peaks Ranger District are published in:—"Arizona Daily Sun", Flagstaff, Arizona.

Red Rock Ranger District Notices are published in:—"Red Rock News", Sedona, Arizona.

*Coronado National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor and Santa Catalina Ranger District are published in:—"The Arizona Daily Star", Tucson, Arizona.

Douglas Ranger District Notices are published in:—"Daily Dispatch", Douglas, Arizona.

Nogales Ranger District Notices are published in:—"Nogales International", Nogales, Arizona.

Sierra Vista Ranger District Notices are published in:—"Sierra Vista Herald", Sierra Vista, Arizona.

Safford Ranger District Notices are published in:—"Eastern Arizona Courier", Safford, Arizona.

*Kaibab National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, North Kaibab Ranger District, Tusayan Ranger District, and Williams Ranger District Notices are published in:—"Arizona Daily Sun", Flagstaff, Arizona.

*Prescott National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Bradshaw Ranger District, Chino Valley Ranger District and Verde Ranger District are published in:—"Daily Courier", Prescott, Arizona.

*Tonto National Forest*

Notices for Availability for Comments, Decisions, and Objections by Forest Supervisor are published in:— "Arizona Capitol Times", in Phoenix, Arizona.

Cave Creek Ranger District Notices are published in:—"Arizona Capitol Times", in Phoenix, Arizona.

Globe Ranger District Notices are published in:—"Arizona Silver Belt", Globe, Arizona. Mesa Ranger District Notices are published in:—"Arizona Capitol Times", in Phoenix, Arizona.

Payson Ranger District, Pleasant Valley Ranger District and Tonto Basin Ranger District Notices are published in:—"Payson Roundup", Payson, Arizona.

**New Mexico National Forests**

*Carson National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Camino Real Ranger District, Tres Piedras Ranger District and Questa Ranger District are published in:—"The Taos News", Taos, New Mexico.

Canjilon Ranger District and El Rito Ranger District Notices are published in:—"Rio Grande Sun", Espanola, New Mexico.

Jicarilla Ranger District Notices are published in:—"Farmington Daily Times", Farmington, New Mexico.

*Cibola National Forest and National Grasslands*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor affecting lands in New Mexico, except the National Grasslands are published in:- "Albuquerque Journal", Albuquerque, New Mexico.

Forest Supervisor Notices affecting National Grasslands in New Mexico, Oklahoma and Texas are published by grassland and location as follows: Kiowa National Grassland in Colfax, Harding, Mora and Union Counties, New Mexico published in:—"Union County Leader", Clayton, New Mexico. Rita Blanca National Grassland in Cimarron County, Oklahoma published in:—"Boise City News", Boise City, Oklahoma. Rita Blanca National Grassland in Dallam County, Texas published in:— "The Dalhart Texan", Dalhart, Texas. Black Kettle National Grassland, in Roger Mills County, Oklahoma published in:—"Cheyenne Star", Cheyenne, Oklahoma. Black Kettle National Grassland, in Hemphill County, Texas published in:—"The Canadian Record", Canadian, Texas. McClellan Creek National Grassland published in:—"The Pampa News", Pampa, Texas.

Mt. Taylor Ranger District Notices are published in:—"Cibola County Beacon", Grants, New Mexico.

Magdalena Ranger District Notices are published in:—"Defensor-Chieftain", Socorro, New Mexico.

Mountainair Ranger District Notices are published in:—"Mountain View Telegraph", Moriarty, New Mexico.

Sandia Ranger District Notices are published in:—"Albuquerque Journal", Albuquerque, New Mexico.

Kiowa National Grassland Notices are published in:—"Union County Leader", Clayton, New Mexico.

Rita Blanca National Grassland Notices in Cimarron County, Oklahoma are published in:—"Boise City News", Boise City, Oklahoma while Rita Blanca National Grassland Notices in Dallam County, Texas are published in:—"The Dalhart Texan", Dalhart, Texas.

Black Kettle National Grassland Notices in Roger Mills County, Oklahoma are published in:— "Cheyenne Star", Cheyenne, Oklahoma, while Black Kettle National Grassland Notices in Hemphill County, Texas are published in:—"The Canadian Record", Canadian, Texas. McClellan Creek National Grassland Notices are published in:—"The Pampa News", Pampa, Texas.

*Gila National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Quemado Ranger District, Reserve Ranger District, Glenwood Ranger District, Silver City Ranger District and Wilderness Ranger District are published in:—"Silver City Daily Press", Silver City, New Mexico.

Black Range Ranger District Notices are published in:—"The Herald", Truth or Consequences, New Mexico.

*Lincoln National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor and the Sacramento Ranger District are published in:— "Alamogordo Daily News", Alamogordo, New Mexico.

Guadalupe Ranger District Notices are published in:—"Carlsbad Current Argus", Carlsbad, New Mexico.

Smokey Bear Ranger District Notices are published in:—"Ruidoso News", Ruidoso, New Mexico.

*Santa Fe National Forest*

Notices for Availability for Comments, Decisions and Objections by Forest Supervisor, Coyote Ranger District, Cuba Ranger District, Espanola Ranger District, Jemez Ranger District and Pecos-Las Vegas Ranger District are published in:—"Albuquerque Journal", Albuquerque, New Mexico.

Dated: April 5, 2010.

**Gilbert Zepeda,**

*Deputy Regional Forester, Southwestern Region.*

[FR Doc. 2010–8440 Filed 4–14–10; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Order No. 1673]**

### Grant of Authority for Subzone Status, CNH America, LLC, (Agricultural Equipment and Component Parts) Racine, WI

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

*Whereas,* the Foreign-Trade Zones Act provides for " * * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

*Whereas,* the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

*Whereas,* the Foreign Trade Zone of Wisconsin, Ltd., grantee of FTZ 41, has made application to the Board for authority to establish special-purpose subzone status with manufacturing authority at the CNH America, LLC (CNH) facilities, located in Racine, Wisconsin (FTZ Docket 42–2009, filed 10/6/2009);

*Whereas,* notice inviting public comment has been given in the **Federal Register** (74 FR 52455, 10/13/2009) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

*Whereas,* the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

*Now, Therefore,* the Board hereby grants authority for subzone status for activity related to the manufacturing and distribution of agricultural equipment at the facilities of CNH America, LLC, located in Racine, Wisconsin (Subzone 41I), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 1st day of April 2010.

**Ronald K. Lorentzen,**

*Deputy Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.*

[FR Doc. 2010–8555 Filed 4–14–10; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–821–801]**

### Solid Urea From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (the Department) is conducting an administrative review of the

antidumping duty order on solid urea from the Russian Federation. The review covers one producer/exporter of the subject merchandise, MCC EuroChem (EuroChem). The period of review (POR) is July 1, 2008, through June 30, 2009. We preliminarily determine that, during the POR, EuroChem sold the subject merchandise at less than normal value.

We invite interested parties to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument.

**EFFECTIVE DATE:** April 15, 2010.

**FOR FURTHER INFORMATION CONTACT:** Dustin Ross or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0747 or (202) 482–1690, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

On July 14, 1987, the Department published the antidumping duty order on solid urea from the Union of Soviet Socialist Republics (Soviet Union). See *Antidumping Duty Order; Urea From the Union of Soviet Socialist Republics*, 52 FR 26367 (July 14, 1987). Following the break–up of the Soviet Union, the antidumping duty order on solid urea from the Soviet Union was transferred to the individual members of the Commonwealth of Independent States. See *Solid Urea From the Union of Soviet Socialist Republics; Transfer of the Antidumping Order on Solid Urea From the Union of Soviet Socialist Republics to the Commonwealth of Independent States and the Baltic States and Opportunity to Comment*, 57 FR 28828 (June 29, 1992). The rate established in the less–than-fair–value investigation for the Soviet Union was applied to each new independent state, including the Russian Federation (Russia).

Pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), the Ad Hoc Committee of Domestic Nitrogen Producers and its individual urea–producing members, CF Industries, Inc., and PCS Nitrogen (collectively, the Ad Hoc Committee), requested an administrative review of the antidumping duty order on solid urea from Russia with respect to EuroChem on July 31, 2009. On August 25, 2009, in accordance with 19 CFR 351.221(c)(1)(i), we published a notice of initiation of administrative review of the order. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 74 FR 42873 (August 25, 2009). We are conducting the administrative review of the order in accordance with section 751(a) of the Act.

## Scope of the Order

The merchandise subject to the order is solid urea, a high–nitrogen content fertilizer which is produced by reacting ammonia with carbon dioxide. The product is currently classified under the Harmonized Tariff Schedules of the United States (HTSUS) item number 3102.10.00.00. Previously such merchandise was classified under item number 480.3000 of the Tariff Schedules of the United States. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

## Sales Analyzed

During the review we learned from the respondent that liquidation of entries of EuroChem's subject merchandise was not suspended due to the importer's misclassification of entries during the POR. EuroChem stated that it requested U.S. Customs and Border Protection (CBP) to do a post–entry adjustment to suspend liquidation. After querying CBP's system, we are satisfied that there is one suspended entry on which to assess collectable duties. See memo to file dated March 29, 2010, which is on file in the Central Records Unit (CRU) of the main Commerce building, room 1117. Therefore, pursuant to section 751(a)(2)(C) of the Act, we have calculated the weighted–average margin using all of EuroChem's sales of solid urea during the POR. For details on our methodology for assessing duties for entries in this POR, see "Assessment Rates" section below.

## Fair–Value Comparisons

To determine whether EuroChem's sales of solid urea from Russia were made in the United States at less than normal value, we compared the constructed export price (CEP) to the normal value as described in the "Constructed Export Price" and "Normal Value" sections of this notice.

When making this comparison in accordance with section 771(16) of the Act, we considered all products sold in the home market as described in the "Scope of the Order" section of this notice, above, that were in the ordinary course of trade for purposes of determining appropriate product comparisons to the U.S. sales of subject merchandise. We compared the U.S. sales to home–market sales of identical merchandise that were most contemporaneous with the U.S. sales in accordance with 19 CFR 351.414(e). Pursuant to section 777A(d)(2) of the Act, we compared the CEP of each U.S. transaction to the weighted–average price of sales of the foreign like product for the calendar month that corresponds most closely to the calendar month of the individual export sale.

## Product Comparisons

We compared U.S. sales to weighted–average prices of home–market contemporaneous sales of the foreign like product. Wherever possible, we compared U.S. sales with sales of the foreign like product in the home market. Specifically, in making our comparisons, if an identical home–market model was reported as described by the characteristics listed below, we made comparisons to weighted–average home–market prices of that model. We calculated the weighted–average home–market prices on a level of trade–specific basis. If there were no contemporaneous sales of an identical model, we identified the most similar home–market model. We found contemporaneous sales of identical merchandise in the home market for all U.S. sales in accordance with section 771(16) of the Act.

In accordance with section 771(16) of the Act, we compared products produced by EuroChem and sold in the U.S. and home markets on the basis of the comparison product which met the physical characteristics of the product sold in the United States. In order of importance, these characteristics are form, grade, nitrogen content, size, urea–formaldehyde content, other additive/conditioning agent, coating agent, and biuret content.

## Date of Sale

Section 351.401(i) of the Department's regulations states that, normally, the Department will use the date of invoice, as recorded in the producer's or exporter's records kept in the ordinary course of business, as the date of sale. The regulation provides further that the Department may use a date other than the date of the invoice if the Secretary is satisfied that a different date better reflects the date on which the material terms of sale are established. The Department has a long–standing practice of finding that, where shipment date precedes invoice date, shipment date better reflects the date on which the material terms of sale are

established. See *Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp From Thailand*, 69 FR 76918 (December 23, 2004), and accompanying Issues and Decision Memorandum at Comment 10; see also *Notice of Final Determination of Sales at Less Than Fair Value: Structural Steel Beams From Germany*, 67 FR 35497 (May 20, 2002), and accompanying Issues and Decision Memorandum at Comment 2.

For all U.S. sales, EuroChem reported shipment dates which preceded the date of invoice. For each of these sales, EuroChem reported the date of invoice as the date of sale. The date of invoice is the date on which the final invoice is printed for the U.S. customer following the transfer of subject urea from the ocean vessel to the barge at the U.S. port. Based on record evidence, all material terms of sale are established at the time of shipment, with provisions between customer and producer for variance between agreed–upon price and quantity and final measured price and quantity at the U.S. port of unloading. Consistent with our normal practice, for all U.S. sales EuroChem reported we used the date of shipment as the date of sale.

With respect to EuroChem's home–market sales, shipment date and invoice date are the same for every transaction. Therefore, we use invoice date as the date of sale for all home–market sales.

**Constructed Export Price**

In accordance with section 772(b) of the Act, we used CEP for EuroChem because the subject merchandise was sold in the United States by a U.S. seller affiliated with the producer and export price was not otherwise indicated.

We calculated CEP based on the free–on-board or delivered price to unaffiliated purchasers in, or for exportation to, the United States. We also made deductions for any movement expenses in accordance with section 772(c)(2)(A) of the Act. In accordance with section 772(d)(1) of the Act, we calculated the CEP by deducting selling expenses associated with economic activities occurring in the United States, which includes direct selling expenses and indirect selling expenses. Finally, we made an adjustment for profit allocated to these expenses in accordance with section 772(d)(3) of the Act.

**Normal Value**

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating normal value (*i.e.*, the aggregate volume of home–market sales of the foreign like product is five percent or more of the aggregate volume of U.S. sales), we compared the volume of EuroChem's home–market sales of the foreign like product to the volume of its U.S. sale of subject merchandise in accordance with section 773(a)(1)(C) of the Act. Based on this comparison, we determined that EuroChem had a viable home market during the POR. Consequently, we based normal value on home–market sales to unaffiliated purchasers made in the usual quantities in the ordinary course of trade and sales made to affiliated purchasers where we find prices were made at arm's length, described in detail below.

We based normal value on the starting prices to home–market customers. Pursuant to section 773(a)(6)(B)(ii) of the Act, we deducted inland–freight expenses EuroChem incurred on its home–market sales. Pursuant to section 773(a)(6)(B)(i) of the Act, we deducted home–market packing costs. We made deductions for direct selling expenses, as appropriate.

The Department may calculate normal value based on a sale to an affiliated party only if it is satisfied that the price to the affiliated party is comparable to the price at which sales are made to parties not affiliated with the exporter or producer, *i.e.*, sales were made at arm's–length prices. See 19 CFR 351.403(c). We excluded from our analysis sales to affiliated customers for consumption in the home market that we determined not to be arm's–length prices. To test whether these sales were made at arm's–length prices, we compared the prices of sales of comparable merchandise to affiliated and unaffiliated customers, net of all rebates, movement charges, direct selling expenses, and packing. Pursuant to 19 CFR 351.403(c) and in accordance with our practice, when the prices charged to an affiliated party were, on average, between 98 and 102 percent of the prices charged to unaffiliated parties for merchandise comparable to that sold to the affiliated party, we determined that the sales to the affiliated party were at arm's–length prices. See *Antidumping Proceedings: Affiliated Party Sales in the Ordinary Course of Trade*, 67 FR 69186 (November 15, 2002). We included in our calculation of normal value those sales to affiliated parties that were made at arm's–length prices.

**Level of Trade**

To the extent practicable, we determined normal value for sales at the same level of trade as the U.S. sales. When there were no sales at the same level of trade, we compared U.S. sales to home–market sales at a different level of trade. The normal–value level of trade is that of the starting–price sales in the home market. To determine whether home–market sales are at a different level of trade than U.S. sales, we examined stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer.

In the home market, EuroChem reported a single channel of distribution. Within this single channel of distribution, EuroChem reported a single level of trade for all three customer types (*i.e.*, distributors, traders, and end–users). EuroChem states that, within this single level of trade, greater selling functions are performed for end–users relative to distributors or traders. After analyzing the data on the record with respect to these functions, we find that EuroChem made all home–market sales at a single marketing stage (*i.e.*, one level of trade) in the home market.

In the U.S. market, EuroChem had only CEP sales through its affiliated reseller to unaffiliated customers through a single channel of distribution and, thus, a single level of trade. See section 772(b) of the Act. We found that there were significant differences between the selling activities associated with the CEP level of trade and those associated with the home–market level of trade. For example, the CEP level of trade involved little or no sales–strategic and economic planning, distributor/dealer training, procurement/sourcing service, order input/processing, and freight/delivery service. Therefore, we considered the CEP level of trade to be different from the home–market level of trade and at a less advanced stage of distribution than the home–market level of trade. Consequently, we could not match U.S. sales to sales at the same level of trade in the home market nor could we determine a level–of-trade adjustment based on EuroChem's home–market sales of the foreign like product. Because the data available do not provide an appropriate basis to determine a level–of-trade adjustment and the home–market level of trade is at a more advanced stage of distribution than the CEP, we have made a CEP–offset adjustment to normal value in accordance with section 773(a)(7)(B) of the Act. The CEP offset is the sum of indirect selling expenses incurred on the home–market sales up to the amount of indirect selling expenses incurred on the U.S. sales.

**Preliminary Results of the Review**

As a result of this review, we preliminarily determine that a dumping margin of 20.92 percent exists for EuroChem for the period July 1, 2008, through June 30, 2009.

**Disclosure and Public Hearing**

We will disclose the calculations used in our analysis to parties to this review within five days of the date of publication of this notice. See 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. See 19 CFR 351.310(c). If a hearing is requested, the Department will notify interested parties of the hearing schedule.

Interested parties are invited to comment on the preliminary results of this review. Interested parties may submit case briefs within 30 days of the date of publication of this notice. See 19 CFR 351.309(c). Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. See 19 CFR 351.309(d). Parties who submit case briefs or rebuttal briefs in this review are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument with an electronic version included.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised in the case briefs, within 120 days after the date on which the preliminary results are published. See 19 CFR 351.213(h)(1).

**Assessment Rates**

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212, we have calculated an importer/customer–specific assessment rate for these preliminary results of review. We divided total dumping margins for the reviewed sales by the entered value of the single suspended entry for this POR. For detailed explanation of our method for assessing duties, see "2008–2009 Administrative Review of the Antidumping Duty Order on Solid Urea from Russia – Preliminary Results Analysis Memorandum for EuroChem" on file in the CRU of the main Commerce building, room 1117. We will instruct CBP to assess the importer/customer–specific rate on the suspended entry of subject merchandise made by the importer during the POR.

The Department clarified its "automatic assessment" regulation on May 6, 2003. This clarification applies to entries of subject merchandise during the POR produced by EuroChem where EuroChem did not know that its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries EuroChem–produced merchandise at the all–others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

The Department intends to issue assessment instructions directly to CBP 15 days after the date of publication of the final results of this administrative review.

**Cash–Deposit Requirements**

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) the cash–deposit rate for EuroChem will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash–deposit rate will continue to be the company–specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less–than-fair–value investigation but the manufacturer is, the cash–deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash–deposit rate will be 64.93 percent, the all–others rate established in *Urea From the Union of Soviet Socialist Republics; Final Determination of Sales at Less Than Fair Value*, 52 FR 19557 (May 26, 1987). These deposit requirements, when imposed, shall remain in effect until further notice.

**Notification to Importer**

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this 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.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 9, 2010.

**Ronald K. Lorentzen,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2010–8644 Filed 4–14–10; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–908]**

### First Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Notice of Preliminary Results of the Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce ("Department") is conducting the first administrative review of the antidumping duty order on sodium hexametaphosphate ("sodium hex") from the People's Republic of China ("PRC") for the period of review ("POR") September 14, 2007, through February 28, 2009. The Department has preliminarily determined that sales have been made below normal value ("NV") by the respondent. If these preliminary results are adopted in our final results of this review, the Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries of subject merchandise during the POR. Interested parties are invited to comment on these preliminary results.

**EFFECTIVE DATE:** April 15, 2010.

**FOR FURTHER INFORMATION CONTACT:** Paul Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0413.

**SUPPLEMENTARY INFORMATION:**

**Case Timeline**

On April 27, 2009, the Department published in the **Federal Register** a notice of initiation of an administrative review of sodium hex from the PRC, covering the POR, for one company, Hubei Xingfa Chemical Group Co., Ltd. ("Xingfa"). *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for*

*Revocation in Part*, 74 FR 19042 (April 27, 2009) ("Initiation").

On November 25, 2009, the Department published a notice extending the time period for issuing the preliminary results by 60 days to January 30, 2010. *See First Antidumping Duty Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Extension of Time Limit for the Preliminary Results*, 74 FR 61656 (November 25, 2009). On February 5, 2010, the Department published a notice extending the time period for issuing the preliminary results by 41 days to March 12, 2010. *See First Antidumping Duty Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Extension of Time Limit for the Preliminary Results*, 75 FR 5946 (February 5, 2010).

As explained in the memorandum from the Deputy Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from February 5, through February 12, 2010. *See* Memorandum to the Record regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Snowstorm," dated February 12, 2010. Thus, all deadlines in this segment of the proceeding have been extended by seven days, and the revised deadline for the preliminary results of this review became March 19, 2010.

On March 26, 2010, the Department published a notice extending the time period for issuing the preliminary results by 17 days to April 5, 2010. *See First Antidumping Duty Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Extension of Time Limit for the Preliminary Results*, 75 FR 14568 (March 26, 2010).

**Submissions by Interest Parties**

As noted above, on April 27, 2009, this administrative review was initiated on one company, Hubei Xingfa. On May 4, 2009, the Department issued Hubei Xingfa the antidumping duty questionnaire. From May 26, 2009 to October 28, 2009, Hubei Xingfa submitted responses to the Department's antidumping duty questionnaires.

On July 6, 2009, the Department sent interested parties a letter inviting comments on surrogate country selection and surrogate value data. On November 6, 2009, Hubei Xingfa and the Petitioners[1] submitted comments on surrogate country and information to value factors of production ("FOP").

**Verification**

Pursuant to 19 CFR 351.307(b)(iv), from November 19–23, 2009, the Department conducted verification of Hubei Xingfa's questionnaire responses. See Memorandum to the File through Scot T. Fullerton, Program Manager, Office 9, from Paul Walker, Senior Case Analyst, "First Administrative Review of Sodium Hexametaphospahte from the People's Republic of China: Verification of Hubei Xingfa Chemical Group Co., Ltd.," dated concurrently with this notice ("Hubei Xingfa Verification Report").

**Scope of the Order**

The merchandise subject to this review is sodium hexametaphosphate. Sodium hexametaphosphate is a water–soluble polyphosphate glass that consists of a distribution of polyphosphate chain lengths. It is a collection of sodium polyphosphate polymers built on repeating $NaPO_3$ units. SHMP has a $P_2O_5$ content from 60 to 71 percent. Alternate names for sodium hexametaphosphate include the following: Calgon; Calgon S; Glassy Sodium Phosphate; Sodium Polyphosphate, Glassy; Metaphosphoric Acid; Sodium Salt; Sodium Acid Metaphosphate; Graham's Salt; Sodium Hex; Polyphosphoric Acid, Sodium Salt; Glass H; Hexaphos; Sodaphos; Vitrafos; and BAC–N-FOS. Sodium hexametaphosphate is typically sold as a white powder or granule (crushed) and may also be sold in the form of sheets (glass) or as a liquid solution. It is imported under heading 2835.39.5000, HTSUS. It may also be imported as a blend or mixture under heading 3824.90.3900, HTSUS. The American Chemical Society, Chemical Abstract Service ("CAS") has assigned the name "Polyphosphoric Acid, Sodium Salt" to SHMP. The CAS registry number is 68915–31–1. However, sodium hexametaphosphate is commonly identified by CAS No. 10124–56–8 in the market. For purposes of the review, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name.

The product covered by this review includes sodium hexametaphosphate in all grades, whether food grade or technical grade. The product covered by this review includes sodium hexametaphosphate without regard to chain length *i.e.*, whether regular or long chain. The product covered by this review includes sodium hexametaphosphate without regard to physical form, whether glass, sheet, crushed, granule, powder, fines, or other form, and whether or not in solution.

However, the product covered by this review does not include sodium hexametaphosphate when imported in a blend with other materials in which the sodium hexametaphosphate accounts for less than 50 percent by volume of the finished product.

**Non–Market Economy ("NME") Country Status**

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. In accordance with section 771(18)(C)(i) of the Act, any determination made that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See, e.g., Brake Rotors from the People's Republic of China: Final Results and Partial Rescission of the 2004/2005 Administrative Review and Notice of Rescission of 2004/2005 New Shipper Review*, 71 FR 66304 (November 14, 2006). None of the parties to this proceeding have contested such treatment. Accordingly, the Department calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

**Surrogate Country**

When the Department reviews imports from an NME country and the available information does not permit the Department to determine NV, pursuant to section 773(a) of the Act, then, pursuant to section 773(c)(4) of the Act, the Department bases NV on an NME producer's FOPs, to the extent possible, in one or more market–economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. The Department determined India, Philippines, Indonesia, Columbia, Thailand, and Peru are countries comparable to the PRC in terms of economic development. *See* July 6, 2009, Letter to All Interested Parties, regarding "Antidumping Duty Administrative Review of Sodium Hexametaphosphate from the People's Republic of China," attaching July 2, 2009, Memorandum to Scot T. Fullerton, Program Manager, Office 9, AD/CVD Operations, from Kelly Parkhill, Acting Director, Office for Policy, regarding "Request for List of Surrogate Countries for an Administrative Review of the Antidumping Duty Order on Sodium Hexametaphosphate from the People's Republic of China" ("Surrogate Country List").

[1] ICL Performance Products and Innophos, Inc. (collectively, the "Petitioners").

Based on publicly available information placed on the record, the Department determines India to be a reliable source for surrogate values because India is at a comparable level of economic development, pursuant to section 773(c)(4) of the Act, is a significant producer of subject merchandise, and has publicly available and reliable data. Furthermore, all the surrogate values placed on the record by the parties were obtained from sources in India. Accordingly, the Department selected India as the surrogate country for purposes of valuing the FOPs because it meets the Department's criteria for surrogate country selection.

**Separate Rates**

In 2005, the Department notified parties of a new application and certification process by which exporters and producers may obtain separate rate status in an NME review. The process requires exporters and producers to submit a separate rate status certification and/or application. *See Policy Bulletin 05.1: Separate–Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non–Market Economy Countries*, (April 5, 2005) ("*Policy Bulletin*"), available at: *http://ia.ita.doc.gov*. However, the standard eligibility criteria for determining whether a firm is eligible for a separate rate (*i.e.*, a demonstration of an absence of both *de jure* and *de facto* government control over export activities), has not changed.

A designation of a country as an NME remains in effect until it is revoked by the Department. *See* section 771(18)(c)(i) of the Act. In proceedings involving NME countries, it is the Department's practice to begin with a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty rate. *See Policy Bulletin; see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China*, 71 FR 53079, 53082 (September 8, 2006); *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China*, 71 FR 29303, 29307 (May 22, 2006) ("*Diamond Sawblades*"). It is the Department's policy to assign all exporters of merchandise subject to review in an NME country this single rate unless an exporter can affirmatively demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *See, e.g., Diamond Sawblades*, 71 FR at 29307. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. *Id*. The Department analyzes each entity exporting the subject merchandise under a test arising from the *Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588, 20589 (May 6, 1991) ("*Sparklers*"), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585, 22586–87 (May 2, 1994) ("*Silicon Carbide*"). However, if the Department determines that a company is wholly foreign–owned or located in a market economy, then a separate rate analysis is not necessary to determine whether it is independent from government control. *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China*, 72 FR 52355, 52356 (September 13, 2007).

*a. Absence of De Jure Control*

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) an absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers*, 56 FR at 20589. The evidence provided by Hubei Xingfa supports a preliminary finding of *de jure* absence of government control based on the following: (1) an absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) there are applicable legislative enactments decentralizing control of the companies; and (3) there are formal measures by the government decentralizing control of companies. *See* Hubei Xingfa's May 26, 2009 submission at 2–11; *see also* Hubei Xingfa's August 21, 2009 submission at 6–16.

*b. Absence of De Facto Control*

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide*, 59 FR at 22587; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from the People's Republic of China*, 60 FR 22544, 22545 (May 8, 1995). The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The evidence provided by Hubei Xingfa supports a preliminary finding of *de facto* absence of government control based on the following: (1) the companies set their own export prices independent of the government and without the approval of a government authority; (2) the companies have authority to negotiate and sign contracts and other agreements; (3) the companies have autonomy from the government in making decisions regarding the selection of management; and (4) there is no restriction on any of the company's use of export revenue. *See* Hubei Xingfa's May 26, 2009 submission at 2–11; see also Hubei Xingfa's August 21, 2009 submission at 6–16. Therefore, the Department preliminarily finds that Hubei Xingfa has established that it qualifies for a separate rate under the criteria established by *Silicon Carbide* and *Sparklers*.

**Date of Sale**

The date of sale is generally the date on which the parties agree upon all substantive terms of the sale. This normally includes the price, quantity, delivery terms and payment terms. *See Carbon and Alloy Steel Wire Rod from Trinidad and Tobago: Final Results of Antidumping Duty Administrative Review*, 72 FR 62824 (November 7, 2007) and accompanying Issues and Decision Memorandum at Comment 1; *see also Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold–Rolled Flat–Rolled Carbon Quality Steel Products from Turkey*, 65 FR 15123 (March 21, 2000) and accompanying Issues and Decision Memorandum at Comment 2.

Section 351.401(i) of the Department's regulations state that, "{i}n identifying the date of sale of the merchandise

under consideration or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business." The Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale. See 19 CFR 351.401(i); *see also Allied Tube*, 132 F. Supp. 2d at 1090–1092. However, as noted by the Court of International Trade ("CIT") in *Allied Tube*, a party seeking to establish a date of sale other than invoice date bears the burden of establishing that " 'a different date better reflects the date on which the exporter or producer establishes the material terms of sale.' " *See Allied Tube & Conduit Corp. v. United States*, 132 F. Supp. 2d at 1087, 1090 (CIT 2001) (quoting 19 CFR 351.401(i)) ("*Allied Tube*").

Hubei Xingfa reported that the date of sale was determined by the invoice issued by the affiliated importer to the unaffiliated United States customer. In this case, as the Department found no evidence contrary to Hubei Xingfa's claims that invoice date was the appropriate date of sale, the Department used invoice date as the date of sale for these preliminary results. *See, e.g.*, Hubei Xingfa's August 21, 2009 submission at 4.

**Fair Value Comparisons**

To determine whether sales of sodium hex to the United States by Hubei Xingfa were made at less than fair value, the Department compared the export price ("EP") to NV, as described in the "U.S. Price," and "Normal Value" sections below.

**U.S. Price**

In accordance with section 772(a) of the Act, we calculated the EP for sales to the United States for Hubei Xingfa. We calculated EP based on the price to unaffiliated purchasers in the United States. In accordance with section 772(c) of the Act, as appropriate, we deducted from the starting price to unaffiliated purchasers foreign inland freight, foreign brokerage and handling, customs duties, domestic brokerage and handling and other movement expenses incurred. For the services provided by an NME vendor or paid for using an NME currency we based the deduction of these movement charges on surrogate values. *See* Surrogate Values Memo for details regarding the surrogate values for movement expenses.

**Normal Value**

Section 773(c)(1) of the Act provides that the Department shall determine the NV using a FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home–market prices, third–country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of government controls on various aspects of non–market economies renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

In its questionnaire responses, Hubei Xingfa claimed to self–produce a portion of the electricity used to produce sodium hex, stating that it owned several hydroelectric power stations which provided a portion of the electricity used to produce sodium hex. In addition, in response to the Department's request for all valid business licenses held by Hubei Xingfa during the POR, Hubei Xingfa did not provide separate licenses for the hydroelectric power stations. *See* Hubei Xingfa's August 21, 2009 submission at 14–15 and Exhibit 13. In addition, because, Hubei Xingfa claimed to self–produce its own electricity, it reported the labor consumed at its hydroelectric power stations *in lieu* of reporting the electricity, or intermediate input, these stations generated. However, at verification the Department discovered that that each of Hubei Xingfa's hydroelectric power stations has its own business license, and thus are separate legal entities that operate apart from Hubei Xingfa. *See* Hubei Xingfa Verification Report at 2.

We do not find that the record evidence sufficiently supports the claim that Hubei Xingfa produced its own electricity because its electricity suppliers operate as distinct legal entities. Pursuant to 19 CFR 351.401(f), the Department will collapse producers and treat them as a single entity where (1) those producers are affiliated, (2) the producers have production facilities for producing similar or identical products that would not require substantial retooling of either facility in order to restructure manufacturing priorities, and (3) there is a significant potential for manipulation of price or production. In *Fish Fillets*, for example, the Department did not collapse a respondent with an affiliated input producer when the affiliate did not have the ability to produce or export similar or identical products, and could not produce such products without substantial retooling. *See Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Resultsof Antidumping Duty Administrative Review and Partial Rescission*, 73 FR 15479 (March 24, 2008) ("*Fish Fillets*") and accompanying Issues and Decision Memorandum at Comment 5C. As a consequence, when valuing the intermediate input to the subject merchandise in its calculation of the NV in *Fish Fillets*, the Department employed a surrogate value, rather than the FOPs used to produce the intermediate input. *Id.* Similarly, because Hubei Xingfa's electricity suppliers represent distinct legal entities that are not involved in the production of the subject merchandise at issue, for these preliminary results, we are applying a surrogate value to the amount of electricity self–produced by Hubei Xingfa. *See* the Hubei Xingfa Verification Report at Exhibits 14 and 16. In addition, because Hubei Xingfa reported labor as the FOP input into self–produced electricity, we have deducted the labor usage rate for self–produced electricity from Hubei Xingfa's overall reported labor. Because these calculations are proprietary, *see* Memorandum to the File, through Scot T. Fullerton, Program Manager, Office 9, from Paul Walker, Senior Analyst, "First Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Hubei Xingfa Chemical Group Co., Ltd.," dated concurrently with this notice ("Hubei Xingfa Analysis Memo"), for further details.

**Factor Valuations**

In accordance with section 773(c) of the Act, we calculated NV based on FOP data reported by Hubei Xingfa. To calculate NV, we multiplied the reported per–unit factor–consumption rates by publicly available surrogate values. In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. *See, e.g., Fresh Garlic from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review*, 67 FR 72139 (December 4, 2002) and accompanying Issues and Decision Memorandum at Comment 6; *see also Final Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms from the People's Republic of China*, 66 FR 31204 (June 11, 2001) and accompanying Issues and Decision Memorandum at Comment 5. As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to Indian import surrogate values a surrogate freight cost using the shorter

of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate. This adjustment is in accordance with the Court of Appeals for the Federal Circuit's decision in *Sigma Corp. v. United States*, 117 F.3d 1401, 1407–08 (Fed. Cir. 1997). For a detailed description of all surrogate values used for Hubei Xingfa, see Memorandum to the File through Scot Fullerton, Program Manager, Office 9, from Paul Walker, Senior Case Analyst, "First Administrative Review of Sodium Hexametaphosphate from the People's Republic of China: Surrogate Factor Valuations for the Preliminary Results," dated concurrently with this notice ("Surrogate Values Memo").

For these preliminary results, in accordance with the Department's practice, we used data from Indian Import Statistics and other publicly available Indian sources in order to calculate surrogate values for Hubei Xingfa's raw materials, packing, by–products, and energy. In selecting the best available information for valuing FOPs, in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, surrogate values which are non–export average values, most contemporaneous with the POR, product–specific, and tax–exclusive. *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam*, 69 FR 42672, 42682 (July 16, 2004), unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from the Socialist Republic of Vietnam*, 69 FR 71005 (December 8, 2004). The record shows that data in the Indian Import Statistics, as well as those from the other Indian sources, are contemporaneous with the POR, product–specific, and tax–exclusive. *See* Surrogate Values Memo. In those instances where we could not obtain publicly available information contemporaneous to the POR with which to value factors, we adjusted the surrogate values using, where appropriate, the Indian Wholesale Price Index ("WPI") as published in the *International Financial Statistics* of the International Monetary Fund. *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China*, 71 FR 77373, 77380 (December 26, 2006)("PSF").

Furthermore, with regard to the Indian import–based surrogate values, we have disregarded import prices that we have reason to believe or suspect may be subsidized. *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Preliminary Results and Preliminary Partial Rescission of Antidumping Duty Administrative Review*, 70 FR 54007, 54011 (September 13, 2005), results unchanged in *Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of the First Administrative Review*, 71 FR 14170 (March 21, 2006); and *China Nat'l Machinery Import & Export Corp. v. United States*, 293 F. Supp. 2d 1334, 1336 (Ct. Int'l. Trade 2003), *aff'd* 104 Fed. Appx. 183 (Fed. Cir. 2004). In determining whether to disregard inputs the Department believes may be subsidized, the Department, guided by the legislative history, does not conduct a formal investigation to ensure that such prices are not subsidized. *See* Omnibus Trade and Competitiveness Act of 1988, Conference Report to accompany H.R. Rep. 100–576 at 590 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1547, 1623–24. Rather, the Department bases its decision on information that is available to it at the time it makes its determination. *See Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value*, 73 FR 24552, 24559 (May 5, 2008), unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Final Determination of Sales at Less Than Fair Value*, 73 FR 55039 (September 24, 2008) ("*PET Film*").

In this instance, we have reason to believe or suspect that prices of inputs from Indonesia, South Korea, and Thailand may have been subsidized because we found in other proceedings that these countries maintain broadly available, non–industry-specific export subsidies. *See, e.g., Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 74 FR 60238 (November 20, 2009). It is thus reasonable to infer that all exports to all markets from these countries may be subsidized. Therefore, we have not used prices from these countries in calculating the Indian import–based surrogate values. Additionally, we disregarded prices from NME countries. Finally, imports that were labeled as originating from an "unspecified" country were excluded from the average value, because the Department could not be certain that they were not from either an NME country or a country with general export subsidies. *See, e.g., PET Film*.

For direct, indirect, and packing labor, consistent with 19 CFR 351.408(c)(3), we used the PRC regression–based wage rate as reported on Import Administration's home page, Import Library, Expected Wages of Selected NME Countries, revised in October 2009. *See 2009 Calculation of Expected Non–Market Economy Wages*, 74 FR 65092 (December 9, 2009), and *http://ia.ita.doc.gov/wages/index.html*. The source of these wage–rate data on the Import Administration's web site is the *Yearbook of Labour Statistics 2005*, ILO (Geneva: 2007), Chapter 5B: Wages in Manufacturing. Because this regression–based wage rate does not separate the labor rates into different skill levels or types of labor, we have applied the same wage rate to all skill levels and types of labor reported by Hubei Xingfa.

We valued electricity using price data for small, medium, and large industries, as published by the Central Electricity Authority of the Government of India in its publication titled *Electricity Tariff & Duty and Average Rates of Electricity Supply in India*, dated March 2008. These electricity rates represent actual country–wide, publicly available information on tax–exclusive electricity rates charged to industries in India. As the rates listed in this source became effective on a variety of different dates, we are not adjusting the average value for inflation.

We valued truck freight expenses using a per–unit average rate calculated from data on the Infobanc Web site: *http://www.infobanc.com/logistics/logtruck.htm*. The logistics section of this Web site contains inland freight truck rates between many large Indian cities. Since this value is contemporaneous with the POR, we did not adjust it for inflation.

We continued our recent practice to value brokerage and handling using a simple average of the brokerage and handling costs that were reported in public submissions that were filed in three antidumping duty cases. Specifically, we averaged the public brokerage and handling expenses reported by Navneet Publications (India) Ltd. in the 2007–2008 administrative review of certain lined paper products from India, Essar Steel Limited in the 2006–2007 antidumping duty administrative review of hot–rolled carbon steel flat products from India, and Himalaya International Ltd. in the 2005–2006 administrative review of

certain preserved mushrooms from India. *See* Surrogate Values Memo. Since the Essar and Navneet brokerage and handling expense are contemporaneous with the POR, we did not adjust them for inflation. However, because the Himalaya brokerage and handling expense is not contemporaneous with the POR, we inflated it using the WPI.

To value factory overhead, selling, general, and administrative ("SG&A") expenses, and profit, the Department used the audited financial statement of Tata Chemicals, as it is the only financial statement on the record of this review.

We made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

We are preliminarily granting a by–product offset to Hubei Xingfa for ferro–phosphorous and slag because Hubei Xingfa provided evidence that these by by–products were produced and sold during the POR.

**Preliminary Results of Review**

The Department preliminarily determines that the following weighted–average dumping margins exist:

| Manufacturer/Exporter | Weighted Average Margin (Percent) |
|---|---|
| Hubei Xingfa ..... | 118.79 |

**Disclosure and Public Hearing**

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. See 19 CFR 351.224(b).

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent–from-the–record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1). *See Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part*, 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum at Comment 2.

Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication of these preliminary results of review. See 19 CFR 351.309(c)(ii). Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than five days after the deadline for filing case briefs. *See* 19 CFR 351.309(d). The Department urges interested parties to provide an executive summary of each argument contained within the case briefs and rebuttal briefs.

The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

**Assessment Rates**

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review excluding any reported sales that entered during the gap period. In accordance with 19 CFR 351.212(b)(1), we calculated exporter/importer (or customer)-specific assessment rates for the merchandise subject to this review. Because we do not have entered values for all U.S. sales, we calculated an *ad valorem* assessment rate by aggregating the antidumping duties due for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer). *See* 19 CFR 351.212(b)(1). To determine whether the duty assessment rates are *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer (or customer)-specific *ad valorem* ratios based on the estimated entered value. Where an importer (or customer)-specific *ad valorem* rate is zero or *de minimis*, we will instruct CBP to liquidate appropriate entries without regard to antidumping duties. *See* 19 CFR 351.106(c)(2).

**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 exporter listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis*, *i.e.*, less than 0.5 percent, no cash deposit will be required for that company); (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC–wide rate of 188.05 percent; and (3) 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 exporters that supplied that non–PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

**Notification to Importers**

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) 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.

These results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

April 5, 2010.

**Ronald K. Lorentzen,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2010–8643 Filed 4–14–10; 8:45 am]

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## COMMODITY FUTURES TRADING COMMISSION

### Request for Comment on a Proposal To Exempt, Pursuant to the Authority in Section 4(c) of the Commodity Exchange Act, the Trading and Clearing of Certain Products Related to ETFS Physical Swiss Gold Shares and ETFS Physical Silver Shares

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice of Proposed Order and Request for comment.

**SUMMARY:** The Commodity Futures Trading Commission ("CFTC" or the "Commission") is proposing to exempt the trading and clearing of certain contracts called "options" and other contracts called "security futures" on each of ETFS Physical Swiss Gold Shares ("Gold Products") and ETFS Physical Silver Shares ("Silver Products") (collectively, "Gold and Silver Products"), which would be traded on national securities exchanges (as to options) and designated contract markets registered with the Securities and Exchange Commission ("SEC") as limited purpose national securities exchanges (as to security futures), and in either case cleared through the Options Clearing Corporation ("OCC") in its capacity as a registered securities clearing agency, from the provisions of the Commodity Exchange Act ("CEA") [1] and the regulations thereunder, to the extent necessary to permit them to be so traded and cleared. Authority for this exemption is found in Section 4(c) of the CEA.[2] The Commission also is requesting comment on whether it should amend all orders issued exempting the trading and clearing of options and futures on gold and silver products from CEA provisions and Commission regulations thereunder, to impose market and large trader reporting requirements under Commission regulations to the trading and clearing of the options in order to assist the Commission in monitoring and addressing, among other things, the effect on designated contract markets of trading in such products.[3]

**DATES:** Comments must be received on or before May 17, 2010.

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail:* ETFSShares@cftc.gov. Include "Options and Security Futures on ETFS Gold and Silver Products" in the subject line of the message.
- *Fax:* 202–418–5521.
- *Mail:* Send to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *Courier:* Same as mail above.

All comments received will be posted without change to *http://www.CFTC.gov/.* All comments must be in English or, if not, accompanied by an English translation.

**FOR FURTHER INFORMATION CONTACT:** Robert B. Wasserman, Associate Director, 202–418–5092, *rwasserman@cftc.gov,* or Lois J. Gregory, Special Counsel, 202–418–5569, *lgregory@cftc.gov,* Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

The OCC is both a Derivatives Clearing Organization ("DCO") registered pursuant to Section 5b of the CEA,[4] and a securities clearing agency registered pursuant to Section 17A of the Securities Exchange Act of 1934 ("the '34 Act").[5]

OCC has filed with the CFTC, pursuant to Section 5c(c) of the CEA and Commission Regulations 39.4(a) and 40.5 thereunder,[6] a request for approval of rules and rule amendments that would enable OCC (1) to clear and settle contracts called "options" ("Options") on Gold and Silver Products traded on national securities exchanges, in its capacity as a registered securities clearing agency (and not in its capacity as a DCO) and (2) to clear and settle contracts called "security futures" ("Security Futures") on Gold and Silver Products traded on designated contract markets [7] registered with the SEC as limited purpose national securities exchanges pursuant to Section 6(g) of the '34 Act [8] ("DCMs") as security futures subject to the CEA and CFTC regulations thereunder governing security futures, in OCC's capacity as a registered securities clearing agency (and not in its capacity as a DCO).[9] Section 5c(c)(3) provides that the CFTC must approve such rules and rule amendments submitted for approval unless it finds that the rules or rule amendments would violate the CEA.

In each case, the shares of the ETFS Gold Trust and the ETFS Silver Trust are designed to reflect the performance of the price of gold and silver bullion, respectively, less the expenses of Trust operations. The shares of each Trust represent beneficial interest in the Trust which in turn holds physical allocated gold bullion (ETFS Gold Trust) and silver bullion (ETFS Silver Trust). The gold and silver bullion is held in vault by or on behalf of the Trust's custodian. Each physical bar is properly segregated and allocated to the property of the Trust. All physical gold and silver conforms to the London Bullion Market Association's rules for good delivery. ETFS Gold Trust Shares and ETFS Silver Trust Shares are listed and traded on NYSEArca.

## II. Section 4(c) of the Commodity Exchange Act

Section 4(c)(1) of the CEA empowers the CFTC to "promote responsible economic or financial innovation and fair competition" by exempting any transaction or class of transactions from any of the provisions of the CEA (subject to exceptions not relevant here) where the Commission determines that the exemption would be consistent with the public interest.[10] The Commission

[1] 7 U.S.C. 1 *et seq.*

[2] 7 U.S.C. 6(c).

[3] The Commission has provided exemptions for gold and silver products on two prior occasions. *See* Order Exempting the Trading and Clearing of Certain Products Related to SPDR® Gold Trust Shares, 73 FR 31981 (June 5, 2008), Order Exempting the Trading and Clearing of SPDR Gold Futures Contracts, 73 FR 31979 (June 5, 2008), and Order Exempting the Trading and Clearing of Certain Products Related to iShares® COMEX Gold Trust Shares and iShares® Silver Trust Shares, 73 FR 79830 (December 30, 2008) (collectively, the "Previous Orders.").

[4] 7 U.S.C. 7a–1.

[5] 15 U.S.C. 78q–l.

[6] 7 U.S.C. 7a–2(c), 17 CFR 39.4(a), 40.5.

[7] *See* Section 5 of the CEA, 7 U.S.C. 7.

[8] 15 U.S.C. 78f(g).

[9] *See* Securities Exchange Act Release No. 61591 (February 25, 2010), 75 FR 9981 (March 4, 2010)(File No. SR–OCC–2009–20 filed with both the Commission and the Securities and Exchange Commission ("SEC")). *See also* Securities Exchange Act Release No. 61483 (February 3, 2010), 75 FR 6753 (February 10, 2010)(SEC approval of securities exchanges' listing and trading options on ETFS Gold Trust and ETFS Silver Trust).

[10] Section 4(c)(1) of the CEA, 7 U.S.C. 6(c)(1), provides in full that:

In order to promote responsible economic or financial innovation and fair competition, the Commission by rule, regulation, or order, after notice and opportunity for hearing, may (on its own initiative or on application of any person, including any board of trade designated or registered as a contract market or derivatives transaction execution facility for transactions for future delivery in any commodity under section 7 of this title) exempt any agreement, contract, or transaction (or class thereof) that is otherwise subject to subsection (a) of this section (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the agreement, contract, or transaction), either unconditionally or on stated terms or conditions or for stated periods and either retroactively or prospectively, or both, from any of the requirements

Continued

may grant such an exemption by rule, regulation or order, after notice and opportunity for hearing, and may do so on application of any person or on its own initiative.

In enacting Section 4(c), Congress noted that the goal of the provision "is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner." [11] Permitting Options and Security Futures on Gold and Silver Products to trade on national securities exchanges (as to Options) and DCMs (as to Security Futures) and in either case to be cleared by OCC in its capacity as a securities clearing agency, as discussed above, may foster both financial innovation and competition. In accordance with the Memorandum of Understanding entered into between the CFTC and the SEC on March 11, 2008, and in particular the addendum thereto concerning *Principles Governing the Review of Novel Derivative Products,* the Commission has permitted novel derivative products that implicate areas of potential overlapping regulatory concern to be permitted to trade in either or both a CFTC- or SEC-regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority). The CFTC is requesting comment on whether it should exempt Options and Security Futures on Gold and Silver Products, as described above, that are traded on a national securities exchange or a DCM, respectively, and cleared through OCC in its capacity as a registered securities clearing agency, from the CEA and the Commission's regulations thereunder, to the extent necessary to permit them to be so traded and cleared. The CFTC previously granted exemptions for similar Options and Security Futures on June 5 and December 30, 2008.[12]

In proposing this exemption, the CFTC need not—and does not—find that Options on the Gold and Silver Products are (or are not) options subject to the CEA, or find that Security Futures on the Gold and Silver Products are (or are not) security futures as defined in Section 1a(31) of the CEA.[13] During the legislative process leading to the enactment of Section 4(c) of the CEA, the House-Senate Conference Committee noted that:

> The Conferees do not intend that the exercise of exemptive authority by the Commission would require any determination beforehand that the agreement, instrument, or transaction for which an exemption is sought is subject to the Act. Rather, this provision provides flexibility for the Commission to provide legal certainty to novel instruments where the determination as to jurisdiction is not straightforward. Rather than making a finding as to whether a product is or is not a futures contract, the Commission in appropriate cases may proceed directly to issuing an exemption.[14]

The Options and Security Futures on Gold and Silver Products described above raise questions involving their nature and the appropriate resulting jurisdiction over them. Given their potential usefulness to the market, however, the Commission believes that this may be an appropriate case for issuing an exemption without making a finding as to the nature of these particular instruments.

*Section 4(c)(2) provides that the Commission may grant exemptions only when it determines:* That the requirements for which an exemption is being provided should not be applied to the agreements, contracts or transactions at issue, and the exemption is consistent with the public interest and the purposes of the CEA; that the agreements, contracts or transactions will be entered into solely between appropriate persons; and that the exemption will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory responsibilities under the CEA.[15]

The purposes of the CEA include "promot[ing] responsible innovation and fair competition among boards of trade, other markets and market participants."[16] It may be consistent with these and the other purposes of the CEA, with the public interest, with the CFTC–SEC Memorandum of Understanding of March 11, 2008, and with the addendum thereto, for the mode of trading and clearing the Options and Security Futures on Gold and Silver Products—whether the mode applicable to options on securities or commodities, or to security futures or futures—to be determined by competitive market forces. Accordingly, the Commission proposes to use its authority under Section 4(c) of the Act to exempt the trading of Options on Gold and Silver Products on national securities exchanges and clearing thereof by OCC in its capacity as a registered securities clearing agency from the CEA and the Commission's regulations thereunder to the extent necessary to permit them to be so traded and cleared. In addition, the Commission proposes to use its authority under Section 4(c) of the Act to exempt the trading and clearing of Security Futures on Gold and Silver Products from those provisions of the Act and the Commission's regulations thereunder that, if the underlying were considered to be a commodity that is not a security, would be inconsistent with the trading and clearing of Security Futures on Gold and Silver Products as security futures. The proposed exemption would require that transactions in such contracts comply with the requirements established for transactions in security futures by the CEA and the Commission's regulations thereunder. The CFTC is requesting comment as to whether these exemptions from the requirements of the CEA and regulations thereunder should be granted in the context of these transactions.

Section 4(c)(3) includes within the term "appropriate persons" a number of specified categories of persons, and also in subparagraph (K) thereof "such other persons that the Commission determines to be appropriate in light of * * * the applicability of appropriate regulatory protections." National securities exchanges and OCC, as well as their members who will intermediate Options on Gold and Silver Products, are subject to extensive and detailed regulation by the SEC under the '34 Act. Similarly, DCMs and OCC, as well as their members who will intermediate

of subsection (a) of this section, or from any other provision of this chapter (except subparagraphs (c)(ii) and (D) of section 2(a)(1) of this title, except that the Commission and the Securities and Exchange Commission may by rule, regulation, or order jointly exclude any agreement, contract, or transaction from section 2(a)(1)(D) of this title), if the Commission determines that the exemption would be consistent with the public interest.

[11] House Conf. Report No. 102–978, 1992 U.S.C.C.A.N. 3179, 3213 ("4(c) Conf. Report").

[12] *See* footnote 3, above.

[13] 7 U.S.C. 1a(31).

[14] 4(c) Conf. Report at 3214–3215.

[15] Section 4(c)(2) of the CEA, 7 U.S.C. 6(c)(2), provides in full that:

The Commission shall not grant any exemption under paragraph (1) from any of the requirements of subsection (a) of this section unless the Commission determines that—

(A) The requirement should not be applied to the agreement, contract, or transaction for which the exemption is sought and that the exemption would be consistent with the public interest and the purposes of this Act; and

(B) The agreement, contract, or transaction—

(i) Will be entered into solely between appropriate persons; and

(ii) Will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory duties under this Act.

[16] CEA 3(b), 7 U.S.C. 5(b). *See also* CEA 4(c)(1), 7 U.S.C. 6(c)(1) (purpose of exemptions is "to promote responsible economic or financial innovation and fair competition.").

Security Futures on Gold and Silver Products, are subject to regulation by the SEC and CFTC. The CFTC is requesting comment as to whether all persons trading Options and Security Futures on Gold and Silver Products on national securities exchanges and DCMs, respectively, and clearing such products on OCC, are appropriate persons.

The Commission held a public meeting on March 25, 2010 to examine the trading of futures and options in the precious and base metals market and analyze how the Commission regulates futures and options markets on commodities of finite supply. The Commission is considering the views expressed at that meeting. For the time being, the Commission continues to decline to determine whether certain products underlain by physical commodities, such as the subject Gold and Silver Products, are subject to the Commission's jurisdiction as commodity options and futures contracts. However, the Commission may make such jurisdictional determinations in the future, and such determinations may inform the Commission's approach to consideration of exemptive orders, and of assessing the rules of registered entities.

## III. Large Trader Reporting; Market and Financial Surveillance

The Commission is considering the question of whether exemptions such as the one discussed herein, as well as those issued previously on substantially similar options and futures on gold and silver products, may interfere with the Commission's ability to discharge its regulatory responsibilities under the CEA or with the self-regulatory duties of contract markets. Options and Security Futures on gold and silver products can be used by those trading them for the same economic purposes served by entering into commodity options and security futures on gold and silver. As a result of highly interconnected physical and derivatives gold and silver markets, the trading of Gold and Silver Products that are options on national securities exchanges, if traded in sufficient volumes, can significantly affect the price discovery function of related commodity futures and option contracts. In addition, the pools of physical gold and silver aggregated by these funds can materially affect supplies that are deliverable under the terms and conditions of related commodity futures and options contracts. In order to preserve the integrity of the price discovery and risk management functions of Commission regulated markets, it may be that national securities exchanges that list the options should comply with market reporting requirements and brokers and traders that carry accounts or trade in options on gold and silver products should comply with large trader reporting requirements.[17] Positions on security futures contracts on gold and silver products are currently required to be reported to the Commission by DCMs and intermediaries.[18] However, there is no such reporting requirement with respect to options on gold and silver products that are exempted from being treated as commodity options. Thus, the Commission seeks comment as to whether such reporting should be required. Such information might enhance the Commission's ability to collect and analyze market data concerning trading in the markets for gold and silver, and its ability effectively to monitor the trading activity and financial risk exposure of market participants and thus the risk exposure of any DCO, such as OCC, clearing as central counterparty (although in its capacity as a registered securities clearing agency). If the Commission determines to impose such requirements as to the gold and silver products that are the subject of the current proposed order, or those that were the subjects of the Previous Orders, a separate notice and request for comments will be issued setting forth proposed specifics of such requirements.

## IV. Request for Comment

The Commission requests comment on all aspects of the issues presented by this proposed order.

## V. Related Matters

### *A. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 ("PRA")[19] imposes certain requirements on Federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The proposed exemptive order would not, if approved, require a new collection of information from any entities that would be subject to the proposed order.

### *B. Cost-Benefit Analysis*

Section 15(a) of the CEA,[20] as amended by Section 119 of the Commodity Futures Modernization Act of 2000, requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. By its terms, Section 15(a) as amended does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, Section 15(a) simply requires the Commission to "consider the costs and benefits" of its action.

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

The Commission is considering the costs and benefits of this proposed order in light of the specific provisions of Section 15(a) of the CEA, as follows:[21]

1. *Protection of market participants and the public.* National securities exchanges, OCC, and their members who would intermediate the above-described Options and Security Futures on Gold and Silver Products are subject to extensive regulatory oversight.

2. *Efficiency, competition, and financial integrity.* The proposed exemption may enhance market efficiency and competition since it could encourage potential trading of Options and Security Futures on Gold and Silver Products through modes other than those normally applicable; that is, designated contract markets or derivatives transaction execution facilities. Financial integrity will not be affected since the Options and Security Futures on Gold and Silver Products

[17] *See* Parts 15 through 21 of the Commission's regulations.

[18] Under Commission Regulation Section 15.03(b), 17 CFR § 15.03(b), the number of contracts that constitute a reportable level for security futures products on an individual equity security is 1,000. In the instant case, when measured in terms of ounces, reporting levels for Security Futures on Gold and Silver Products would be significantly less than that for futures contracts on gold and silver currently trading on Comex. Thus, visibility with respect to the Security Futures may be greater than it would under large trader reporting requirements.

[19] 44 U.S.C. 3507(d).

[20] 7 U.S.C. 19(a).

[21] *See also* Previous Orders, 73 FR at 31982 (June 5, 2008), 73 FR at 3 FR at 31980 (June 5, 2008), and 73 FR at 79832 (December 30, 2008).

will be cleared by OCC, a DCO and SEC-registered clearing agency, intermediated by SEC-registered broker-dealers.

3. *Price discovery.* Price discovery may be enhanced through market competition.

4. *Sound risk management practices.* The Options and Security Futures on Gold and Silver Products will be subject to OCC's current risk-management practices including its margining system.

5. *Other public interest considerations.* The proposed exemption may encourage development of derivative products through market competition without unnecessary regulatory burden.

After considering these factors, the Commission has determined to seek comment on the proposed order as discussed above. The Commission invites public comment on its application of the cost-benefit provision.

Issued in Washington, DC, on April 9, 2010 by the Commission.

**David A. Stawick,**

*Secretary of the Commission.*

[FR Doc. 2010–8630 Filed 4–14–10; 8:45 am]

BILLING CODE P

## CONSUMER PRODUCT SAFETY COMMISSION

### Sunshine Act Meetings

**TIME AND DATE:** Wednesday, April 21, 2010, 9 a.m.–11 a.m.

**PLACE:** Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

**STATUS:** Commission Meeting—Open to the Public.

**MATTERS TO BE CONSIDERED:** Pending Decisional Matters: Testing and Labeling to Product Certification—Notice of Proposed Rulemaking (NPR) and Testing Component Parts—Notice of Proposed Rulemaking (NPR).

A live webcast of the Meeting can be viewed at *http://www.cpsc.gov/webcast/index.html.*

For a recorded message containing the latest agenda information, call (301) 504–7948.

**CONTACT PERSON FOR MORE INFORMATION:** Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: April 13, 2010.

**Todd A. Stevenson,**

*Secretary.*

[FR Doc. 2010–8805 Filed 4–13–10; 4:15 pm]

BILLING CODE 6355–01–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID DOD–2010–OS–0048]**

### Privacy Act of 1974; System of Records

**AGENCY:** Defense Security Cooperation Agency, DoD.

**ACTION:** Notice to alter a system of records.

**SUMMARY:** The Office of the Secretary of Defense proposes to alter a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**DATES:** This proposed action would be effective without further notice on May 17, 2010 unless comments are received which result in a contrary determination.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

*Instructions:* All submissions received must include the agency name and docket number 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.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cindy Allard at (703) 588–6830.

**SUPPLEMENTARY INFORMATION:** The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington DC 20301–1155.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on March 31, 2010, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals" dated February 8, 1996 (February 20, 1996; 61 FR 6427).

Dated: April 12, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**DSCA 01**

**SYSTEM NAME:**

International Affairs Personnel Initiatives Database. (November 23, 2005; 70 FR 70789).

**CHANGES:**

* * * * *

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Delete entry and replace with "Civilians and military personnel employed with the Department of Defense who wish to become certified by the DoD International Affairs Certification Program, a voluntary program sponsored by the Defense Security Cooperation Agency and Departments of the Army, Navy and Air Force."

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Delete entry and replace with "Full name; e-mail address; work mailing address, telephone and fax numbers.

Employment and education information that includes if individual is civilian or military; major command and mailing address, name of organization, office symbol/code, job title, job function, grade/rank, job series, military specialty, start date, total months in International Affairs related work, billet information, current certification level, highest education completed, and field of study. Supervisor Information that consists of first and last name, e-mail address, organization, office symbol, work phone and fax number."

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Delete entry and replace with "10 U.S.C. 134, Under Secretary of Defense for Policy and DoD Directive 5105.65, Defense Security Cooperation Agency."

**PURPOSE(S):**

Delete entry and replace with "International Affairs Personnel Initiatives Database (IAPID) is a single central facility with the Department of Defense (DoD) that maintains and

verifies information provided by individuals seeking international affairs certification based on their current experience and training.

* * * * *

**SAFEGUARDS:**

Delete entry and replace with "Records are maintained in controlled areas accessible only to authorized personnel. Government computers requiring a Common Access Card to access personal information is further restricted by the use of passwords that are changed periodically. Physical entry is restricted by the locks, security personnel and administrative procedures."

**RETENTION AND DISPOSAL:**

Delete entry and replace with "Disposition is pending until the National Archives and Records Administration approves the retention and disposal schedule, records will be treated as permanent."

**SYSTEM MANAGER(S) AND ADDRESS:**

Delete entry and replace with "U.S. Army Personnel: Deputy Assistant Secretary of the Army for Defense Exports (DASA DE&C), 1777 North Kent Street, Rosslyn, VA 22209–2185.

U.S. Navy/U.S. Marine Corps Personnel: Navy International Programs Office, 2521 S. Clark Street, Suite 800, Arlington, VA 22202–3928.

U.S. Air Force Personnel: Security Assistance Policy and International Training and Education Division (SAF/IAPX), 1550 Wilson Blvd., Suite 900, Arlington VA 22209–1080.

Other Defense Personnel: Defense Institute of Security Assistance Management (DISAM), Project Manager, Building 52, 2475 K Street, Wright-Patterson AFB, Ohio 45433–7641."

**NOTIFICATION PROCEDURE:**

Delete entry and replace with "Individuals seeking to determine whether information about themselves is contained in this system should address written request to the appropriate system manager listed above.

Written requests should include the full name, organization, job series and title and be signed."

**RECORD ACCESS PROCEDURES:**

Delete entry and replace with "Individuals seeking access to records about themselves contained in this system should address written request to the appropriate system manager listed above.

Written requests should include the full name, organization, job series and title and be signed."

**CONTESTING RECORD PROCEDURES:**

Delete entry and replace with "The Office of the Secretary of Defense rules for accessing records for contesting contents and appealing initial agency determinations are published in Office of the Secretary of Defense Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager."

* * * * *

## DSCA 01

**SYSTEM NAME:**

International Affairs Personnel Initiatives Database.

**SYSTEM LOCATION:**

Defense Institute of Security Assistance Management, Research Directorate, 2475 K Street, Wright-Patterson AFB, OH 45433–7641.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Civilians and military personnel employed with the Department of Defense who wish to become certified by the DoD International Affairs Certification Program, a voluntary program sponsored by the Defense Security Cooperation Agency and Departments of the Army, Navy and Air Force.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Full name; e-mail address; work mailing address, telephone and fax numbers.

Employment and education information that includes if individual is civilian or military; major command and mailing address, name of organization, office symbol/code, job title, job function, grade/rank, job series, military specialty, start date, total months in International Affairs related work; billet information, current certification level, highest education completed, and field of study. Supervisor Information that consists of first and last name, e-mail address, organization, office symbol, work phone and fax number.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

10 U.S.C. 134, Under Secretary of Defense for Policy and DoD Directive 5105.65, Defense Security Cooperation Agency.

**PURPOSE(S):**

International Affairs Personnel Initiatives Database (IAPID) is a single central facility with the Department of Defense (DoD) that maintains and verifies information provided by individuals seeking international affairs certification based on their current experience and training.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of OSD's compilation of systems of records notices apply to this system.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained on electronic storage media.

**RETRIEVABILITY:**

Records are retrieved by the individual's name, organization, and level of certification.

**SAFEGUARDS:**

Records are maintained in controlled areas accessible only to authorized personnel. Government computers requiring a Common Access Card to access personal information is further restricted by the use of passwords that are changed periodically. Physical entry is restricted by the locks, security personnel and administrative procedures.

**RETENTION AND DISPOSAL:**

Disposition is pending until the National Archives and Records Administration approves the retention and disposal schedule, records will be treated as permanent.

**SYSTEM MANAGER(S) AND ADDRESS:**

U.S. Army Personnel: Deputy Assistant Secretary of the Army for Defense Exports (DASA DE&C), 1777 North Kent Street, Rosslyn, VA 22209–2185.

U.S. Navy/U.S. Marine Corps Personnel: Navy International Programs Office, 2521 S. Clark Street, Suite 800, Arlington, VA 22202–3928.

U.S. Air Force Personnel: Security Assistance Policy and International Training and Education Division (SAF/IAPX), 1550 Wilson Blvd., Suite 900, Arlington VA 22209–1080.

Other Defense Personnel: Defense Institute of Security Assistance Management (DISAM), Project Manager, Building 52, 2475 K Street, Wright-Patterson AFB, Ohio 45433–7641.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves

is contained in this system should address written request to the appropriate system manager listed above.

Written requests should include the full name, organization, job series and title and be signed.

**RECORD ACCESS PROCEDURES:**

Individuals seeking access to records about themselves contained in this system should address written request to the appropriate system manager listed above.

Written requests should include the full name, organization, job series and title and be signed.

**CONTESTING RECORD PROCEDURES:**

The Office of the Secretary of Defense rules for accessing records for contesting contents and appealing initial agency determinations are published in Office of the Secretary of Defense Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the individual and immediate supervisors.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 2010–8653 Filed 4–14–10; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID DOD–2010–OS–0045]**

### Privacy Act of 1974; System of Records

**AGENCY:** Defense Logistics Agency, DoD.

**ACTION:** Notice to amend a system of records.

**SUMMARY:** The Defense Logistics Agency is proposing to amend a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**DATES:** The proposed action will be effective without further notice on May 17, 2010 unless comments are received which would result in a contrary determination.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

*Instructions:* All submissions received must include the agency name and docket number 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.

**FOR FURTHER INFORMATION CONTACT:** Ms. Jody Sinkler at (703) 767–5045.

**SUPPLEMENTARY INFORMATION:** The Defense Logistics Agency's system of record notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the Chief Privacy and FOIA Officer, Headquarters Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: April 12, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**S330.10**

**SYSTEM NAME:**

DLA Telework Program Records (May 5, 2006; 71 FR 26476).

**CHANGES:**

**SYSTEM ID NUMBER:**

Delete entry and replace with "S375.80".

**SYSTEM NAME:**

Delete entry and replace with "Alternate Worksite Records".

**SYSTEM LOCATION:**

Delete entry and replace with "Office of the Director, Human Resources, Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Suite 6231, Fort Belvoir, VA 22060–6221, and heads of the DLA Primary Level Field activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices."

* * * * *

**STORAGE:**

Delete entry and replace with "Records are maintained on paper and electronic storage media."

* * * * *

**NOTIFICATION PROCEDURE:**

Delete entry and replace with "Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221."

**RECORD ACCESS PROCEDURES:**

Delete entry and replace with "Individuals seeking access to information about themselves contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals must supply their name and the DLA facility or activity where employed at the time they requested to participate in the Alternate Worksite Program."

**CONTESTING RECORD PROCEDURES:**

Delete entry and replace with "The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221."

* * * * *

**S375.80**

**SYSTEM NAME:**

Alternate Worksite Records.

**SYSTEM LOCATION:**

Office of the Director, Human Resources, Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Suite 6231, Fort Belvoir, VA 22060–6221, and heads of the DLA Primary Level Field activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have been granted and/or denied participation in the DLA Telework Program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Records include individual's name; position title, grade, and job series; last

performance evaluation rating; duty station address and telephone number; approved alternative worksite address, telephone number(s), telephone installation and local fees (if applicable); Telework request forms (Telework Request and Approval Form, Telework Agreement, Self-Certification Home Safety Checklist, and Supervisor-Employee Checklist); approvals/disapprovals; home safety reports; description of government owned equipment and software provided to the Teleworker; and the digital identifier of the individual used to authenticate document approvals.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Pub. L. 106–346, section 359, Department of Transportation and Related Agencies Appropriations Act 2001; 5 U.S.C. 6120, Telecommuting in Executive Agencies; Under Secretary of Defense for Personnel and Readiness Memorandum, Department of Defense Telework Policy and Guide for Civilian Employees, October 22, 2001; and DoD Directive 1035.1, Telework Policy for Department of Defense.

**PURPOSE(S):**

Records are used by supervisors and program coordinators for managing, evaluating, and reporting DLA Telework Program activity/participation. Data on participation in the DLA Telework Program, minus personal identifiers, is provided to the DoD for a consolidated DoD response to the Office of Personnel Management (OPM) Telework Survey. Portions of the files are used by Information Technology offices for determining equipment and software needs; for ensuring appropriate technical safeguards are in use at alternative work sites; and for evaluating and mitigating vulnerabilities associated with connecting to DLA computer systems from remote locations.

Portions of the files may be used by Information Security offices for determining equipment and software needs; for ensuring appropriate technical safeguards are in use at alternative work sites; and for evaluating and mitigating vulnerabilities associated with connecting to DLA computer systems from remote locations. Portions of the records may also be used by telephone control offices to validate and reimburse participants for costs associated with telephone use.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records or information contained therein may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Home address, home safety checklists, and home safety reports may be disclosed to the Department of Labor when an employee is injured while working at home.

To the American Federation of Government Employees Council 169 to provide raw statistical data on the DLA telework program. Data to be disclosed includes number of positions designated as eligible for Telework by job title, series and grade; number of employees requesting Telework; and the number approved for Telework by the local activity. No personal identifiers or personally identifying data is provided.

The DoD 'Blanket Routine Uses' set forth at the beginning of DLA's compilation of systems of records notices apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

**STORAGE:**

Records are maintained on paper and electronic storage media.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

Access to the database is limited to those who require the records in the performance of their official duties. Access is further restricted by the use of passwords, which are changed periodically. Physical entry is restricted by the use of locks, guards, and administrative procedures. Employees are periodically briefed on the consequences of improperly accessing restricted databases.

**RETENTION AND DISPOSAL:**

Records are destroyed 1 year after employee's participation in the program ends. Unapproved requests are destroyed 1 year after the request is rejected.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Human Resources, Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Suite 6231, Fort Belvoir, VA 22060–6221; and the heads of DLA Primary Level Field activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

**RECORD ACCESS PROCEDURES:**

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individuals must supply their name and the DLA facility or activity where employed at the time they requested to participate in the Alternate Worksite Program.

**CONTESTING RECORD PROCEDURES:**

The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Office, Headquarters, Defense Logistics Agency, *Attn:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

**RECORD SOURCE CATEGORIES:**

Data is supplied by participants, supervisors, and information technology offices.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 2010–8654 Filed 4–14–10; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID: DOD–2010–OS–0047]**

### Privacy Act of 1974; Systems of Records

**AGENCY:** Defense Logistics Agency, DoD.

**ACTION:** Notice to delete a system of records.

**SUMMARY:** The Defense Logistics Agency proposes to delete a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

**DATES:** This proposed action will be effective without further notice on May 17, 2010 unless comments are received which result in a contrary determination.

**ADDRESSES:** You may submit comments, identified by dock number and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

*Instructions:* All submissions received must include the agency name and docket number 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.

**FOR FURTHER INFORMATION CONTACT:** Jody Sinkler at (703) 767–5045.

**SUPPLEMENTARY INFORMATION:** The Defense Logistics Agency systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the Chief Privacy and FOIA Officer, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

The Agency proposes to delete a system of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: April 12, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**Deletion:**

S340.20 CAHS

**SYSTEM NAME:**

Official Records for Host Enrollee Programs (November 16, 2004; 69 FR 67112).

**REASON:**

System notice is no longer needed. The program has been discontinued and records have been destroyed.

[FR Doc. 2010–8655 Filed 4–14–10; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID: DOD–2010–OS–0046]**

### Privacy Act of 1974; Systems of Records

**AGENCY:** Defense Logistics Agency, DoD.

**ACTION:** Notice to delete a system of records.

**SUMMARY:** The Defense Logistics Agency proposes to delete a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

**DATES:** This proposed action will be effective without further notice on May 17, 2010 unless comments are received which result in a contrary determination.

**ADDRESSES:** You may submit comments, identified by dock number and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

*Instructions:* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is of 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.

**FOR FURTHER INFORMATION CONTACT:** Jody Sinkler at (703) 767–5045.

**SUPPLEMENTARY INFORMATION:** The Defense Logistics Agency systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the Chief Privacy and FOIA Officer, Headquarters Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

The Agency proposes to delete a system of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: April 12, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**Deletion:**

S900.10.

**SYSTEM NAME:**

Personnel Roster/Locator Files (December 26, 2002; 67 FR 78780).

**REASON:**

Records are now being maintained under a DoD-wide system of records identified as DPR 39 DoD, entitled "DoD Personnel Accountability and Assessment System."

[FR Doc. 2010–8656 Filed 4–14–10; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

### Notice of Intent To Grant Exclusive Patent License: SciTech Medical Inc.

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice.

**SUMMARY:** The Department of the Navy hereby gives notice of its intent to grant a partially exclusive license to SciTech Medical Inc. The proposed license is a revocable, nonassignable, partially exclusive license to practice several inventions throughout the United States, the District of Columbia, the Commonwealth of Puerto Rico, and all other United States territories and possessions and throughout the world as covered by all related filings. The Secretary of the Navy has an ownership interest in these inventions, and they are covered by U.S. Patent No. 7,128,714: Non-Contact Waveform Monitor; U.S. Patent App. Ser. No. 12/131,472: Remote Blood Pressure Sensing Method and Apparatus; and, U.S. Provisional Patent App. Ser. No. 61/255,258: Non-Contact System and Method For Monitoring A Physiological Condition and various related foreign applications.

**DATES:** Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

**ADDRESSES:** Written objections are to be filed with the Naval Undersea Warfare Center Division, Newport, 1176 Howell St., Bldg 990, Code 07TP, Newport, RI 02841.

**FOR FURTHER INFORMATION CONTACT:** Dr. Theresa A. Baus, Head, Technology Partnership Enterprise Office, Naval

Undersea Warfare Center Division, Newport, 1176 Howell St., Bldg 990, Code 07TP, Newport, RI 02841, telephone 401–832–8728, or e-mail *Theresa.baus@navy.mil.*

**Authority:** 35 U.S.C. 207, 37 CFR part 404.

Dated: April 7, 2010.

**A.M. Vallandingham,**

*Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.*

[FR Doc. 2010–8657 Filed 4–14–10; 8:45 am]

**BILLING CODE 3810–FF–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

### Meeting of the Chief of Naval Operations (CNO) Executive Panel

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice of open meeting.

**SUMMARY:** The CNO Executive Panel will deliberate on the findings and proposed recommendations of the Subcommittee on Improved Concept Generation Development. The matters to be discussed include: Navy's concept generation and concept development processes and procedures.

**DATES:** The meeting will be held on April 30, 2010, at 10 a.m. and last no longer than two hours.

**ADDRESSES:** The meeting will be held in the Boardroom, CNA, 4825 Mark Center Drive, Alexandria, VA 22311–1846. Some members of the Executive Panel may participate remotely via teleconference and webinar.

**FOR FURTHER INFORMATION CONTACT:** Ms. Bree A. Hartlage, CNO Executive Panel, 4825 Mark Center Drive, Alexandria, VA 22311–1846, 703–681–4907.

**SUPPLEMENTARY INFORMATION:** Individuals or interested groups may submit written statements for consideration by the Chief of Naval Operations Executive Panel at any time or in response to the agenda of the scheduled meeting. All requests or statements must be submitted to the Designated Federal Officer at the address detailed below at least five days prior to the meeting to allow adequate time for consideration. Requests or statements will not be allowed during the meeting that is the subject of this notice.

The Designated Federal Officer will review all timely submissions with the CNO Executive Panel Chairperson and will ensure they are provided to members of the CNO Executive Panel before the meeting that is the subject of this notice.

Individuals desiring to participate remotely via teleconference or webinar must submit their contact information (to include e-mail address) to Ms. Hartlage via the below address. There will be limited availability to participate remotely and requests will be handled on a first-come, first-served basis.

To contact the Designated Federal Officer, write to Executive Director, CNO Executive Panel (N00K), 4825 Mark Center Drive, 2nd Floor, Alexandria, VA 22311–1846.

Dated: April 7, 2010.

**A.M. Vallandingham,**

*Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.*

[FR Doc. 2010–8661 Filed 4–14–10; 8:45 am]

**BILLING CODE 3810–FF–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

**[Docket ID USN–2010–0008]**

### Privacy Act of 1974; System of Records

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice to amend a system of records.

**SUMMARY:** The Department of the Navy proposes to amend a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**DATES:** The changes will be effective on May 17, 2010 unless comments are received that would result in a contrary determination.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

*Instructions:* All submissions received must include the agency name and docket number 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.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Miriam Brown-Lam (202) 685–6545.

**SUPPLEMENTARY INFORMATION:** The Department of the Navy systems of records notice subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, has been published in the **Federal Register** and is available from Mrs. Miriam Brown-Lam, HEAD, FOIA/Privacy Act Policy Branch, the Department of the Navy, 2000 Navy Pentagon, Washington, DC 20350–2000.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: April 12, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**N01070–3**

**SYSTEM NAME:**

Navy Military Personnel Records System (January 29, 2007; 72 FR 3981).

**CHANGES:**

* * * * *

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Delete entry and replace with "Full name, Social Security Number (SSN), enlisted service number, or officer file number, personnel service jackets and service records, correspondence and records concerning classification, assignment, distribution, promotion, advancement, performance, recruiting, retention, reenlistment, separation, training, education, morale, personal affairs, benefits, entitlements, discipline and administration of naval personnel."

* * * * *

**SYSTEM MANAGER(S) AND ADDRESS:**

Delete entry and replace with "Commander, Navy Personnel Command (PERS–31), 5720 Integrity Drive, Millington, TN 38055–3130: Commanding Officers, Officers in Charge, and Heads of Department of the Navy activities.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices."

**NOTIFICATION PROCEDURE:**

Delete entry and replace with "Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to:

For permanent records of all active duty and reserve members (except Individual Ready Reserve (IRR)), former members discharged, deceased, or

retired since 1995, should be addressed to the Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120.

Inquiries regarding records of former members discharged, deceased, or retired before 1995 should be addressed to the Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100.

Inquiries regarding field service records of current members should be addressed to the Personnel Office or Personnel Support Detachment providing administrative support to the local activity to which the individual is assigned.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should contain first, middle, and last name and the last four of the Social Security Number (SSN) (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records."

**RECORD ACCESS PROCEDURES:**

Delete entry and replace with "Individuals seeking access to records about themselves contained in this system of records should address written inquiries to Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120, for records of all active duty and reserve members (including Individual Ready Reserve (IRR)).

Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100, for records of former members discharged, deceased, or retired before 1995.

The Personnel Office or Personnel Support Detachment providing administrative support to the local activity to which the individual is assigned for field service records of current members.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should contain first, middle, and last name and the last four of the Social Security Number (SSN) (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

Current members, active and reserve, may visit the Navy Personnel Command, Records Review Room, Bldg 769, Room 109, Millington, TN 38055–3130, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons having such cards, or other picture-bearing identification."

* * * * *

**N01070–3**

**SYSTEM NAME:**

Navy Military Personnel Records System.

**SYSTEM LOCATION:**

Primary locations: Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120 for records of all active duty Navy and reserve members (including Individual Ready Reserve (IRR)); and for records of members that were retired, discharged, or died while in service since 1995. Write to the National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100, for records of members that were retired, discharged, or died while in service prior to 1995.

Secondary locations: Personnel Offices and Personnel Support Detachments providing administrative support for the local activity where the individual is assigned.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All Navy military personnel: Officers, enlisted, active, inactive, reserve, fleet reserve, retired, midshipmen, officer candidates, and Naval Reserve Officer Training Corps personnel.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Full name, Social Security Number (SSN), enlisted service number, or officer file number, personnel service jackets and service records, correspondence and records concerning classification, assignment, distribution, promotion, advancement, performance, recruiting, retention, reenlistment, separation, training, education, morale, personal affairs, benefits, entitlements, discipline and administration of naval personnel.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

10 U.S.C. 5013, Secretary of the Navy; 42 U.S.C. 10606 as implemented by DoD Instruction 1030.1, Victim and Witness Assistance Procedures; and E.O. 9397 (SSN), as amended.

**PURPOSE(S):**

To assist officials and employees of the Navy in the management, supervision and administration of Navy personnel (officer and enlisted) and the operations of related personnel affairs and functions.

**ROUTINE USERS OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To officials and employees of the National Research Council in Cooperative Studies of the National History of Disease, of Prognosis and of Epidemiology. Each study in which the records of members and former members of the naval service are used must be approved by the Chief of Naval Personnel.

To officials and employees of the Department of Health and Human Services, in the performance of their official duties related to eligibility, notification and assistance in obtaining health and medical benefits by members and former members of the Navy.

To the U.S. Citizenship and Immigration Services for use in alien admission and naturalization inquiries.

To the Office of Personnel Management for verification of military service for benefits, leave, or reduction-in-force purposes, and to establish Civil Service employee tenure and leave accrual rate.

To the Director of Selective Service System in the performance of official duties related to registration with the Selective Service System.

To the Social Security Administration to obtain or verify Social Security Numbers or to substantiate applicant's credit for Social Security compensation.

To officials and employees of the Department of Veterans Affairs in the performance of their duties relating to approved research projects, and for processing and adjudicating claims, benefits, and medical care.

To officials of the U.S. Coast Guard (USCG) for the purpose of creating service records for current USCG members that had prior service with the Navy.

To officials and employees of Navy Relief and the American Red Cross in the performance of their duties relating to the assistance of the members and their dependents and relatives, or related to assistance previously furnished such individuals, without regard to whether the individual assisted or his/her sponsor continues to be a member of the Navy. Access will be limited to those portions of the member's record required to effectively assist the member.

To duly appointed Family Ombudsmen in the performance of their duties related to the assistance of the members and their families.

To state and local agencies in the performance of their official duties related to verification of status for determination of eligibility for Veterans Bonuses and other benefits and entitlements.

To officials and employees of the Office of the Sergeant at Arms of the United States House of Representatives in the performance of their official duties related to the verification of the active duty naval service of Members of Congress. Access is limited to those portions of the Member's record required to verify service time.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

Information as to current military addresses and assignments may be provided to military banking facilities who provide banking services overseas and who are reimbursed by the Government for certain checking and loan losses. For personnel separated, discharged or retired from the Armed Forces information as to last known residential or home of record address may be provided to the military banking facility upon certification by a banking facility officer that the facility has a returned or dishonored check negotiated by the individual or the individual has defaulted on a loan and that if restitution is not made by the individual the United States Government will be liable for the losses the facility may incur.

To Federal, state, local, and foreign (within Status of Forces agreements) law enforcement agencies or their authorized representatives in connection with litigation, law enforcement, or other matters under the jurisdiction of such agencies.

Information relating to professional qualifications of chaplains may be provided to civilian certification boards and committees, including, but not limited to, state and federal licensing authorities and ecclesiastical endorsing organizations.

To governmental entities or private organizations under government contract to perform random analytical research into specific aspects of military personnel management and administrative procedures.

To Federal agencies, their contractors and grantees, and to private organizations, such as the National Academy of Sciences, for the purposes of conducting personnel and/or health-related research in the interest of the Federal government and the public. When not considered mandatory, the names and other identifying data will be eliminated from records used for such research studies.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of system of record notices also apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

**STORAGE:**

Paper records and electronic storage media.

**RETRIEVABILITY:**

By name, Social Security Number (SSN), enlisted service number or officer file number.

**SAFEGUARDS:**

Computer facilities and terminals are located in restricted areas accessible only to authorized persons that are properly screened, cleared and trained. Manual records and computer printouts are available only to authorized personnel having a need-to-know.

**RETENTION AND DISPOSAL:**

Those documents that are designated as temporary in the prescribing regulations remain in the record until their obsolescence, or the member is separated from the Navy, then are removed and provided to the individual. Those documents designated as permanent are submitted to Navy Personnel Command at predetermined times to form a single personnel record in the Electronic Military Personnel Records System (EMPRS), and remain in EMPRS permanently. Permanent records are transferred to the National Archives and Records Administration 62 years after the completion of the service member's obligated service.

**SYSTEM MANAGER(S) AND ADDRESS:**

Commander, Navy Personnel Command (PERS–31), 5720 Integrity Drive, Millington, TN 38055–3130: Commanding Officers, Officers in Charge, and Heads of Department of the Navy activities.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to:

For permanent records of all active duty and reserve members (except Individual Ready Reserve (IRR)), former members discharged, deceased, or retired since 1995, should be addressed to the Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120.

Inquiries regarding records of former members discharged, deceased, or retired before 1995 should be addressed to the Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100.

Inquiries regarding field service records of current members should be addressed to the Personnel Office or Personnel Support Detachment providing administrative support to the local activity to which the individual is assigned.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should contain first, middle, and last name and the last four of the Social Security Number (SSN) (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

**RECORD ACCESS PROCEDURES:**

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to Commander, Navy Personnel Command (PERS–312), 5720 Integrity Drive, Millington, TN 38055–3120, for records of all active duty and reserve members (including Individual Ready Reserve (IRR)).

Director, National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100, for records of former members discharged, deceased, or retired before 1995.

The Personnel Office or Personnel Support Detachment providing

administrative support to the local activity to which the individual is assigned for field service records of current members.

Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should contain first, middle, and last name and the last four of the Social Security Number (SSN) (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

Current members, active and reserve, may visit the Navy Personnel Command, Records Review Room, Bldg 769, Room 109, Millington, TN 38055–3130, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons having such cards, or other picture-bearing identification.

**CONTESTING RECORD PROCEDURES:**

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

**RECORD SOURCE CATEGORIES:**

Correspondence; educational institutions; federal, state, and local court documents; civilian and military investigatory reports; general correspondence concerning the individual; official records of professional qualifications; Navy Relief and American Red Cross requests for verification of status.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 2010–8652 Filed 4–14–10; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board Charter Renewal

Pursuant to Section 14(a)(2)(A) of the Federal Advisory Committee Act (Pub. L. No. 92–463), and in accordance with Title 41 of the Code of Federal Regulations, section 102–3.65(a), and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Environmental Management Site-Specific Advisory Board will be renewed for a two-year period beginning April 11, 2010.

The Board provides the Assistant Secretary for Environmental Management (EM) with information, advice, and recommendations concerning issues affecting the EM program at various sites. These site-specific issues include clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities.

Additionally, the renewal of the Environmental Management Site-Specific Advisory Board has been determined to be essential to conduct Department of Energy business and to be in the public interest in connection with the performance of duties imposed on the Department of Energy by law and agreement. The Board will operate in accordance with the provisions of the Federal Advisory Committee Act, and rules and regulations issued in implementation of that Act. Further information regarding this Advisory Board may be obtained from Ms. Catherine Alexander Brennan, Designated Federal Officer, at (202) 586–7711.

Issued in Washington, DC, on April 11, 2010.

**Carol A. Matthews,**

*Committee Management Officer.*

[FR Doc. 2010–8658 Filed 4–14–10; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. IC10–80–000]**

### Commission Information Collection Activities (FERC Form 80); Comment Request; Extension

April 8, 2010.

**AGENCY:** Federal Energy Regulatory Commission.

**ACTION:** Notice of proposed information collection and request for comments.

**SUMMARY:** In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A) (2006), (Pub. L. 104–13), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the proposed information collection described below.

**DATES:** Comments in consideration of the collection of information are due 60 days after publication of this Notice in the **Federal Register**.

**ADDRESSES:** Comments may be filed either electronically (eFiled) or in paper format, and should refer to Docket No. IC10–80–000. Documents must be prepared in an acceptable filing format and in compliance with Commission submission guidelines at *http://www.ferc.gov/help/submission-guide.asp.* eFiling instructions are available at: *http://www.ferc.gov/docs-filing/efiling.asp.* First time users must follow eRegister instructions at: *http://www.ferc.gov/docs-filing/eregistration.asp,* to establish a user name and password before eFiling. The Commission will send an automatic acknowledgement to the sender's e-mail address upon receipt of eFiled comments. Commenters making an eFiling should not make a paper filing. Commenters that are not able to file electronically must send an original and two (2) paper copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

Users interested in receiving automatic notification of activity in this docket may do so through eSubscription at *http://www.ferc.gov/docs-filing/esubscription.asp.* In addition, all comments and FERC issuances may be viewed, printed or downloaded remotely through FERC's eLibrary at: *http://www.ferc.gov/docs-filing/elibrary.asp,* by searching on Docket No. IC10–80. For user assistance, contact FERC Online Support by e-mail at *ferconlinesupport@ferc.gov,* or by phone, at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

**FOR FURTHER INFORMATION CONTACT:** Ellen Brown may be reached by telephone at (202) 502–8663, by fax at (202) 273–0873, and by e-mail at *DataClearance@FERC.gov.*

**SUPPLEMENTARY INFORMATION:** The information collected on the FERC Form 80 (also known as "FERC–80," OMB Control No. 1902–0106), "Licensed Hydropower Development Recreation Report," is used by the Commission to implement the statutory provisions of sections 4(a), 10(a), 301(a), 304 and 309 of the Federal Power Act (FPA), 16 U.S.C. sections 797, 803, 825c & 8254. The authority for the Commission to collect this information comes from

section 10(a) of the FPA which requires the Commission to be responsible for ensuring that hydro projects subject to its jurisdiction are consistent with the comprehensive development of the nation's waterway for recreation and other beneficial public uses. In the interest of fulfilling these objectives, the Commission expects licensees subject to its jurisdiction, to recognize the resources that are affected by their activities and to play a role in protecting such resources.

FERC Form 80 is a report on the use and development of recreational facilities at hydropower projects licensed by the Commission. Applications for amendments to licenses and/or changes in land rights frequently involve changes in resources available for recreation. Commission staff utilizes FERC Form 80 data when analyzing the adequacy of existing public recreational facilities and when processing and reviewing possible amendments to help determine the impact of such changes. In addition, the Commission's regional office staff uses the FERC Form 80 data when conducting inspections of licensed projects. The Commission's inspectors use the data in evaluating compliance with various license conditions and in identifying recreational facilities at hydropower projects.

The data required by FERC Form 80 are specified by Title 18 of the Code of Federal Regulations (CFR) under 18 CFR 8.11 and 141.14 (and are discussed at *http://www.ferc.gov/docs-filing/forms.asp#80*). The FERC Form 80 is collected once every six years. The last collection was due on April 1, 2009, for data compiled during the calendar year ending December 31, 2008. The next collection of the FERC Form 80 is due on April 1, 2015, with subsequent collections due every sixth year, for data compiled during the previous calendar year.

The current OMB clearance expires on 9/30/2010. With the next collection due in 2015, FERC Form 80 will not be collected during the requested upcoming three-year OMB clearance cycle. Because the requirements for Form 80 are contained in the Commission's regulations, FERC plans to submit FERC Form 80 to the Office of Management and Budget (OMB) for review, to ensure the OMB clearance remains continuous and current.

*Updates and corrections to the instructions include*:

- Reflecting the FERC preference for electronic filing
- Stating that paper filings, if any, should be submitted to FERC's Office of the Secretary [1] (rather than the FERC Regional Office)
- Providing the current contact information for both FERC and OMB
- Indicating the need and timing for initial Form No. 80 filings, in accordance with 18 CFR 8.11(b).

The proposed updates to the general information, instructions, and title of Schedule 1 are attached. The remainder of the form, instructions, and glossary remain unchanged and are not attached.

*Action:* The Commission is requesting a three-year extension of the FERC–80 reporting requirements, with the indicated updates and corrections to the general and identifying instructions. These updates do not affect the data collected or regulations, which are not being revised.

*Burden Statement:* For the collection cycle, which occurs every sixth year, the estimated public reporting burden is: (a) 400 respondents, (b) 1 response/respondent, and (c) 3 hours per response, giving a total of 1,200 burden hours. The estimated annual burden figures and costs (provided below and to be submitted to OMB) are averaged over the six-year collection cycle.

| FERC–80 | Number of respondents (1) | Average Number of reponses per respondent (2) | Average burden hours per response (3) | Total burden hours (1) × (2) × (3) |
|---|---|---|---|---|
| Annual, estimates—averaged and spread over the 6-year collection cycle ... | 400/6 = 66.67 | 1/6 = 0.167 | 3/6 = 0.5 | 1200/6 = 200 |

The total estimated annual cost burden to respondents (spread over the 6-year collection cycle) is $13,257.11 (200 hours/2080 hours [2] per year, times $137,874 [3]).

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

*Comments are invited on:* (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including 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.

**Kimberly D. Bose,**

*Secretary.*

## FERC Form 80, Licensed Hydropower Development Recreation Report

### *General Information*

This form collects data on recreational resources at projects licensed by the

[1] Filings submitted to the FERC's Office of the Secretary (similar to other forms) will be available more quickly to both the public and staff, and the processing costs will be reduced.

[2] Number of hours an employee works each year.

[3] Estimated average annual cost per employee.

Federal Energy Regulatory Commission (Commission) under the Federal Power Act (16 U.S.C. 791a–825r). This form must be submitted by licensees of all projects except those specifically exempted under 18 CFR 8.11 (c).

For regular, periodic filings, submit this form on or before April 1, 2015. Submit subsequent filings of this form on or before April 1, every 6th year thereafter (for example, 2021, 2027, etc.).

For initial Form No. 80 filings (18 CFR 8.11(b)), each licensee of an unconstructed project shall file an initial Form No. 80 after such project has been in operation for a full calendar year prior to the filing deadline. Each licensee of an existing (constructed) project shall file an initial Form No. 80 after such project has been licensed for a full calendar year prior to the filing deadline.

Filing electronically is the preferred manner of filing. (*See http://www.ferc.gov* for more information.) If you cannot file electronically, submit an original and two copies of the form to the: Federal Energy Regulatory Commission, Office of the Secretary, 888 First St., NE., Washington, DC 20426.

The public burden estimated for this form is three hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information. Send comments regarding the burden estimate or any aspect of this collection of information, including suggestions for reducing burden, to the:

- Federal Energy Regulatory Commission (FERC), e-mail to *DataClearance@FERC.gov*; or mail to FERC, 888 First Street NE., Washington, DC 20426 (Attention: Information Clearance Officer), and
- Office of Management and Budget (OMB), e-mail to *oira_submission@omb.eop.gov;* or mail to OMB, Office of Information and Regulatory Affairs, Attention: Desk Officer for the Federal Energy Regulatory Commission, Washington, DC 20503. Include OMB Control Number 1902–0106 as a point of reference.

No person shall be subject to any penalty for failing to comply with a collection of information if the collection of information does not display a valid control number (44 U.S.C. 3512 (a)).

*Instructions*

a. All data reported on this form must represent recreational facilities and services located within the development/project boundary.

b. To ensure a common understanding of terms, please refer to the Glossary.

c. Report actual data for each item. If actual data are unavailable, then please estimate.

**Schedule 1. General Data**

**Note:** The remainder of the FERC Form 80 (form, instructions, and glossary) are unchanged and are not included here.]

[FR Doc. 2010–8584 Filed 4–14–10; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 12747–001]**

### San Diego County Water Authority; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

April 7, 2010.

On March 1, 2010, San Diego County Water Authority filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the San Vicente Pumped Storage Water Power Project No. 13747. The proposed project would be located at the existing San Vicente dam and reservoir on San Vicente Creek in San Diego County, California. The project would consist of the existing San Vicente reservoir functioning as the lower reservoir of the project and one of three alternatives as an upper reservoir: the Iron Mountain Alternative, the Foster Canyon Alternative, and the East Reservoir Alternative. Specific details about each of these alternatives are described below. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

All three of the alternatives would use the San Vicente reservoir as the lower reservoir of the pumped storage project. The San Vicente reservoir portion of the project would consist of:

(1) an existing dam, currently being raised to a dam height of 337 feet, and a length of 1,442 feet; and (2) an existing impoundment, that upon completion of the dam raise will have a surface area of 1,600 acres, and storage capacity of 247,000 acre-feet with a normal maximum water surface elevation of 767 feet above mean sea level (msl).

The three alternatives for the upper reservoir are described below.

**Iron Mountain Alternative**

(1) A proposed 235-foot-high, 1,250-foot-long upper dam located 3 miles north of San Vicente reservoir; (2) a proposed reservoir with a surface area of 93 acres having a storage capacity of 8,070 acre-feet and a normal maximum water surface elevation of 2,110 feet above msl; (3) a proposed 12,300-foot-long, 20-foot-diameter concrete power tunnel; (4) two proposed 500-foot-long, steel-lined penstocks; (5) a proposed powerhouse containing two generating units having a total installed capacity of 500 megawatts; (6) a proposed 3,300-foot-long, 24-foot-diameter concrete tailrace; (7) a proposed 14,000-foot-long, 230-kilovolt transmission line; and (8) appurtenant facilities.

**Foster Canyon Alternative**

(1) A proposed upper dam approximately one half mile north of San Vicente reservoir; (2) a proposed upper reservoir with a surface area of 100 acres normal maximum water surface elevation of 1,490 feet above msl; (3) a proposed 3,000-foot-long, 20-foot-long, concrete power tunnel; (4) two proposed 300-foot-long, steel-lined penstocks; (5) a proposed powerhouse containing two generating units having a total installed capacity of 480 megawatts; (6) a proposed 2,700-foot-long, 24-foot-diameter concrete tailrace; (7) a proposed 9,000-foot-long, 230-kilovolt transmission line; and (8) appurtenant facilities.

**The East Reservoir Alternative**

(1) A proposed upper dam approximately 0.8 miles east of San Vicente Reservoir; (2) a proposed upper reservoir with a surface area of 60 acres and a normal maximum water surface elevation of 1,600 feet above msl; (3) a proposed 6,000-foot-long, 20-foot-long concrete power tunnel; (4) two proposed 300-foot-long, steel-lined penstocks; (5) a proposed powerhouse containing two generating units having a total installed capacity of 570 megawatts; (6) a proposed 2,600-foot-long, 24-foot-diameter concrete tailrace; (7) a proposed 15,000-foot-long, 230-kilovolt transmission line; and (8) appurtenant facilities.

The proposed project would have a maximum estimated annual generation of up to 1,000 gigawatt-hours, which would be sold to a local utility.

*Applicant Contact:* Frank Belock, Deputy General Manager, San Diego

County Water Authority, 4677 Overland Avenue, San Diego, CA 92123; phone: (858) 522–67881.

*FERC Contact:* Joseph P. Hassell, 202–502–8079

*Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications:* 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–12747) in the docket number field to access the document. For assistance, contact FERC Online Support.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8590 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings No. 1

April 07, 2010.

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG10–29–000.

*Applicants:* Big Horn Wind Project LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Big Horn II Wind Project LLC.

*Filed Date:* 04/07/2010.

*Accession Number:* 20100407–5039.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

*Docket Numbers:* EG10–30–000.

*Applicants:* Juniper Canyon Wind Power LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Juniper Canyon Wind Power LLC.

*Filed Date:* 04/07/2010.

*Accession Number:* 20100407–5040.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER99–1435–022; ER10–390–001; ER00–1814–010.

*Applicants:* Avista Corporation; Avista Turbine Power, Inc.; Avista Turbine Power, Inc.

*Description:* Request for Waiver of Avista Corporation.

*Filed Date:* 04/02/2010.

*Accession Number:* 20100402–5073.

*Comment Date:* 5 p.m. Eastern Time on Friday, April 23, 2010.

*Docket Numbers:* ER10–822–001.

*Applicants:* Southwest Power Pool, Inc.

*Description:* Southwest Power Pool, Inc submits an errata to their Meter Agent Service Agreement filed on March 2, 2010.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0208.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1016–000.

*Applicants:* Duke Energy Indiana, Inc.

*Description:* Duke Energy Indiana, Inc submits updated summary schedules for the Transmission and Local Facilities Agreement for the Calendar Year 2008 with Wabash Valley Power Association, Inc.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100406–0207.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1018–000.

*Applicants:* PacifiCorp.

*Description:* PacifiCorp submits First Revised Sheet 9 *et al.* to First Revised Rate Schedule FERC 239.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100406–0211.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1019–000.

*Applicants:* PacifiCorp.

*Description:* PacifiCorp submits Revision 8 to Appendix A of First Revised Schedule FERC 297.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100406–0212.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1021–000.

*Applicants:* Connecticut Yankee Atomic Power Company.

*Description:* Connecticut Yankee Atomic Power Co submits petition for waiver of tariff provision.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0213.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1022–000.

*Applicants:* Just Energy Texas LP.

*Description:* Just Energy Texas LP submits notice of cancellation of its market-based rate tariff designated as First Revised Rate Schedule FERC No 1, Original Volume No 1.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0211.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1023–000.

*Applicants:* Just Energy, LLC.

*Description:* Just Energy, LLC submits Notice of Cancellation of its market-based rate tariff designated as Second Revised Rate Schedule FERC 1, Original Volume 1.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0210.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1024–000.

*Applicants:* Midwest Independent Transmission System Operator, Inc.

*Description:* Midwest Independent Transmission System Operator, Inc submits Commission acceptance and approval of the proposed classification for certain Grandfathered Agreement of Big Rivers Electric Corp. *etc.*

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0209.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1025–000.

*Applicants:* Just Energy Ohio, LLC.

*Description:* Just Energy Ohio, LLC submits Notice of Cancellation of its market-based rate tariff designated as First Revised Rate Schedule FERC 1, Original Volume 1.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0207.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1026–000.

*Applicants:* Just Energy New York, LLC.

*Description:* Just Energy New York, LLC submits Notice of Cancellation of their market-based rate tariff, designated as First Revised Rate Schedule FERC No 1, Original Volume No 1.

*Filed Date:* 04/06/2010.

*Accession Number:* 20100407–0206.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1027–000.
*Applicants:* Southern California Edison Company.
*Description:* Southern California Edison Company submits a Small Generator Interconnection Agreement and a Service Agreement for Wholesale Distribution Service between the Transmission Distribution Business Unit of SCE.
*Filed Date:* 04/06/2010.
*Accession Number:* 20100407–0205.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 27, 2010.

*Docket Numbers:* ER10–1028–000.
*Applicants:* Madison Paper Industries.
*Description:* Madison Paper Industries submits tariff filing per 35.12: Baseline Filing to be effective 3/1/2009.
*Filed Date:* 04/07/2010.
*Accession Number:* 20100407–5029.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

Take notice that the Commission received the following open access transmission tariff filings:

*Docket Numbers:* OA10–3–000.
*Applicants:* Crystal Lake Wind II, LLC.
*Description:* Crystal Lake Wind, LLC Amendment to Petition for Waiver of Commission Rules.
*Filed Date:* 04/05/2010.
*Accession Number:* 20100405–5109.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 15, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Nathaniel J. Davis, Sr.,**
*Deputy Secretary.*
[FR Doc. 2010–8612 Filed 4–14–10; 8:45 am]
**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

April 01, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP10–524–000.
*Applicants:* Trunkline Gas Company, LLC.
*Description:* Trunkline Gas Company, LLC submits Fourth Revised Sheet No. 28 *et al.* to FERC Gas Tariff, Third Revised Volume No.1, to be effective 4/1/10.c
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0218.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–525–000.
*Applicants:* National Fuel Gas Supply Corporation.
*Description:* National Fuel Gas Supply Corporation submits the 134th Revised Sheet 9 to FERC Gas tariff, Fourth Revised Volume 1, to become effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0225.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–526–000.
*Applicants:* Kern River Gas Transmission Company.
*Description:* Kern River Gas Transmission Company submits a report supporting its gas compressor fuel factors and los and unaccounted-for gas factors for calendar year 2009.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0224.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–527–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits First Revised Sheet 34L *et al.* to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0255.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–528–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits Original Sheet 35C.13 *et al.* to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0256.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–529–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits Third Revised Sheet 33D.01 *et al.* to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0257.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–530–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits an amendment with a negotiated rate exhibit to an existing maximum recourse rate Storage Rate Schedule NNS agreement.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0258.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–531–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits a new negotiated rate storage Rate Schedule NNS agreement with Anadarko Energy Service Company.

*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0259.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–532–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits an amendment with a negotiated rate exhibit to an existing maximum recourse rate Storage Rate Schedule NNS agreement.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0260.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–533–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits First Revised Sheet 33I to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0261.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–534–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits Original Sheet 35C.14 to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0262.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–535–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America LLS submits First Revised Sheet 33J *et al.* to FERC Gas Tariff, Seventh revised Volume 1, to become effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0263.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–536–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits Original Sheet 34C.06 *et al.* to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0264.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–537–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits Third Revised Sheet 35C *et al.* to its FERC Gas Tariff, Seventh Revised Volume 1 to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0265.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–538–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America, LLC submits report of the refunds of penalty revenues to its FERC Gas Tariff, Seventh Revised Volume 1.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0266.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–539–000.
*Applicants:* Discovery Gas Transmission LLC.
*Description:* Discovery Gas Transmission LLC submits First Revised Sheet No. 1 *et al.* to FERC Gas Tariff, Original Volume No. 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0241.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–540–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America LLC submits First Revised Sheet No. 35C.08 to FERC Gas Tariff, Seventh Revised Volume No. 1, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0235.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–541–000.
*Applicants:* Natural Gas Pipeline Company of America.
*Description:* Natural Gas Pipeline Company of America LLC submits Original Sheet No. 35C.10 to FERC Gas Tariff, Seventh Revised Volume No. 1, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0236.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–542–000.
*Applicants:* Trailblazer Pipeline Company LLC.
*Description:* Trailblazer Pipeline Company LLC submits Third Revised Sheet No. 11 to FERC Gas Tariff, Fourth Revised Volume No. 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0237.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–543–000.
*Applicants:* Transwestern Pipeline Company, LLC.
*Description:* Transwestern Pipeline Company LLC submits Seventh Revised Sheet No. 6 to FERC Gas Tariff, Third Revised Volume No. 1, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0238.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–544–000.
*Applicants:* Northern Natural Gas Company.
*Description:* Northern Natural Gas Company submits Fifth Revised Sheet No. 66B.01b *et al.* to FERC Gas Tariff, Fifth Revised Volume No. 1, to effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0233.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–545–000.
*Applicants:* Quest Pipelines (KPC).
*Description:* Quest Pipelines (KPC) submits First Revised Sheet No. 112 to FERC Gas Tariff, Second Revised Volume No. 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0239.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–546–000.
*Applicants:* Northern Natural Gas Company.
*Description:* Northern Natural Gas Company submits Fourteenth Revised Sheet No. 66B.01a *et al.* to FERC Gas Tariff, Fifth Revised Volume No. 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0234.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–547–000.
*Applicants:* Rockies Express Pipeline LLC.
*Description:* Rockies Express Pipeline LLC submits Eighteenth Revised Sheet No. 10 to FERC Gas Tariff, Second Revised Volume No. 1, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100331–0240.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–548–000.
*Applicants:* East Tennessee Natural Gas, LLC.
*Description:* East Tennessee Natural Gas, LLC submits its cashout report for November 2008 through October 2009.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0223.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–549–000.
*Applicants:* Equitrans, LP.
*Description:* Equitrans, LP submits First Revised Sheet 319 *et al.* to its FERC Gas Tariff, Original Volume 1, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0224.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–550–000.
*Applicants:* Gas Transmission Northwest Corporation.
*Description:* Gas Transmission Northwest Corporation submits First Revised Sheet 0 *et al.* to its FERC Gas Tariff, Original Volume 1, to be effective 4/30/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0215.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–551–000.
*Applicants:* Northern Border Pipeline Company.
*Description:* Northern Border Pipeline Company submits Fifteenth Revised Sheet 99 *et al.* to its FERC Gas Tariff, First Revised Volume 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0216.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–552–000.
*Applicants:* Tuscarora Gas Transmission Company.
*Description:* Tuscarora Gas Transmission Company submits First Revised Sheet No. 0, 66, 120, 204, 213, 222, and 229 to FERC Gas Tariff, First Revised Volume No. 1, to be effective 4/30/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0217.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–553–000.
*Applicants:* Midcontinent Express Pipeline LLC.
*Description:* Midcontinent Express Pipeline, LLC submits Second Revised Sheet 7 *et al.* to its FERC Gas Tariff, Original Volume 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0218.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–554–000.
*Applicants:* Transcontinental Gas Pipe Line Company.
*Description:* Transcontinental Gas Pipe Line Company, LLC submits Fifth Revised Sheet 81 *et al.* to its FERC Gas Tariff, Fourth Revised Volume 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0219.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–555–000.
*Applicants:* ANR Pipeline Company.
*Description:* ANR Pipeline Company submits amendments to the negotiated rate agreements, Rate Schedule ETS, Rate Schedule NNS et al., to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0220.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–556–000.
*Applicants:* ANR Pipeline Company.
*Description:* ANR Pipeline Company submits Rate Schedule FSS, Rate Schedule ETS, and Rate Schedule FTS–1 negotiated rate service agreements, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0221.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–557–000.
*Applicants:* ANR Pipeline Company.
*Description:* ANR Pipeline Company submits Seventeenth Revised Sheet 17A et al. to its FERC Gas Tariff, Second Revised Volume 1, to be effective 5/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0222.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–558–000.
*Applicants:* Kinder Morgan Interstate Gas Transmission.
*Description:* Kinder Morgan Interstate Gas Transmission LLC submits Sixth Revised Sheet 4O to FERC Gas Tariff, Fourth Revised Volume 1A, to be effective 4/1/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0228.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–559–000.
*Applicants:* Tuscarora Gas Transmission Company.
*Description:* Tuscarora Gas Transmission Company submits Original Sheet 7 et al. to FERC Gas Tariff, First Revised Volume 1, to be effective 4/30/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0227.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–560–000.
*Applicants:* North Baja Pipeline, LLC.
*Description:* North Baja Pipeline, LLC submits Second Revised Sheet 9A to FERC Gas Tariff, Original Volume 1, to be effective 4/30/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0229.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–561–000.
*Applicants:* Dominion Transmission, Inc.
*Description:* Dominion Transmission, LLC submits Eighteenth Revised Sheet 1300 et al. to FERC Gas Tariff, Third Revised Volume 1, to be effective 4/30/10.
*Filed Date:* 03/31/2010.
*Accession Number:* 20100401–0230.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2010–8611 Filed 4–14–10; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings No. 2

March 31, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP08–426–013.
*Applicants:* El Paso Natural Gas Company.
*Description:* El Paso Natural Gas Company submits Thirty-Second Revised Sheet 28 *et al.* to its FERC Gas Tariff, Second Revised Volume 1A, to be effective 5/1/10.
*Filed Date:* 03/25/2010.
*Accession Number:* 20100329–0209.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 06, 2010.

*Docket Numbers:* RP10–481–001.
*Applicants:* Eastern Shore Natural Gas Company.
*Description:* Eastern Shore Natural Gas Company submits FERC Gas Tariff, Second Revised Volume 1 of Sub 71st Revised Sheet 7, to be effective 4/1/10.
*Filed Date:* 03/25/2010.
*Accession Number:* 20100325–0227.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 06, 2010.

*Docket Numbers:* RP10–271–001. RP10–350–001.
*Applicants:* Southern LNG, Inc.
*Description:* Southern LNG, Inc submits Substitute Original Sheet No 32E *et al.,* to be effective 3/1/2010.
*Filed Date:* 03/29/2010.
*Accession Number:* 20100330–0205.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–271–002; RP10–350–002.
*Applicants:* Southern LNG, Inc.
*Description:* Southern LNG, Inc submits SLNG–1 Service Agreement No SLNG11 dated 5/27/03 and SLNG–3 Service Agreement No SLNG25 dated 10/5/07.
*Filed Date:* 03/29/2010.
*Accession Number:* 20100330–0204.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–342–001.
*Applicants:* Elba Express Company, LLC.
*Description:* Elba Express Company, LLC submits Substitute Original Sheet 143 *et al.* to FERC Gas Tariff, Original Volume 1, to be effective 3/1/10.
*Filed Date:* 03/29/2010.
*Accession Number:* 20100330–0203.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–386–001.
*Applicants:* Elba Express Company, LLC.
*Description:* Elba Express Company, LLC submits EEC Service Agreement No EEC–1 dated 10/5/07 with Shell NA LNG LLC, to be effective 3/1/2010.
*Filed Date:* 03/29/2010.
*Accession Number:* 20100330–0202.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern Time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2010–8610 Filed 4–14–10; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings No. 1

March 31, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP10–520–000.
*Applicants:* Vector Pipeline, L.P.
*Description:* Vector Pipeline L.P. submits the annual fuel use report.
*Filed Date:* 03/30/2010.
*Accession Number:* 20100330–0241.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–521–000.
*Applicants:* Saltville Gas Storage Company LLC.
*Description:* Saltville Gas Storage Company LLC submits First Revised Sheet 22D to FERC Gas Tariff, Original Volume 1, reflecting an effective date of 4/1/10.
*Filed Date:* 03/30/2010.
*Accession Number:* 20100330–0243.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–522–000.
*Applicants:* Columbia Gas Transmission, LLC.
*Description:* Columbia Gas Transmission, LLC submits its FTS Service Agreement No 15260, Ninth Revised Sheet No 503.01 to FERC Gas Tariff, Third Revised Volume No 1, to be effective April 1, 2010.
*Filed Date:* 03/30/2010.
*Accession Number:* 20100331–0204.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

*Docket Numbers:* RP10–523–000.
*Applicants:* Columbia Gas Transmission, LLC.
*Description:* Columbia Gas Transmission, LLC submits its FTS Service Agreement No 15245 to FERC Gas Tariff, Third Revised Volume No 1, to be effective 4/1/2010.
*Filed Date:* 03/30/2010.
*Accession Number:* 20100331–0205.
*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission

in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

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**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2010–8609 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

March 30, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP10–514–000.

*Applicants:* Southern Star Central Gas Pipeline, Inc.

*Description:* Southern Star Central Gas Pipeline, Inc., submits Fifth Revised Sheet 2 *et al.,* to its FERC Gas Tariff, Original Volume 1 to be effective 5/1/10.

*Filed Date:* 03/26/2010.

*Accession Number:* 20100326–0204.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 07, 2010.

*Docket Numbers:* RP10–515–000.

*Applicants:* Algonquin Gas Transmission, LLC.

*Description:* Algonquin Gas Transmission LLC submits Third Revised Sheet No. 625 to FERC Gas Tariff, Fifth Revised Volume No. 1, to be effective 3/26/10.

*Filed Date:* 03/26/2010.

*Accession Number:* 20100326–0205.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 07, 2010.

*Docket Numbers:* RP10–516–000.

*Applicants:* Guardian Pipeline, LLC.

*Description:* Guardian Pipeline, LLC submits Third Revised Sheet 9 to its Tariff, to be effective 4/1/10.

*Filed Date:* 03/26/2010.

*Accession Number:* 20100326–0207.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 07, 2010.

*Docket Numbers:* RP10–518–000.

*Applicants:* Trunkline LNG Company, LLC.

*Description:* Trunkline LNG Company, LLC submits Sixth Revised Sheet No. 6 to FERC Gas Tariff, Second Revised Volume No. 1–A, to be effective 3/11/2010.

*Filed Date:* 03/26/2010.

*Accession Number:* 20100329–0208.

*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 07, 2010.

*Docket Numbers:* RP10–519–000.

*Applicants:* Northern Border Pipeline Company.

*Description:* Northern Border Pipeline Company submits Twenty-Fourth Revised Sheet 99A et al., to its FERC Gas Tariff, First Revised Volume 1, to be effective 4/1/10.

*Filed Date:* 03/29/2010.

*Accession Number:* 20100329–0218.

*Comment Date:* 5 p.m. Eastern Time on Monday, April 12, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2010–8608 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings # 1

April 08, 2010.

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC10–59–000.

*Applicants:* EquiPower Resources Corp., BG Dighton Power, LLC, Lake Road Generating Co LP, Masspower.

*Description:* Joint Application for Authorization of Transaction under Section 203 of the PFA, and Requests for Waivers of Filing Requirements, Confidential Treatment of Transaction Documents, Shortened Comment Period and Expedited Consideration.

*Filed Date:* 04/08/2010.

*Accession Number:* 20100408–5098.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG10–31–000.
*Applicants:* Loraine Windpark Project, LLC.
*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Loraine Windpark Project, LLC.
*Filed Date:* 04/08/2010.
*Accession Number:* 20100408–5097.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER99–2948–020; ER00–2918–019; ER01–1654–022; ER01–556–018; ER02–2567–019; ER04–485–017; ER05–261–012; ER07–244–011; ER05–728–012; ER07–245–011; ER07–247–011; ER08–860–001; ER10–346–005.
*Applicants:* Constellation Energy Commodities Group, R.E. Ginna Nuclear Power Plant, LLC, Baltimore Gas and Electric Company, Constellation Pwr Source Generation LLC, Constellation NewEnergy, Inc., Nine Mile Point Nuclear Station, LLC, CER Generation II, LLC, Handsome Lake Energy, LLC, Constellation Energy Commodities Group M, Calvert Cliffs Nuclear Power Plant LLC, Raven One, LLC, Raven Three, LLC, Raven Two, LLC.
*Description:* Update to Notice of Change in Status of Constellation MBR Entities.
*Filed Date:* 04/08/2010.
*Accession Number:* 20100408–5012.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

*Docket Numbers:* ER10–1029–000
*Applicants:* West Oaks Energy, LP.
*Description:* West Oaks Energy NY/NE, LP submits Application for Market-Based Rate Authorization, designation of Category 1 Status, and Request for waivers and Blanket Approvals.
*Filed Date:* 04/07/2010.
*Accession Number:* 20100407–0238.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

*Docket Numbers:* ER10–1030–000.
*Applicants:* West Oaks Energy NY/NE, LP.
*Description:* West Oaks Energy NY/NE, LP submits Application for Market-Based Rate Authorization, designation of Category 1 Status, and Request for waivers and Blanket Approvals.
*Filed Date:* 04/07/2010.
*Accession Number:* 20100407–0237.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

*Docket Numbers:* ER10–1031–000.
*Applicants:* Crestwood Energy, LP.
*Description:* Crestwood Energy LP submits FERC Electric Tariff, Original Volume No 1 effective 4/8/2010.
*Filed Date:* 04/07/2010.
*Accession Number:* 20100407–0215.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 28, 2010.

*Docket Numbers:* ER10–1033–000.
*Applicants:* Beaver Ridge Wind, LLC.
*Description:* Beaver Ridge Wind, LLC submits tariff filing per 35.12: Market Based Rate Authorization to be effective 7/1/2008.
*Filed Date:* 04/08/2010.
*Accession Number:* 20100408–5106.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

*Docket Numbers:* ER10–1034–000.
*Applicants:* Competitive Energy.
*Description:* Competitive Energy submits tariff filing per 35.12: Competitive Energy Tariff to be effective 8/1/2001.
*Filed Date:* 04/08/2010.
*Accession Number:* 20100408–5109.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES10–32–000.
*Applicants:* NSTAR Electric Company.
*Description:* Application of NSTAR Electric Company for Authority to Issue Short-Term Debt Securities.
*Filed Date:* 04/08/2010.
*Accession Number:* 20100408–5085.
*Comment Date:* 5 p.m. Eastern Time on Thursday, April 29, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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**Nathaniel J. Davis, Sr.,**
*Deputy Secretary.*

[FR Doc. 2010–8607 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

April 5, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP10–562–000.
*Applicants:* Wisconsin Electric Power Company, Wisconsin Gas LLC.
*Description:* Request of Wisconsin Electric Power Company and Wisconsin Gas LLC for Temporary Waiver and Expedited Action.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–5093.
*Comment Date:* 5 p.m. Eastern Time on Friday, April 9, 2010.

*Docket Numbers:* RP10–563–000.
*Applicants:* Alliance Pipeline L.P.
*Description:* Alliance Pipeline L.P. submits tariff filing per 154.203: Baseline Filing to be effective 4/1/2010.
*Filed Date:* 04/01/2010.

*Accession Number:* 20100401–5101.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–564–000.
*Applicants:* Gulf South Pipeline Company, LP.
*Description:* Gulf South Pipeline Company, LP submits a capacity release agreement containing negotiated rate provisions.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0251.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–565–000.
*Applicants:* Gulf South Pipeline Company, LP.
*Description:* Gulf South Pipeline Company, LP submits a capacity release agreement containing negotiated rate provisions.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0250.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–566–000.
*Applicants:* Texas Gas Transmission, LLC.
*Description:* Texas Gas Transmission, LLC submits Second Revised Sheet 52 to FERC Gas Tariff, Third Revised Volume 1.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0249.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–567–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits Tenth Revised Sheet No. 1 *et al.* to FERC Gas Tariff, Sixth Revised Volume No. 1.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0273.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–568–000.
*Applicants:* Transcontinental Gas Pipe Line Company, LLC.
*Description:* Transcontinental Gas Pipe Line Company, LLC submits negotiated rate agreement containing non-conforming provisions.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0268.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–570–000.
*Applicants:* ANR Pipeline Company.
*Description:* ANR Pipeline Company submits negotiated rate agreements.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100401–0267.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–571–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits negotiated rate agreements with Laclede Energy Resources, Inc., *et al.* to be effective 4/1/10.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0206.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–572–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits the Amended and Restated Firm (Rate Schedule FT) Transportation Service Agreement.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0205.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–573–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits new negotiated rate agreement to provide firm transportation services under Rate Schedule EFT to Southwestern Electric Power Company.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0204.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–574–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits Third Revised Sheet 686 of its FERC Gas Tariff, Sixth Revised Volume 1, to be effective 4/1/2010.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0209.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–575–000.
*Applicants:* Columbia Gas Transmission Company.
*Description:* Columbia Gas Transmission Company submits First Sheet No. 187 *et al.* to FERC Gas Tariff, Second Revised Volume No. 1, to be effective 5/1/10.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0203.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–576–000.
*Applicants:* Columbia Gas Transmission, LLC.
*Description:* Columbia Gas Transmission, LLC submits Original Sheet No. 503.02 to FERC Gas Tariff, Third Revised Volume No. 1, to be effective 5/1/10.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0202.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–577–000.
*Applicants:* Columbia Gas Transmission, LLC.
*Description:* Columbia Gas Transmission, LLC submits First Revised Sheet 278 *et al.* to its FERC Gas Tariff, Third Revised Volume 1, to be effective 5/1/10.
*Filed Date:* 04/01/2010.
*Accession Number:* 20100402–0201.
*Comment Date:* 5 p.m. Eastern Time on Tuesday, April 13, 2010.

*Docket Numbers:* RP10–578–000.
*Applicants:* Gulf Crossing Pipeline Company, LLC.
*Description:* Gulf Crossing Pipeline Company, LLC submits amendment to a negotiated rate letter agreement executed by their customers in relation to the Gulf Crossing Project.
*Filed Date:* 04/02/2010.
*Accession Number:* 20100402–0212.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 14, 2010.

*Docket Numbers:* RP10–579–000.
*Applicants:* CenterPoint Energy Gas Transmission Company.
*Description:* CenterPoint Energy Gas Transmission Company submits an amended Rate Schedule FT negotiated rate agreement with XTO Energy, Inc.
*Filed Date:* 04/02/2010.
*Accession Number:* 20100402–0213.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 14, 2010.

*Docket Numbers:* RP10–580–000.
*Applicants:* Dauphin Island Gathering Partners.
*Description:* Dauphin Island Gathering Partners submits Fifty-Second Revised Sheet 9 *et al.* to FERC Gas Tariff, First Revised Volume 1, to be effective 4/3/10.
*Filed Date:* 04/02/2010.
*Accession Number:* 20100402–0225.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that

document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2010–8606 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. PF10–5–000]**

### Empire Pipeline, Inc.; Notice of Intent To Prepare an Environmental Assessment for the Planned Tioga County Extension Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Meeting

April 7, 2010.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Tioga County Extension Project, involving construction and operation of facilities by Empire Pipeline, Inc. (Empire) in Tioga County, Pennsylvania and Steuben and Ontario Counties, New York. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues need to be evaluated in the EA. Please note that the scoping period will close on May 7, 2010.

Comments may be submitted in written form or verbally. Further details on how to submit written comments are provided in the Public Participation section of this notice. In lieu of or in addition to sending written comments, we invite you to attend the public scoping meetings scheduled as follows:

| Date and time | Location |
|---|---|
| April 27, 2010, 7 p.m. local time. | Radisson Hotel—Corning, 125 Denison Parkway East, Corning, New York 14830. 607–962–5000. |
| April 28, 2010, 7 p.m. local time. | Hampton Inn, 7637 New York State Rte 96, Victor, New York 14564. 585–924–4400. |

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with State law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" is available for viewing on the FERC Web site (*http://www.ferc.gov*). This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

#### Summary of the Planned Project

Empire plans to construct and operate approximately 16 miles of 24-inch-diameter pipeline and replace approximately 1.3 miles of existing 24-inch-diameter pipeline. According to Empire, its project would enable Empire to provide firm transportation services requested by producers connecting extensive Marcellus Shale production along the proposed pipeline corridor. The Tioga County Extension Project would provide about 350,000 dekatherms per day of capacity to various market areas in New York, New England, and eastern Canada along the Millenium Pipeline, Tennessee Gas Pipeline Company 200 Line, TransCanada Pipeline, and Empire's existing systems.

The Tioga County Extension Project would consist of the following facilities:

- Construction of 16 miles of 24-inch-diameter pipeline from Tioga County, Pennsylvania to Steuben County, New York;
- Replacement of 1.3 miles of existing 24-inch-diameter pipeline in Victor, Ontario County, New York;
- Construction of a new interconnect with Tennessee Gas Pipeline Company in the Town of Canandaigua, Ontario County, New York; and
- Miscellaneous modifications at existing measurement and compressor stations.

The general location of the project facilities is shown in appendix 1.[1]

#### Land Requirements for Construction

Construction of the planned facilities would disturb about 223 acres of land for the aboveground facilities and the pipeline. Following construction, about 113 acres would be maintained for permanent operation of the project's facilities; the remaining acreage would be restored and allowed to revert to former uses. About 31 percent of the planned pipeline route parallels an existing pipeline right-of-way.

#### The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *http://www.ferc.gov* using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

*In the EA we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:*

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise; and
- Endangered and threatened species.

We will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before an application is filed with the FERC. As part of our pre-filing review, we have begun to contact some Federal and State agencies to discuss their involvement in the scoping process and the preparation of the EA.

Our independent analysis of the issues will be presented in the EA. The EA will be placed in the public record and, depending on the comments received during the scoping process, may be published and distributed to the public. A comment period will be allotted if the EA is published for review. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure your comments are considered, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. These agencies may choose to participate once they have evaluated the proposal relative to their responsibilities. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

[2] "We", "us", and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

**Public Participation**

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that they will be received in Washington, DC on or before May 7, 2010.

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You may file your comments electronically by using the Quick Comment feature, which is located at *http://www.ferc.gov* under the link called *Documents and Filings.* A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the "eFiling" feature that is listed under the *Documents and Filings* link. eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file to your submission. New eFiling users must first create an account by clicking on the links called *Sign up* or *eRegister.* You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

**Environmental Mailing List**

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If the EA is published for distribution, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

**Becoming an Intervenor**

Once Empire files its application with the Commission, you may want to become an "intervenor", which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the "e-filing" link on the Commission's Web site. Please note that you may not request intervenor status at this time. You must wait until a formal application for the project is filed with the Commission.

**Additional Information**

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF10–5). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which

allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8591 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL10–23–002]**

### Sagebrush, a California Partnership; Notice of Filing

April 7, 2010.

Take notice that on April 5, 2010, Sagebrush, a California partnership (Sagebrush) submits for filing a revised open access transmission tariff (OATT) to govern the terms of new interconnection and transmission service on Sagebrush's existing transmission line, pursuant to the Commission's February 4, 2010, *Order Accepting in Part and Rejecting in Part Tariff Filing and Directing Compliance Filing,* 130 FERC ¶ 61,093 (2010).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5 p.m. Eastern Time on April 26, 2010.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8589 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER10–1031–000]**

### Crestwood Energy LP; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

April 8, 2010.

This is a supplemental notice in the above-referenced proceeding of Crestwood Energy LP's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 28, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8583 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER10–1029–000]**

### West Oaks Energy LP; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

April 8, 2010.

This is a supplemental notice in the above-referenced proceeding of West Oaks Energy LP's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 28, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8586 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER10–1030–000]**

### West Oaks Energy NY/NE, LP; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

April 8, 2010.

This is a supplemental notice in the above-referenced proceeding of West Oaks Energy NY/NE LP's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 28, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8582 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of FERC Staff Attendance at the Entergy Regional State Committee Meeting

April 8, 2010.

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

**Entergy Regional State Committee Meeting**

April 22, 2010 (8:30 a.m.–5 p.m.), W Hotel New Orleans, 333 Poydras Street, New Orleans, LA 70130, 504–525–9444.

The discussions may address matters at issue in the following proceedings:

| | |
|---|---|
| Docket No. OA07–32. | Entergy Services, Inc. |
| Docket No. OA08–59. | Entergy Services, Inc. |
| Docket No. EL00–66. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL01–88. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL05–15. | *Arkansas Electric Cooperative Corp.* v. *Entergy Arkansas, Inc.* |
| Docket No. EL07–52. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL08–51. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL08–60. | *Ameren Services Co.* v. *Entergy Services, Inc.* |
| Docket No. EL09–43. | *Arkansas Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL09–61. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. EL09–78. | *South Mississippi Electric Power Association* v. *Entergy Services, Inc.* |
| Docket No. EL10–55. | *Louisiana Public Service Commission* v. *Entergy Services, Inc.* |
| Docket No. ER05–1065. | Entergy Services, Inc. |
| Docket No. ER07–682. | Entergy Services, Inc. |
| Docket No. ER07–956. | Entergy Services, Inc. |
| Docket No. ER08–767. | Entergy Services, Inc. |
| Docket No. ER08–1056. | Entergy Services, Inc. |
| Docket No. ER08–1057. | Entergy Services, Inc. |
| Docket No. ER09–636. | Entergy Services, Inc. |
| Docket No. ER09–833. | Entergy Services, Inc. |

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|---|---|
| Docket No. ER09–877. | Entergy Services, Inc. |
| Docket No. ER09–882. | Entergy Services, Inc. |
| Docket No. ER09–1214. | Entergy Services, Inc. |
| Docket No. ER09–1224. | Entergy Services, Inc. |
| Docket No. ER10–794. | Entergy Services, Inc. |
| Docket No. ER10–879. | Entergy Services, Inc. |
| Docket No. ER10–984. | Entergy Services, Inc. |

*These meetings are open to the public.*

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8585 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. PR10–14–000]**

### Enterprise Texas Pipeline LLC; Notice of Petition for Rate Approval

April 7, 2010.

Take notice that on April 1, 2010, Enterprise Texas Pipeline LLC (Enterprise Texas) filed a petition for rate approval pursuant to section 284.123(b)(2) of the Commission's regulations. Enterprise Texas proposes rates of $0.6090 per MMBtu for Rate Zone 1—Legacy Assets and $0.6744 for Rate Zone 2—Sherman Extension Facilities.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before 5 p.m. Eastern time on the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5 p.m. Eastern Time on Wednesday April 21, 2010.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8588 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. PF08–26–001]**

### Denali—The Alaska Gas Pipeline LLC; Notice of Request for Approval of Plan for Conducting an Open Season

April 8, 2010.

Take notice that on April 7, 2010, pursuant to section 157.38 of the Commission's Regulations governing Open Seasons for Alaska Natural Gas Transportation Projects, Denali—The Alaska Gas Pipeline LLC (Denali) filed a Request for Commission Approval of its Plan for Conducting an Open Season. The proposed Open Season is being held to solicit binding commitments for gas treatment plant services (treating and compression) and firm natural gas transportation provided by Denali's proposed Alaska Project, which is more fully described in the filing.

This filing is accessible online at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reading Room in Washington, DC. There is an "eSubscription" link on the Commission's Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Please note that the review of Denali's Alaska's Open Season Plan is being done as part of the pre-filing phase of Denali's Alaska Project. Docket No. PF08–26–001 has been reserved for the Open Season Plan and commenters should use the –001 sub-docket for filings regarding the Open Season Plan. The Commission's Web page for eSubscription allows for subscription only to this specific sub-docket, Docket No. PF08–26–001 or, for those interested in the entire pre-filing process to, "Subscribe to root docket and all existing and new sub-dockets."

Denali states that, when completed, the Alaska Project will consist of two FERC-jurisdictional transmission lines on the North Slope of Alaska, a FERC-jurisdictional gas treatment plant that will treat North Slope gas for pipeline transportation, and a FERC-jurisdictional gas mainline that will extend from the Alaska North Slope to the border between Alaska and Canada.

Pursuant to section 157.38 of the Commission's Regulations, the Commission plans to act on the Denali proposed Open Season Plan by June 7, 2010. Denali states that if its Open Season Plan is approved by the Commission, the Open Season will commence on July 6, 2010, and conclude on October 4, 2010.

Any questions regarding this Request for Approval of Denali's Open Season Plan may be directed to:

James F. Moriarty, Locke Lord Bissell & Liddell LLP, 701 8th Street, NW.—Suite 700, Washington, DC 20001. (202) 220–6915. *jmoriarty@lockelord.com.*

Patrick J. Coughlin, Vice President & General Counsel, Denali—The Alaska Gas Pipeline LLC, 188 West Northern Lights Blvd., P.O. Box 241747, Anchorage, AK 99524–1747. (907) 865–4709. *Patrick.Coughlin@denalipipeline.com.*

Any person desiring to comment on this filing or file a motion to intervene in this phase of the project must file in accordance with the Rule 212 of Commission's Rules of Practice and Procedure. All comments will be considered by the Commission in determining the appropriate action to be taken. In addition to the filing of comments, the Commission will permit the filing of reply comments pursuant to its authority under Rule 213 of the Commission's Rules of Practice and

Procedure. The due dates for motions to intervene, comments and reply comments are listed below.

The Commission strongly urges electronic filings of comments and reply comments in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of their comments or reply comments to: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. (Label cover letter or first page with case name, Denali—The Alaska Gas Pipeline LLC—Docket No. PF08–26–001)

*Comment Date:* April 30, 2010.

*Reply Comment Date:* May 13, 2010.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8581 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP10–118–000]**

### Cheniere Creole Trail Pipeline, L.P.; Notice of Request Under Blanket Authorization

April 7, 2010.

Take notice that on April 2, 2010, Cheniere Creole Trail Pipeline, L.P. (Creole Trail), 700 Milam, Suite 800, Houston, Texas 77002, filed in Docket No. CP10–118–000, a prior notice request pursuant to sections 157.205, 157.208, and 157.212 of the Commission's regulations under the Natural Gas Act (NGA). Creole Trail seeks authorization to construct and operate approximately 550 feet of 12-inch diameter pipe (no above ground facilities will be constructed) from an existing tap on Segment 1 of Creole Trail's system to an existing meter station at Cameron Meadows Processing Plant, owned by PSI Midstream Partners, L.P., all located in Johnson Bayou, Cameron Parish, Louisiana, to enable the delivery of up to 250 MMcf per day of re-gasified LNG to the plant for processing. The cost is estimated to be $450,000. Creole Trail proposes to perform these activities under its blanket certificate issued in Docket No. CP05–358–000 [115 FERC ¶ 61,331 (2006)], all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application may be directed to Karri Mahmoud, Manager, Regulatory and Compliance, Cheniere Energy, Inc., 700 Milam, Suite 800, Houston, Texas 77002, or phone at (713) 375–5000.

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the "e-Filing" link. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8592 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Revocation of Market-Based Rate Tariff

April 8, 2010.

| | |
|---|---|
| Electric Quarterly Reports | Docket No. ER02–2001–014. |
| G&G Energy, Inc | Docket No. ER07–514–000. |
| NCSU Energy, Inc | Docket No. ER07–177–000. |
| Primary Power Marketing LLC | Docket No. ER98–4333–000. |
| WASP Energy, LLC | Docket No. ER05–1020–000. |

On March 18, 2010, the Commission issued an order announcing its intent to revoke the market-based rate authority of the above captioned public utilities, which had failed to file their required Electric Quarterly Reports.[1] The Commission provided the utilities fifteen days in which to file their overdue Electric Quarterly Reports or face revocation of their market-based rate tariffs.

In Order No. 2001, the Commission revised its public utility filing requirements and established a requirement for public utilities, including power marketers, to file Electric Quarterly Reports summarizing the contractual terms and conditions in their agreements for all jurisdictional services (including market-based power sales, cost-based power sales, and transmission service) and providing transaction information (including rates) for short-term and long-term power sales during the most recent calendar quarter.[2]

In the March 18 Order, the Commission directed G&G Energy, Inc.; NCSU Energy, Inc.; Primary Power Marketing LLC. and WASP Energy, LLC to file the required Electric Quarterly Reports within 15 days of the date of issuance of the order or face revocation of their authority to sell power at market-based rates and termination of their electric market-based rate tariffs.[3]

The time period for compliance with the March 18 Order has elapsed. The four companies identified in the March 18 Order (G&G Energy, Inc.; NCSU

[1] *Electric Quarterly Reports,* 130 FERC ¶ 61,187 (2010) (March 18 Order).

[2] *Revised Public Utility Filing Requirements,* Order No. 2001, 67 FR 31,043, FERC Stats. & Regs. ¶ 31,127, *reh'g denied,* Order No. 2001–A, 100 FERC ¶ 61,074, *reconsideration and clarification denied,* Order No. 2001–B, 100 FERC ¶ 61,342, *order directing filings,* Order No. 2001–C, 101 FERC ¶ 61,314 (2002), *order directing filing,* Order No. 2001–D, 102 FERC ¶ 61,334 (2003).

[3] March 18 Order at Ordering Paragraph A.

Energy, Inc.; Primary Power Marketing LLC. and WASP Energy, LLC) have failed to file their delinquent Electric Quarterly Reports.

The Commission hereby revokes the market-based rate authority and terminates the electric market-based rate tariffs of the above-captioned public utilities.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2010–8580 Filed 4–14–10; 8:45 am]

**BILLING CODE 6717–01–P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Notices

**AGENCY:** Federal Election Commission.

### Cancellation

**DATE AND TIME:** Wednesday, April 14, 2010, at 11 a.m.

**PLACE:** 999 E Street, NW., Washington, DC (Ninth Floor).

**STATUS:** This hearing has been canceled.

**AUDIT HEARING:** Biden For President, Inc.

* * * * *

**DATE AND TIME:** Thursday, April 15, 2010, at 10 a.m.

**PLACE:** 999 E Street, NW., Washington, DC (Ninth Floor).

**STATUS:** This Meeting Will Be Open To The Public.

### Items To Be Discussed

Correction and Approval of Minutes.

Report of the Audit Division on the Tennessee Democratic Party (TDP).

Report of the Audit Division on Friends for Menor Committee.

2010 Rulemaking Schedule.

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Darlene Harris, Acting Commission Secretary, at (202) 694–1040, at least 72 hours prior to the hearing date.

**PERSON TO CONTACT FOR INFORMATION:** Judith Ingram, Press Officer, Telephone: (202) 694–1220.

**Darlene Harris,**

*Acting Secretary of the Commission.*

[FR Doc. 2010–8452 Filed 4–14–10; 8:45 am]

**BILLING CODE 6715–01–M**

## FEDERAL RESERVE SYSTEM

### Federal Open Market Committee; Domestic Policy Directive of March 16, 2010

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on March 16, 2010.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long–run objectives, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to complete the execution of its purchases of about $1.25 trillion of agency MBS and of about $175 billion in housing–related agency debt by the end of March. The Committee directs the Desk to engage in dollar roll transactions as necessary to facilitate settlement of the Federal Reserve's agency MBS transactions. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.

By order of the Federal Open Market Committee, April 8, 2010.

**Brian F. Madigan,**

*Secretary, Federal Open Market Committee.*

[FR Doc. 2010–8593 Filed 4–14–10; 8:45 am]

**BILLING CODE 6210–01–S**

[1] Copies of the Minutes of the Federal Open Market Committee at its meeting held on March 16, 2010, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

## FEDERAL TRADE COMMISSION

### Agency Information Collection Activities; Submission for OMB Review; Comment Request

**AGENCY:** Federal Trade Commission ("FTC" or "Commission").

**ACTION:** Notice and request for comment.

**SUMMARY:** The information collection requirements described below will be submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA"). The FTC is seeking public comments on its proposal to extend through May 31, 2013, the current PRA clearance for information collection requirements contained in its Contact Lens Rule. That clearance expires on May 31, 2010.

**DATES:** Comments must be received on or before May 17, 2010.

**ADDRESSES:** Interested parties are invited to submit written comments electronically or in paper form, by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Comments in electronic form should be submitted by using the following Web link: (*https://public.commentworks.com/ftc/contactlensrulepra2*) (and following the instructions on the web-based form). Comments in paper form should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H–135 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580, in the manner detailed in the **SUPPLEMENTARY INFORMATION** below.

**FOR FURTHER INFORMATION CONTACT:** Requests for copies of the collection of information and supporting documentation should be addressed to Karen Jagielski, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., NJ– 3212, Washington, DC 20580, (202) 326-2509.

**SUPPLEMENTARY INFORMATION:**

### Background

Under the PRA, 44 U.S.C. 3501-3520, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c).

On December 24, 2009, the FTC sought comment on the information collection requirements associated with the Contact Lens Rule (the Rule), 16 CFR part 315. No comments were received. Pursuant to the OMB regulations, 5 CFR Part 1320, that implement the PRA, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule (OMB Control No. 3084-0095). All comments should be filed as prescribed in the **ADDRESSES** section above and in the Request for

Comments (found below), and must be received on or before May 17, 2010.

The Rule was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act ("FCLCA"), Pub. L. 108–164 (December 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires the release and verification of contact lens prescriptions and contains recordkeeping requirements applying to both prescribers and sellers of contact lenses.

Specifically, the Rule requires that prescribers provide a copy of the prescription to the consumer upon the completion of a contact lens fitting and verify or provide prescriptions to authorized third parties. The Rule also mandates that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either: (a) Has received from the patient or prescriber; or (b) has verified through direct communication with the prescriber. In addition, the Rule imposes recordkeeping requirements on contact lens prescribers and sellers. For example, the Rule requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one year. The Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.

The information retained under the Rule's recordkeeping requirements is used by the Commission to substantiate compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

**Request for Comments**

Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to "Contact Lens Rule: FTC File No. P054510" to facilitate the organization of comments. Please note that your comment — including your name and your state — will be placed on the public record of this proceeding, including on the publicly accessible FTC Web site, at (*http://www.ftc.gov/os/publiccomments.shtm*).

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . ," as provided in Section 6(f) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c).

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following Web link: (*https://public.commentworks.com/ftc/contactlensrulepra2*) (and following the instructions on the web-based form). If this Notice appears at (*http://www.regulations.gov*), you may also file an electronic comment through that Web site. The Commission will consider all comments that regulations.gov forwards to it.

A comment filed in paper form should include the "Contact Lens Rule: FTC File No. P054510" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H–135 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

Comments on any proposed recordkeeping, or disclosure requirements that are subject to Paperwork Reduction Act review by the Office of Management and Budget should additionally be submitted to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-5167 because U.S. postal mail at the OMB is subject to delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC's Web site, to the extent practicable, at (*http://www.ftc.gov/os/publiccomments.shtm*). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC's Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at (*http://www.ftc.gov/ftc/privacy.shtm*).

**Burden Statement**

Commission staff estimates the paperwork burden of the FCLCA and Rule based on its knowledge of the eye care industry. Staff believes there will be some burden on individual prescribers to provide contact lens prescriptions, although it involves merely writing a few items of information onto a slip of paper and handing it to the patient, or perhaps mailing or faxing it to a third party. In addition, there will be some recordkeeping burden on contact lens sellers—including retaining prescriptions or records of "direct communications"—pertaining to each sale of contact lenses to consumers who received their original prescription from a third party prescriber.

*Estimated total annual hours burden:* 850,000 hours (rounded to the nearest thousand). Based upon staff knowledge of the industry, this figure is derived by adding approximately 567,000 disclosure hours for contact lens prescribers to approximately 283,000 recordkeeping hours for contact lens sellers, for a combined industry total of 850,000 hours. This is slightly lower than the estimates previously submitted to OMB (the similar figure was 950,000 hours in 2006); and is due to a drop in the estimated number of contact lens wearers from 36 million (2006) to 34 million (2008).

No provisions in the Rule have been amended since staff's prior submission to OMB. The Rule's disclosure and recordkeeping requirements, therefore, remain the same. As noted above, the number of contact lens wearers in the

United States is estimated to be approximately 34 million.[1] Therefore, assuming an annual contact lens exam for each contact lens wearer, 34 million people would receive a copy of their prescription each year under the Rule. At an estimated one minute per prescription, the annual time spent by prescribers complying with the disclosure requirement would be a maximum of 567,000 hours. [(34 million × 1 minute)/60 minutes = 566,667 hours]

As required by the FCLCA, the Rule also imposes two recordkeeping requirements. First, prescribers must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. The OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement. 5 CFR 1320.3(B)(3)(2).

Second, the Rule requires contact lens sellers to maintain certain documents relating to contact lens sales. As noted above, a seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The FCLCA requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

Staff believes that the burden of complying with this requirement is low. Sellers who seek verification of contact lens prescriptions must retain one or two records for each contact lens sale: Either the relevant prescription itself, or the verification request and any response from the prescriber. Staff estimates that such recordkeeping will entail a maximum of five minutes per sale, including time spent preparing a file and actually filing the record(s).

Staff also believes that, based on its knowledge of the industry, this burden will fall primarily on mail order and Internet-based sellers of contact lenses, as they are the entities in the industry most reliant on obtaining or verifying contact lens prescriptions. Based on conversations with the industry, staff estimates that these entities currently account for approximately 10% of sales in the contact lens market[2] and, by extension, that approximately 3.4 million consumers—10% of the 34 million contact lens wearers in the United States—purchase their lenses from them.

At an estimated five minutes per sale to each of 3.4 million consumers, contact lens sellers will spend a total of 283,300 burden hours complying with the recordkeeping requirement. [(3.4 million × 5 minutes)/60 minutes = 283,333.3 hours] This estimate likely overstates the actual burden, however, because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by sellers to the extent that records (*e.g.*, verification requests) are generated and stored automatically and electronically, which staff understands is the case for some larger online sellers.

*Estimated labor costs:* $32,317,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff estimates, based on its knowledge of the industry, that optometrists account for approximately 75% of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2008, salaried optometrists earn an average wage of $50.58 per hour and general office clerical personnel earn an average of $12.90 per hour.[3]

With these categories of personnel, respectively, likely to perform the brunt of the disclosure (for optometrists) and recordkeeping (for office clerks) aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately $32.8 million. [($50.58 × 566,666.7 hours) + ($12.90 × 283,333.3 hours) = $32,317,000]

The contact lens market is a multibillion dollar market; one recent survey estimates that contact lens sales totaled $2.37 billion from Jan 1, 2006 to Dec 31, 2006.[4] Thus, the total labor cost burden estimate of $32.3 million represents approximately 1.5% of the overall market.

*Estimated annual non-labor cost burden:* $0 or minimal.

Staff believes that the Rule's disclosure and recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.*, prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

**Willard Tom,**

*General Counsel.*

[FR Doc. 2010–8647 Filed 4–14–10: 8:45 am]

**BILLING CODE: 6750–01–S**

[1] *See* Contact Lenses, Frequently Asked Questions, Nov. 2009, available at (*http://www.allaboutvision.com/faq/contactlens.htm.*) *See* also Nichols, J. "Annual Report: Contact Lenses 2008," Contact Lens Spectrum, Jan. 2009, available at (*http://www.clspectrum.com/article.aspx?article=102473*).

[2] The FTC's February 2005 study, "The Strength of Competition in the Rx Sale of Contact Lenses: An FTC Study," cites various data that, averaged together, suggests that approximately 10% of contact lens sales are by online and mail-order sellers. The report is available online at (*http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf*).

[3] Mean and median worker hourly wages for optometrists and general office clerks are drawn from the Bureau of Labor Statistics (BLS) Occupational Employment and Statistics Survey, May 2008, based on BLS-sampled data it collected over a 3-year period. See (*http://www.bls.gov/news.release/pdf/ocwage.pdf*) (Table 1).

[4] The Vision Council of America and Jobson Optical Research have conducted large scale continuous consumer research under the name VisionWatch, which reports on the vision care industry. The basis for this statistic is on file with the Federal Trade Commission.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–0371.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities (OMB No. 0915–0281)—Revision**

The AIDS Education and Training Centers (AETC) Program, under the Title XXVI of the Public Health Service Act, as amended, Ryan White HIV/AIDS Program legislation, supports a network

of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects forms on AETC training events, and the centers are required to report aggregate data on their activities to HRSA and the HIV/AIDS Bureau (HAB). This data collection provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by the AETC trainees, and the increase in capacity achieved through training events. Collection of this information allows HRSA and HAB to provide information on training activities and types of education and training provided to Ryan White HIV/AIDS Program Grantees, resource allocation, and capacity expansion.

Trainees are asked to complete the Participant Information Form (PIF) for each activity they complete, and trainers, are asked to complete the Event Record (ER). The estimated annual response burden to trainers as well as attendees of training programs is as follows:

| Form | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| PIF | 116,624 | 1 | 116,624 | 0.167 | 19,476.2 |
| ER | 18,070 | 1 | 18,070 | 0.2 | 3,614 |
| Total | 134,694 | | 134,694 | | 23,090.2 |

The estimated annual burden to AETCs is as follows:

| | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Aggregate data set | 12 | 2 | 24 | 32 | 768 |

The total burden hours are 23,858.2.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: April 7, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–8622 Filed 4–14–10; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 350(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995 Public Law 104–13, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call HRSA Reports Clearance Officer at 301–443–1129.

*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 and; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques of other forms of information technology.

**Proposed Project: Scholarships for Disadvantaged Students Program (OMB No. 0915–0149) Extension**

The Scholarships for Disadvantaged Students (SDS) Program has as its purpose the provision of funds to eligible schools to provide scholarships to full-time students with financial need from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding priorities must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working

in medically underserved communities (section 737(c) of the PHS Act).

The estimated response burden is as follows:

| Form | Number of respondents | Responses per respondents | Hours per response | Total burden hours |
|---|---|---|---|---|
| SDS Application | 600 | 1 | 13 | 7,800 |
| SDS Report | 600 | 1 | 1 | 600 |
| Total | 600 | 1 | 14 | 8,400 |

E-mail comments to *paperwork@hrsa.gov* or mail to the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 6, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–8623 Filed 4–14–10; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0031]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices-Foreign Letters of Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 17, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0264. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Export of Medical Devices-Foreign Letters of Approval (OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of January 26, 2010 (75 FR 4086), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Section of the Federal Food, Drug, and Cosmetic Act | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Operating and Maintenance Costs[2] |
|---|---|---|---|---|---|---|
| 801(e)(2) | 38 | 1 | 38 | 3 | 114 | $6,250 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Due to a clerical error, the operating and maintenance costs that appeared in the notice issued in the FEDERAL REGISTER of January 26, 2010, were reported as zero. The correct figure is in Table 1 of this document.

Dated: April 9, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–8572 Filed 4–14–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Migrant Health.

*Dates and Times:* May 3, 2010, 8:30 a.m. to 5 p.m. May 4, 2010, 8:30 a.m. to 5 p.m.

*Place:* Hard Rock Hotel San Diego, 207 5th Avenue, San Diego, California 92101, Telephone: 619–702–3000, Fax: 877–344–7625.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

The Council meeting is being held in conjunction with the National Farmworker Conference sponsored by the National Association of Community Health Centers, which is being held in San Diego, California, May 5–7, 2010.

Agenda items are subject to change as priorities indicate. **FOR FURTHER INFORMATION CONTACT:** Gladys Cate, Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594–0367.

Dated: April 7, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–8624 Filed 4–14–10; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Privacy Act of 1974; Report of an Altered System of Records

**AGENCY:** Department of Health and Human Services (HHS), Health Resources & Services Administration (HRSA).

**ACTION:** Notice of an Altered System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to alter an existing System of Records. The existing system of records, "State-Provided Physician Records for the Application Submission & Processing System (ASAPS), Office of Shortage Designation (OSD), Bureau of Health Professions (BHPr), HRSA," SORN #09–15–0066, originally published on January 10, 2005, covers health care practitioners who are the subjects of databases collected and maintained by State Primary Care Offices/Associations. Such health care practitioners include physicians (both M.D.s and D.O.s), licensed or otherwise authorized by a State to provide health care services, dentists, and mental health professionals. This State collected data may now also be made available to contractors employed by the OSD to assist in the application review process. The States affected have signed a Data Use Agreement permitting the contractors to have access to their data.

The purposes of these alterations are to update the system manager location, authority for maintenance of the system, categories of individuals covered by the system and categories of records in the system. Additionally, HRSA is adding new routine uses numbers 4 and 5, to include the reviewing and processing assistance from contractors and the breach notification language. This system of records is required to comply with the implementation directives of Section 332 of the Public Health Service Act. The records will be used to support the ASAPS electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is accurate data on the location of health care providers relative to the population. To this end, OSD continually tries to obtain the latest data on primary care, dental, and mental health providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations.

**DATES:** HRSA filed an altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on March 1, 2010. To ensure all parties have adequate time in which to comment, the altered system, including the routine uses, will become effective 30 days from the publication of the notice or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless HRSA receives comments that require alterations to this notice.

**ADDRESSES:** Please address comments to the Application Submission & Processing System (ASAP) System Manager, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8A–08, Rockville, Maryland 20857; telephone (301) 594–4473. This is not a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., (Eastern Standard Time zone), Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Please contact the ASAPS, System Manager, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 8A–08, Rockville, Maryland 20857; telephone (301) 594–4473. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** The following changes/additions are being made to the current System of Records Routine Uses: (4) The Office of Shortage Designation (OSD) has contracted with a vendor to assist OSD in the review and processing of the HPSA and/or MUA/P applications received by the State offices. Such access will only be granted to the contractors with the States' written permission, and all such contractors shall be required to sign a Rules of Behavior document, maintain Privacy Act safeguards with respect to such records, and return all records to HRSA; (5) The SORN will now include specific language to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting

the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance. Also being modified with this Altered System of Records Notice is the room number and program name for the location of the system manager. The room number is being changed from 8C–26 to 8A–08 and the program name is being changed from the Shortage Designation Branch to the Office of Shortage Designation. Lastly, the authority for the maintenance of the system has been changed from 42 CFR, chapter 1, part 5—Designation of Health Professional Shortage Areas and section 332 of the Public Health Service (PHS) Act to just section 332 of the Public Health Service (PHS) Act.

Dated: March 24, 2010.

**Mary K. Wakefield,**

*Administrator.*

**SYSTEM NUMBER: 09–15–0066**

**SYSTEM NAME:**

State-Provided Physician Records for the Application Submission & Processing System, OSD, BHPr, HRSA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

The Application Submission and Processing System (ASAPS) System Manager is located in Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8A–08, Rockville, Maryland 20857. The actual computer server is located in Office of Information Technology, Health Resources and Services Administration, 5600 Fishers Lane, Room 10A–08, Rockville, Maryland 20857.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Health care practitioners who are the subjects of databases collected and maintained by State Primary Care Offices/Associations. Such health care practitioners include physicians (both M.D.s and D.O.s), dentists, and mental health care providers, licensed or otherwise authorized by a State to provide health care services.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The system will include records that show a value for each of the following fields for all of the physicians that are included in each States' database:

- Provider ID (System-Assigned).
- Provider Type.
- Provider Status.
- First Name.
- Middle Name.
- Last Name.
- Suffix.
- Physician License Number.
- Specialty Code.
- Visa Status.
- Federal Employee Status.
- National Health Service Corps Status.
- MD/DO/DDS.
- AMA ID.
- AOA ID.
- Hospital Privileges Status.
- Gender.
- Source Type.
- Address 1.
- Address 2.
- Address 3.
- City.
- State.
- Zip.
- FIPS State.
- FIPS County.
- Census Tract.
- Minor Civil Division.
- Longitude.
- Latitude.
- Address FTE.
- Office Visits (Per Year).
- New Patients Waiting Time For Appointments (days).
- Current Patients Waiting Time For Appointments (days).
- Average Wait for New Patient (hours).
- Average Wait for Current Patient (hours).
- Patient Percent—Homeless.
- Patient Percent—Medicaid.
- Patient Percent—Migrant Farmworker.
- Patient Percent—Native American.
- Patient Percent—Sliding Fee Scale.
- Patient Percent—Language Barrier Present.
- Patient Percent—Migrant/Seasonal Farmworker.
- Patient Percent—Other Population.
- Medicaid Claims.
- Hours Given Include Time Spent in Hospital.
- Accepts New Patients.
- Tour Hours in Direct Patient Care for this Address.
- Sub Specialty.
- Sub Specialty Percent.
- Language 1.
- Language 1 Percent.
- Language 2.
- Language 2 Percent.
- Language 3.
- Language 3 Percent.
- Age/Date of Birth (Dentists only).
- Number of Auxillaries (Dentists only).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 332 of the Public Health Service Act provides that the Secretary of Health and Human Services shall designate health professional shortage areas, or HPSAs, and/or Medically Underserved Populations, or MUPs, based on criteria established by regulation. The authority for designation of HPSAs is delegated to the Bureau of Health Professions Office of Shortage Designation (OSD). Criteria and the process used for designation of HPSAs and/or MUPs were developed in accordance with the requirements of Section 332. Designation as a HPSA is a prerequisite to application for National Health Service Corps recruitment assistance. To accomplish this task, the OSD relies on data specified in 42 CFR Part 5, which implements Section 332, and HPSA and/or MUP guidelines, to review applications submitted by State Primary Care Offices (PCO) and their affiliates for designation status.

**PURPOSE(S):**

The sole purpose of the system is to support the Application Submission and Processing System electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is accurate data on the location of health care providers relative to the population. To this end, Office of Shortage Designation continually tries to obtain the latest data on health care providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Each State Primary Care Office (and a few Primary Care Associations) may have access to provider data within their own State for Medically Underserved Population/Area (MUA/P) and/or Health Professional Shortage Area (HPSA) applications. These users will also have access to bordering States' data (one county-deep) at an aggregate level only.

2. Disclosure may be made to contractors engaged by the Department to geocode the physicians' address so that it may be seen on a computerized map, or to load the provider data into the Application Submission and Processing Systems. All such contractors shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.

3. Disclosure may be made to contractors engaged by the Department to assist OSD in the review and processing of the HPSA and/or MUA/P applications received by the State offices. Such access will only be made with the State's permission (through a Data Use Agreement) and all such contractors shall be required to sign a Rules of Behavior document, maintain Privacy Act safeguards with respect to such records, and return all records to HRSA.

4. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in file folders and in computer data files.

**RETRIEVABILITY:**

Retrieval of physician records is by use of personal identifiers used when entering the system.

**SAFEGUARDS:**

1. *Authorized users:* Access to records is limited to designated HRSA, HRSA hired contractors, and PCO/A staff. These employees are the only authorized users. HRSA maintains current lists of authorized users.

2. *Physical Safeguards:* All computer equipment and files are stored in areas where fire and life safety codes are strictly enforced. All automated and non-automated documents are protected on a 24-hour basis. Perimeter security includes intrusion alarms, on-site guard force, random guard patrol, key/passcard/combination controls, and receptionist controlled area. Hard copy files are maintained in a file room used solely for this purpose with access limited by combination lock to authorized users identified above. Computer files are password protected and are accessible only by use of computers which are password protected.

3. *Procedural Safeguards:* A password is required to access computer files. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised area. All authorized users sign a "Rules of Behavior" document. All passwords, keys and/or combinations are changed when a person leaves or no longer has authorized duties. Access to records is limited to those authorized personnel trained in accordance with the Privacy Act and ADP security procedures. The safeguards described above were established in accordance with DHHS Chapter 45–13 and supplementary chapter PHS hf:45–13 of the General Administration Manual; and the DHHS Information Resources Management Manual, Part 6, "ADP Systems Security."

**RETENTION AND DISPOSAL:**

HRSA is working with the Records Officer and NARA to obtain the appropriate retention value.

**SYSTEM MANAGER(S) AND ADDRESS:**

Application Submission & Processing System System Manager, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8A–08, Rockville, Maryland 20857.

**NOTIFICATION PROCEDURE:**

Write to the Application Submission & Processing System System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a fine.

**RECORD ACCESS PROCEDURE:**

To obtain access to a record, contact the Application Submission and Processing System (ASAPS) System Manager at the address specified above. Requesters should provide the same information as is required under the Notification Procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under Notification Procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, incorrect, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Data are collected from the State Primary Care Offices and a few State Primary Care Associations.

[FR Doc. 2010–8620 Filed 4–14–10; 8:45 am]

**BILLING CODE 4160–15–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection Agency Information Collection Activities: Customs-Trade Partnership Against Terrorism (C–TPAT)

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; extension of an existing information collection: 1651–0077.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Customs-Trade Partnership Against Terrorism (C–TPAT). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (75 FR 6678) on February 10, 2010, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before May 17, 2010.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

**SUPPLEMENTARY INFORMATION:** U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information

collection requests pursuant to the Paperwork Reduction Act (Pub. L.104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

*Title:* Customs-Trade Partnership Against Terrorism (C–TPAT).

*OMB Number:* 1651–0077.

*Form Number:* None.

*Abstract:* The Customs-Trade Partnership Against Terrorism (C–TPAT) Program is designed to provide expedited processing to participants in this Program at certain, high-risk locations by prescreening participants. The C–TPAT Program applies to air, land and sea. This Program was mandated by the SAFE Port Act. This information collection is an on-line application that must be completed by companies or individuals wishing to participate in the C–TPAT program. This application can be found on *www.cbp.gov.*

*Current Actions:* There are no changes to the information collection. This submission is being made to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses, Individuals.

*Estimated Number of Respondents:* 6,500.

*Estimated Time per Respondent:* 5 hours.

*Estimated Total Annual Burden Hours:* 32,500.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

Dated: April 12, 2010.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2010–8632 Filed 4–14–10; 8:45 am]

BILLING CODE 9111–14–P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[Docket No. USCBP–2010–0013]**

### Notice of Meeting of the Advisory Committee on Commercial Operations of Customs and Border Protection (COAC)

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security (DHS).

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The Advisory Committee on Commercial Operations of U.S. Customs and Border Protection (COAC) will meet on May 11, 2010 in Philadelphia, Pennsylvania. The meeting will be open to the public.

**DATES:** COAC will meet Tuesday, May 11, 2010 from 1 p.m.–5 p.m. Please note that the meeting may close early if the committee completes its business. If you plan on attending, please register either online at *https://apps.cbp.gov/te_registration/?w=18,* or by e-mail to *tradeevents@dhs.gov* by close-of-business on May 6, 2010.

**ADDRESSES:** The meeting will be held at the Loews Philadelphia Hotel, 1200 Market Street, Regency Ballroom A, Philadelphia, Pennsylvania 19107. The public is invited to submit comments and/or written material on any of the identified agenda items as set forth below. Please note that any comments or written materials that are mailed should reach the contact person at the address listed below before May 6, 2010, so that copies of your submitted materials can be distributed to committee members prior to the meeting. Comments must be identified by USCBP–2010–0013 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: tradeevents@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* 202–325–4290.
- *Mail:* Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, 1300 Pennsylvania Avenue, NW.; Room 5.2–A, Washington, DC 20229.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received by COAC, go to *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, 1300 Pennsylvania Avenue, NW., Room 5.2–A, Washington, DC 20229; *tradeevents@dhs.gov;* telephone 202–344–1440; facsimile 202–325–4290.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Federal Advisory Committee Act (5 U.S.C. App.), DHS hereby announces the meeting of the Advisory Committee on Commercial Operations of Customs and Border Protection (COAC). COAC is tasked with providing advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within DHS or the Department of the Treasury.

The fifth meeting of the eleventh term of COAC will be held at the date, time and location specified above. A tentative agenda for the meeting is set forth below.

**Tentative Agenda**

1. Importer Security Filing ("10+2").
2. Intellectual Property Rights Enforcement Subcommittee.
3. Agriculture Subcommittee.
4. Air Cargo Security Subcommittee.
5. Automation Subcommittee.
6. Import Safety.
7. Bond Subcommittee.
8. Trade Facilitation Subcommittee.

**Procedural**

This meeting is open to the public; however, participation in COAC deliberations is limited to committee members, Department of Homeland Security officials, and persons invited to attend the meeting for special presentations. Please note that the meeting may close early if all business is finished.

All visitors must check-in at the Loews Philadelphia Hotel at the Regency Ballroom A with CBP officials at the registration desk.

Since seating is limited, all persons attending this meeting should provide

notice by close-of-business on May 6, 2010, by registering online at *https://apps.cbp.gov/te_registration/?w=18* or, alternatively, by contacting Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, Department of Homeland Security, 1300 Pennsylvania Avenue, NW., Washington, DC 20229; *tradeevents@dhs.gov;* telephone 202–344–1440; facsimile 202–325–4290.

**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate as soon as possible.

Dated: April 9, 2010.

**Kimberly Marsho,**

*Director, Office of Trade Relations, U.S. Customs and Border Protection.*

[FR Doc. 2010–8597 Filed 4–14–10; 8:45 am]

BILLING CODE 9111–14–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLNV952000 L14200000.BJ0000 241A; 10–08807; MO# 4500012873; TAS: 14X1109]**

### Filing of Plats of Survey; Nevada

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The purpose of this notice is to inform the public and interested State and local government officials of the filing of Plats of Survey in Nevada.

**DATES:** *Effective Dates:* Filing is effective at 10 a.m. on the dates indicated below.

**FOR FURTHER INFORMATION CONTACT:** David D. Morlan, Chief, Branch of Geographic Sciences, Bureau of Land Management (BLM), Nevada State Office, 1340 Financial Blvd., P.O. Box 12000, Reno, Nevada 89520, 775–861–6541.

**SUPPLEMENTARY INFORMATION:**

1. The Plats of Survey of the following described lands were officially filed at the Nevada State Office, Reno, Nevada, on February 4, 2010:

The plat, in two (2) sheets, representing the dependent resurvey of a portion of the east boundary and a portion of the subdivisional lines, the subdivision of section 12 and metes-and-bounds surveys of the easterly and westerly right-of-way lines of the Nevada Northern Railway through section 1 and a portion of section 12, Township 18 North, Range 63 East, Mount Diablo Meridian, Nevada, under Group No. 840, was accepted February 2, 2010.

The plat, in five (5) sheets, representing the dependent resurvey of portions of the south and north boundaries and a portion of the subdivisional lines, metes-and-bounds surveys of Tracts 37 and 38, and metes-and-bounds surveys of the easterly and westerly right-of-way lines of the Nevada Northern Railway through sections 1, 12, 13, 24, 25 and 36, Township 19 North, Range 63 East, Mount Diablo Meridian, Nevada, under Group No. 840, was accepted February 2, 2010.

These surveys were executed to meet certain administrative needs of the Bureau of Land Management.

2. The Plat of Survey of the following described lands was officially filed at the Nevada State Office, Reno, Nevada, on February 19, 2010:

The plat, in six (6) sheets, representing the dependent resurvey of the Fourth Standard Parallel North, through a portion of Range 63 East, a portion of the east boundary and a portion of the subdivisional lines, the subdivision of sections 24 and 25, and metes-and-bounds surveys of portions of the easterly and westerly right-of-way lines of the Nevada Northern Railway, Township 20 North, Range 63 East, Mount Diablo Meridian, Nevada, under Group No. 856, was accepted February 18, 2010.

This survey was executed to meet certain administrative needs of the Bureau of Land Management.

3. The above-listed surveys are now the basic record for describing the lands for all authorized purposes. These surveys have been placed in the open files in the BLM Nevada State Office and are available to the public as a matter of information. Copies of the surveys and related field notes may be furnished to the public upon payment of the appropriate fees.

Dated: April 7, 2010.

**David D. Morlan,**

*Chief Cadastral Surveyor, Nevada.*

[FR Doc. 2010–8602 Filed 4–14–10; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS-R9-IA-2010-N079]**

**[96300-1671-0000-P5]**

### 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 a Federal permit is issued that allows such activities. The ESA laws require that we invite public comment before issuing these permits.

**DATES:** We must receive requests for documents or comments on or before May 17, 2010.

**ADDRESSES:** Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358-2280; or e-mail *DMAFR@fws.gov*.

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2280 (fax); *DMAFR@fws.gov* (e-mail).

**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 e-mail 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 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, e-mail 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, the Endangered Species Act of 1973, section 10(a)(1)(A), as amended (16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 17 require that we invite public comment before final action on these permit applications.

III. Permit Applications

**Applicant: Jean Dubach, Ph.D., Wildlife Genetics Lab, Loyola University Medical Center, Maywood, IL; PRT-06638A**

The applicant requests a permit to import biological specimens from up to 4 captive held Sumatran orangutans (*Pongo abelii*) from the Toronto Zoo, Ontario, Canada, for the purpose of enhancement of the survival of the species.

**Applicant: New England Wild Flower Society (NEWFS), Framingham, MA;**

**PRT-06998A**

The applicant requests a permit to export leaf cuttings from Jesup's milk-vetch (*Astragalus robbinsii var. jesupi*) to the Canadian Museum of Nature, Ottawa, Ontario, Canada for the purpose of enhancement of the species through scientific research. This notification covers activities conducted by the applicant for a 5–year period.

**Applicant: Western Connecticut State University, Danbury, CT; PRT-234773**

The applicant requests a permit to import blood samples from Olive Ridley sea turtles (*Lepidochelys olivacea*), obtained from six wild females for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5–year period.

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: Wilton Hardesty, Okmulgee, OK; PRT-07800A**

**Applicant: Roger Jarvis, Cypress, TX; PRT-07801A**

Dated: April 09, 2010

**Brenda Tapia**

*Program Analyst, Branch of Permits, Division of Management Authority*

[FR Doc. 2010–8651 Filed 4–14–10; 8:45 am]

**BILLING CODE 4310–55–S**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–149 (Third Review)]**

## Barium Chloride From China

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice of Commission determination to conduct a full five-year review concerning the antidumping duty order on barium chloride from China.

**SUMMARY:** The Commission hereby gives notice that it will proceed with a full review pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) to determine whether revocation of the antidumping duty order on barium chloride from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the review will be established and announced at a later date. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

**DATES:** *Effective Date:* October 5, 2009.

**FOR FURTHER INFORMATION CONTACT:** Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:** On October 5, 2009, the Commission determined that it should proceed to a full review in the subject five-year review pursuant to section 751(c)(5) of the Act. The Commission found that the domestic interested party group response to its notice of institution (74 FR 31757, July 2, 2009) was adequate and that the respondent interested party group response was inadequate. The Commission also found that other circumstances warranted conducting a full review.[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

**Authority:** This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 14, 2009.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

**Editorial Note:** This document was received in the Office of the Federal Register on April 9, 2010.

[FR Doc. 2010–8568 Filed 4–14–10; 8:45 am]

**BILLING CODE 7020–02–P**

[1] Commissioners Charlotte R. Lane, Irving A. Williamson, and Dean A. Pinkert found that no other circumstances warranted conducting a full review and voted for an expedited review.

## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 731–TA–776–779 (Second Review)]**

### Preserved Mushrooms From Chile, China, India, and Indonesia; Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (Commission) determines, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), that revocation of the antidumping duty orders on preserved mushrooms from Chile, China, India, and Indonesia would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

**Background**

The Commission instituted these reviews on October 1, 2009 (74 FR 50818) and determined on January 4, 2010 that it would conduct expedited reviews (75 FR 3756, January 22, 2010).

The Commission transmitted its determinations in these reviews to the Secretary of Commerce on April 9, 2010. The views of the Commission are contained in USITC Publication 4135 (April 2010), entitled *Preserved Mushrooms from Chile, China, India, and Indonesia: Investigation Nos. 731–TA–776–779 (Second Review).*

By order of the Commission.

Issued: April 9, 2010.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. 2010–8598 Filed 4–14–10; 8:45 am]

**BILLING CODE 7020–02–P**

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

[2] Vice Chairman Daniel R. Pearson determines that revocation of the antidumping duty order on preserved mushrooms from Indonesia would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

## INTERNATIONAL TRADE COMMISSION

**[USITC SE–10–009]**

### Government in the Sunshine Act Meeting Notice

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** April 21, 2010, at 9:30 a.m.

**PLACE:** Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205–2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agenda for future meetings: none.
2. Minutes.
3. Ratification List.
4. Inv. No. 731–TA–1070A (Review) (Crepe Paper Products from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before April 30, 2010.)
5. Outstanding action jackets:

(1) Document No. GC–10–028 concerning Inv. No. 337–TA–644 (Certain Composite Wear Components and Products Containing Same).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier announcement of this meeting was not possible.

Issued: April 12, 2010.

By order of the Commission.

**William R. Bishop,**

*Hearings and Meetings Coordinator.*

[FR Doc. 2010–8697 Filed 4–13–10; 11:15 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[OMB Number 1117–0042]**

### Agency Information Collection Activities: Proposed Collection; Comments Requested: National Clandestine Laboratory Seizure Report

**ACTION:** 60-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), 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. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until June 14, 2010. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Clark R. Fleming, Field Division Counsel, El Paso Intelligence Center, 11339 SSG Sims Blvd., El Paso, TX 79908.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies 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.

**Overview of Information Collection 1117–0042**

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* National Clandestine Laboratory Seizure Report.

(3) *Agency form number, if any and the applicable component of the Department sponsoring the collection:*

*Form number:* EPIC Form 143.

*Component:* El Paso Intelligence Center, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* State, Local or Tribal Government.

*Other:* None.

*Abstract:* Records in this system are used to provide clandestine laboratory seizure information to the El Paso Intelligence Center, Drug Enforcement Administration, and other Law enforcement agencies, in the discharge of their law enforcement duties and responsibilities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are one thousand twenty-seven (1027) total respondents for this information collection. Three thousand seven hundred fifty-four (3754) responded using paper at 1 hour a response and five thousand four

hundred seven (5407) responded electronically at 1 hour a response, for nine thousand one hundred sixty-one (9161) annual responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that there are 9161 annual burden hours associated with this collection.

*If additional information is required contact:* Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 12, 2010.

**Lynn Bryant,**

*Department Clearance Officer, PRA, U.S. Department of Justice.*

[FR Doc. 2010–8633 Filed 4–14–10; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

**[OMB Number 1121–NEW]**

### Bureau of Justice Assistance; Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 60-Day Notice of Information Collection Under Review: New Collection Bureau of Justice Assistance Application Form: Federal Law Enforcement Officers Congressional Badge of Bravery.

The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, will be submitting the following information collection request to the Office of Management and Budget for review and clearance in accordance with the Paperwork Reduction Act of 1995. This proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until June 14, 2010. If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact M. Berry at 202–616–6500/1–866–268–0079, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice, 810 7th Street, NW., Washington, DC 20531 via facsimile at 202–305–1367 or by e-mail at *M.A.Berry@ojp.usdoj.gov.*

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—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.

### Overview of This Information Collection

(1) *Type of information collection:* New collection.

(2) *The title of the form/collection:* Federal Law Enforcement Officers Congressional Badge of Bravery.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection: None.* Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* Law Enforcement officials.

*Abstract:* The information collected on this application will provide for the nomination of law enforcement officers for the Federal, and the State and Local Congressional Badge of Bravery awards. The awards will recognize law enforcement officers who (1) were injured while engaged in lawful duties and performing an act of bravery that put such officer at personal risk; or (2) though not injured; performed an act of bravery that placed such officer at risk of serious physical injury or death.

*Others:* None.

(5) *An estimate of the total number of respondents and the amount of time needed for an average respondent to respond is as follows:* An estimated 200 applications/nominations for each Board has been adopted from a similar awards program and will be used for the Federal Law Enforcement Officers Congressional Badge of Bravery. The applicant should take approximately 25 minutes to gather the required information and complete the form. Actual preparation time is dependent on the number of nominees per application.

(5) An estimate of the total public burden (in hours) associated with the collection is 83 hours.

*Total Annual Reporting Burden:* 200 × 25 minutes = 5,000 minutes/60 = 83.33 hours for each award category.

If additional information is required, please contact, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 12, 2010.

**Lynn Bryant,**

*Department Clearance Officer, PRA, United States Department of Justice.*

[FR Doc. 2010–8635 Filed 4–14–10; 8:45 am]

BILLING CODE 4410–18–P

## DEPARTMENT OF LABOR

### Office of the Secretary of Labor

### Request for Information on Business Practices To Reduce the Likelihood of Forced Labor or Child Labor in the Production of Goods

**AGENCY:** Bureau of International Labor Affairs, Labor.

**ACTION:** Request for information.

**SUMMARY:** The Department of Labor (DOL) is seeking information on current practices of firms, business associations, and other private sector groups to reduce the likelihood of child labor and forced labor in the production of goods. This information will aid DOL in fulfilling its mandate under the Trafficking Victims Protection Reauthorization Act of 2005 to work with persons who are involved in the production of goods made with forced labor or child labor to create a standard set of practices that will reduce the likelihood that such persons will produce goods using such labor.

**DATES:** Information should be submitted to the Office of Child Labor, Forced Labor and Human Trafficking (OCFT) within the Bureau of International Labor Affairs (ILAB) via one of the methods described below by 5 p.m., on June 14, 2010.

*To Submit Information, or for Further Information, Contact:* ILAB/OCFT, U.S. Department of Labor, at (202) 693–4843 (this is not a toll free number). Comments, identified as "Docket No. DOL–2010–0002," may be submitted by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* The portal

includes instructions for submitting comments. Parties submitting responses electronically are encouraged not to submit paper copies.

• *Facsimile (fax):* OCFT at 202–693–4830.

• *Mail, Express Delivery, Hand Delivery, and Messenger Service (2 copies):* Charita Castro or Rachel Rigby at U.S. Department of Labor, ILAB/OCFT, 200 Constitution Avenue, NW., Room S–5317, Washington, DC 20210. Note that security-related screening may result in significant delays in receiving materials by regular mail.

• *E-mail: ilab-tvpra@dol.gov.*

All submissions should clearly identify the person and/or organization filing the submission and should be signed and dated.

In addition to these formal submission methods, the public will be able to view this notice via DOL's Facebook page at *http://www.facebook.com/departmentoflabor* and Twitter account at *http://twitter.com/usdol*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 105(b)(1) of the Trafficking Victims Protection Reauthorization Act of 2005 ("TVPRA of 2005"), Public Law 109–164 (2006), directed the Secretary of Labor, acting through the Bureau of International Labor Affairs, to "carry out additional activities to monitor and combat forced labor and child labor in foreign countries." Section 105(b)(2) of the TVPRA of 2005, 22 U.S.C. 7112(b)(2), listed these activities as:

(A) Monitor the use of forced labor and child labor in violation of international standards;

(B) Provide information regarding trafficking in persons for the purpose of forced labor to the Office to Monitor and Combat Trafficking of the Department of State for inclusion in [the] trafficking in persons report required by section 110(b) of the Trafficking Victims Protection Act of 2000 (22 U.S.C. 7107(b));

(C) Develop and make available to the public a list of goods from countries that the Bureau of International Labor Affairs has reason to believe are produced by forced labor or child labor in violation of international standards;

(D) Work with persons who are involved in the production of goods on the list described in subparagraph (C) to create a standard set of practices that will reduce the likelihood that such persons will produce goods using the labor described in such subparagraph; and

(E) Consult with other departments and agencies of the United States Government to reduce forced and child labor internationally and ensure that products made by forced labor and child labor in violation of international standards are not imported into the United States.

Pursuant to part (D) of the TVPRA of 2005 mandate, ILAB is seeking information on current practices of firms, business associations, and other private sector groups to reduce the likelihood of child labor and forced labor in the production of goods. Many firms have policies, activities and/or systems in place to monitor labor rights in their supply chains and remediate violations. Such policies, activities and systems vary depending on location, industry, and many other factors. ILAB seeks to identify practices that have been effective in specific contexts, analyze their replicability, and disseminate those that have potential to be effective on a broader scale. For further details see the "Information Requested" section of this notice.

## II. Definitions of Forced Labor and Child Labor

"Child Labor"—"Child labor" under international standards means all work performed by a person below the age of 15. It also includes all work performed by a person below the age of 18 in the following practices:

(A) All forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and serfdom, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict;

(B) The use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes;

(C) The use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and

(D) Work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children. The work referred to in subparagraph (D) is determined by the laws, regulations, or competent authority of the country involved, after consultation with the organizations of employers and workers concerned, and taking into consideration relevant international standards. This definition will not apply to work specifically authorized by national laws, including work done by children in schools for general, vocational or technical education or in other training institutions, where such work is carried out in accordance with international standards under conditions prescribed by the competent authority, and does not prejudice children's attendance in school or their capacity to benefit from the instruction received.

"Forced Labor"—"Forced labor" under international standards means all work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily, and includes indentured labor. "Forced labor" includes work provided or obtained by force, fraud, or coercion, including:

(1) By threats of serious harm to, or physical restraint against any person;

(2) By means of any scheme, plan, or pattern intended to cause the person to believe that, if the person did not perform such labor or services, that person or another person would suffer serious harm or physical restraint; or

(3) By means of the abuse or threatened abuse of law or the legal process. For purposes of this definition, forced labor does not include work specifically authorized by national laws where such work is carried out in accordance with conditions prescribed by the competent authority, including: any work or service required by compulsory military service laws for work of a purely military character; work or service which forms part of the normal civic obligations of the citizens of a fully self-governing country; work or service exacted from any person as a consequence of a conviction in a court of law, provided that the said work or service is carried out under the supervision and control of a public authority and that the said person is not hired to or placed at the disposal of private individuals, companies or associations; work or service required in cases of emergency, such as in the event of war or of a calamity or threatened calamity, fire, flood, famine, earthquake, violent epidemic or epizootic diseases, invasion by animal, insect or vegetable pests, and in general any circumstance that would endanger the existence or the well-being of the whole or part of the population; and minor communal services of a kind which, being performed by the members of the community in the direct interest of the said community, can therefore be considered as normal civic obligations incumbent upon the members of the community, provided that the members of the community or their direct representatives have the right to be consulted in regard to the need for such services.

## III. Information Requested

ILAB is seeking general information on the practices of business entities to

reduce the likelihood of child labor and forced labor in the production of goods. ILAB welcomes any and all information, which could include, *e.g.,* codes of conduct, standards used to implement such codes of conduct, auditing/monitoring systems, supply-chain management practices designed to monitor informal workplaces, homework, and other challenging work environments, training modules, reporting practices, collaborative practices and strategies, grassroots projects, or other relevant information. ILAB is also seeking information on government practices to collaborate with private sector entities to reduce child labor and forced labor in the production of goods. Submissions may include documents in various formats, such as policy statements, reports, and case studies. However, the specific format of any submission is not important provided that the document presents and/or evaluates practices implemented by business entities, or governments in partnership with business entities, to reduce the likelihood of child labor and forced labor in the production of goods.

Information should be submitted to the addresses and within the time period set forth above. DOL seeks information that can be used to inform the development of tools and resources to be disseminated publicly on the DOL Web site and/or in other publications. Internal documents or confidential documents that cannot be shared with the public will not be used. Submissions containing confidential or personal information may be redacted by DOL before being made available to the public, in accordance with applicable laws and regulations. DOL does not intend to respond directly to a submission or to return a submission to a submitter, but DOL may communicate with the submitter regarding any matters relating to the submission.

DOL will compile and analyze submissions pursuant to this Notice, and of many other practices as described above, in coordination with a contractor, the Center for Reflection, Education, and Action (CREA). For more information about CREA's contract with DOL, or to discuss relevant practices directly with CREA, please contact Project Director Ruth Rosenbaum at *ruth_rosenbaum@crea-inc.org.*

Signed at Washington, DC this 12th day of April, 2010.

**Sandra Polaski,**

*Deputy Undersecretary, Bureau of International Labor Affairs.*

[FR Doc. 2010–8642 Filed 4–14–10; 8:45 am]

BILLING CODE 4510–28–P

## OFFICE OF MANAGEMENT AND BUDGET

### Determination of Benchmark Compensation Amount for Certain Executives

**AGENCY:** Office of Federal Procurement Policy, OMB.

**ACTION:** Notice.

**SUMMARY:** The Office of Management and Budget is publishing the attached memorandum to the Heads of Executive Departments and Agencies concerning the determination of the benchmark compensation amount for certain executives that will be allowable under Government contracts during contractors' Fiscal Year 2010—$693,951. This determination is required under Section 39 of the Office of Federal Procurement Policy Act, 41 U.S.C. 435, as amended. The benchmark compensation amount applies equally to both defense and civilian procurement agencies.

**FOR FURTHER INFORMATION CONTACT:** Raymond Wong, Office of Federal Procurement Policy, Office of Management and Budget, telephone at 202–395–6805 and *e-mail: rwong@omb.eop.gov.*

**Daniel I. Gordon,**

*Administrator, Office of Federal Procurement Policy.*

### Memorandum for the Heads of Executive Departments and Agencies

*From:* Daniel I. Gordon, Administrator, Office of Federal Procurement Policy.

*Subject:* Determination of Benchmark Compensation Amount for Certain Executives, Pursuant to Section 39 of the Office of Federal Procurement Policy Act, 41 U.S.C. 435, as amended.

This memorandum sets forth the benchmark compensation amount for certain executives as required by Section 39 of the Office of Federal Procurement Policy (OFPP) Act, as amended. Under Section 39, the benchmark compensation amount for certain executives is the median amount of the compensation provided for all senior executives of all benchmark corporations for the most recent year for which data is available. The benchmark compensation benchmark amount for certain executives established by Section 39 limits the allowability of compensation costs under Government contracts as implemented at FAR 31.205–6(p), limiting the amount of reimbursable executive compensation. The benchmark compensation amount for certain executives does not limit the compensation that an executive may otherwise receive. This amount is based upon a review of commercially available surveys of executive compensation that analyze the relevant data made available by the Securities and Exchange Commission. More specifically, as required by Section 39 of the OFPP Act, the determination is made on the median (50th percentile) amount of compensation over a recent 12-month period for the five most highly compensated employees in management positions at each home office and each segment of all publicly-owned companies with annual sales over $50 million. Compensation for the fiscal year means the total amount of wages, salary, bonuses and deferred compensation for the year, whether paid, earned, or otherwise accruing, as recorded in the employer's cost accounting records for the year. After consultation with the Director of the Defense Contract Audit Agency, we have determined pursuant to the requirements of Section 39 that the benchmark compensation amount for certain executives for the contractors' Fiscal Year (FY) 2010 is $693,951. This amount is for contractors' FY 2010 and subsequent contractor fiscal years, unless and until revised by OFPP. The benchmark compensation amount for certain executives applies to contract costs incurred after January 1, 2010, under covered contracts of both the defense and civilian procurement agencies as specified in Section 39 of the OFPP Act, 41 U.S.C. 435, as amended.

Questions concerning this memorandum may be addressed to Raymond Wong, OFPP, at 202–395–6805.

[FR Doc. 2010–8641 Filed 4–14–10; 8:45 am]

BILLING CODE P

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (10–044)]**

### NASA Advisory Council; Science Committee; Planetary Protection Subcommittee; Meeting

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Protection Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

**DATES:** Thursday, May 13, 2010, 9 a.m. to 4:30 p.m., and Friday, May 14, 2010, 9 a.m. to 4 p.m. EDT.

**ADDRESSES:** NASA Headquarters, 300 E Street, SW., Room 3H46, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

—Review European Space Agency-NASA Coordination on Planetary Protection.
—Update on National Research Council Studies on Planetary Protection.
—Implications for Planetary Protection of Changes in the Human Spaceflight Program.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at *mnorris@nasa.gov* or by telephone at (202) 358–4452.

Dated: April 12, 2010.

**P. Diane Rausch,**

*Advisory Committee Management Officer, National Aeronautics and Space Administration.*

[FR Doc. 2010–8659 Filed 4–14–10; 8:45 am]

**BILLING CODE 7510–13–P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (10–043)]**

### Aerospace Safety Advisory Panel; Meeting

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announce a forthcoming meeting of the Aerospace Safety Advisory Panel.

**DATES:** Friday, April 30, 2010, 12:30 p.m. to 2:30 p.m.

**ADDRESSES:** NASA Headquarters, 300 E. Street, SW., Room 9H40, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kathy Dakon, Aerospace Safety Advisory Panel Executive Director, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–0732.

**SUPPLEMENTARY INFORMATION:** The Aerospace Safety Advisory Panel will hold its 2nd Quarterly Meeting for 2010. This discussion is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The agenda will include: Space Shuttle and International Space Station Updates; Commercial Space; Mishap Investigation Process and Metrics; Industrial Safety Metrics.

The meeting will be open to the public up to the seating capacity of the room. Seating will be on a first-come basis. Photographs will only be permitted during the first 10 minutes of the meeting. During the first 30 minutes of the meeting, members of the public may make a 5-minute verbal presentation to the Panel on the subject of safety in NASA. To do so, please contact Ms. Susan Burch at *susan.burch@nasa.gov* at least 48 hours in advance. Any member of the public is permitted to file a written statement with the Panel at the time of the meeting. Verbal presentations and written comments should be limited to the subject of safety in NASA. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Susan Burch via e-mail at *susan.burch@nasa.gov* or by telephone at (202) 358–0550. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: April 9, 2010.

**P. Diane Rausch,**

*Advisory Committee Management Officer, National Aeronautics and Space Administration.*

[FR Doc. 2010–8569 Filed 4–14–10; 8:45 am]

**BILLING CODE P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Advisory Committee on Presidential Libraries Meeting

**AGENCY:** National Archives and Records Administration.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on Presidential Libraries. The meeting will be held to discuss the Presidential Library program and topics related to the public-private partnership between the Presidential Libraries and their Presidential Foundations.

**DATES:** The meeting will be held on May 11, 2010 from 10 a.m. to 1 p.m.

**ADDRESSES:** Southern Methodist University, Hughes Trigg Student Center, 3140 Dyer Street, Ballroom West, Dallas, Texas 75206.

**FOR FURTHER INFORMATION CONTACT:** Sharon Fawcett, Assistant Archivist for Presidential Libraries, at the National Archives and Records Administration, 8601 Adelphi Road, College Park, Maryland 20740, telephone number (301) 837–3250. Contact the Presidential Libraries staff at *Kathleen.mead@nara.gov*.

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public. Meeting attendees may park at the Binkley Parking Garage, located at 3101 Binkley Ave. The garage's hourly rates will apply.

Dated: April 12, 2010.

**Mary Ann Hadyka,**

*Committee Management Officer.*

[FR Doc. 2010–8787 Filed 4–14–10; 8:45 am]

**BILLING CODE 7515–01–P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Records Schedules; Availability and Request for Comments

**AGENCY:** National Archives and Records Administration (NARA).

**ACTION:** Notice of availability of proposed records schedules; request for comments.

**SUMMARY:** The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

**DATES:** Requests for copies must be received in writing on or before May 17, 2010. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

**ADDRESSES:** You may request a copy of any records schedule identified in this notice by contacting the Life Cycle Management Division (NWML) using one of the following means:

*Mail:* NARA (NWML), 8601 Adelphi Road, College Park, MD 20740–6001.

*E-mail: request.schedule@nara.gov.*

*Fax:* 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

**FOR FURTHER INFORMATION CONTACT:** Laurence Brewer, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1539. E-mail: *records.mgt@nara.gov.*

**SUPPLEMENTARY INFORMATION:** Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless specified otherwise. An item in a schedule is media neutral when the disposition instructions may be applied to records regardless of the medium in which the records are created and maintained. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is limited to a specific medium. (See 36 CFR 1225.12(e).)

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

**Schedules Pending**

1. Department of the Army, Agency-wide (N1–AU–10–1, 1 item, 1 temporary item). Master files of an electronic information system that contains information on military family members enrolled in special needs programs. Included are eligibility documentation, evaluations, and treatment plans.

2. Department of the Army, Agency-wide (N1–AU–10–14, 1 item, 1 temporary item). Master files of an electronic information system that is used to account for the status of Army personnel and their families following a natural or man-made disaster.

3. Department of Defense, Defense Logistics Agency (N1–361–10–1, 2 items, 2 temporary items). Master files and outputs of a web-based electronic information system used by agencies to order goods and services.

4. Department of Health and Human Services, Office of the Secretary (N1–468–09–1, 2 items, 2 temporary items). Master files of a learning management system that contains agency training course materials and student training records.

5. Department of Homeland Security, U.S. Customs and Border Protection (N1–568–09–2, 1 item, 1 temporary item). Master files of an electronic information system used for inventory management and tracking maintenance and repair activities relating to agency marine vessels.

6. Department of Homeland Security, U.S. Customs and Border Protection (N1–568–09–3, 1 item, 1 temporary item). Master files of an electronic information system used to process permit applications and fees for multiple border crossings.

7. Department of Homeland Security, U.S. Customs and Border Protection (N1–568–09–5, 1 item, 1 temporary item). Master files of an electronic information system that contains images of cars, trucks, packages, luggage and their contents that is used at ports of entry into the United States to detect contraband.

8. Department of Housing and Urban Development, Office of the Chief Information Officer (N1–207–09–2, 1 item, 1 temporary item). Master files of an electronic information system used to analyze the agency's baseline and target enterprise architecture.

9. Department of the Interior, National Business Center (N1–48–09–9, 2 items, 2 temporary items). Case files accumulated by the Federal Consulting Group which provides consulting services, such as executive coaching and leadership assessment, aimed at overcoming organizational challenges. Also included are reports generated for clients from the American Customer Satisfaction Index.

10. Department of Justice, Office of the Inspector General (N1–60–09–72, 1 item, 1 temporary item). Master files of an electronic information system used for management and tracking of audits.

11. Department of Justice, Bureau of Prisons (N1–129–09–26, 1 item, 1 temporary item). Master files of an electronic information system used to track budget allocations and spending.

12. Department of Justice, Bureau of Prisons (N1–129–09–27, 1 item, 1 temporary item). Master files of an electronic information system used to track contracts with outside specialists involved in drug abuse treatment programs.

13. Department of Justice, Bureau of Prisons (N1–129–09–28, 1 item, 1 temporary item). Master files of an electronic information system which contains data relating to the construction of new facilities during the pre-construction phase.

14. Board of Governors of the Federal Reserve System, Agency-wide (N1–82–09–2, 9 items, 4 temporary items). Web site records relating to nominees for the agency's Consumer Advisory Council, including data on nominees and Web-generated letters confirming receipt of nominations and rejections of nominees. Also included are data files summarized or extracted from research function data bases. Proposed for permanent retention are master files and reports associated with an electronic information system that contains data gathered by multiple Federal agencies in connection with the Community Reinvestment Act.

15. Millennium Challenge Corporation, Agency-wide (N1–561–08–1, 94 items, 66 temporary items). Records relating to routine housekeeping matters, such as procurement, meeting management, and fiscal accounting, informal calendars, working papers and drafts, case files and other records relating to routine grants, donor case files, international relations files, files of committees dealing with routine matters, environmental assessments, and other records that do not document significant or precedent setting policies, procedures, or actions. Proposed for permanent retention are such records as files accumulated by the Board of Directors and senior level officials, case files relating to precedent setting grants, congressional correspondence, files of significant committees, publications, and reports.

16. National Indian Gaming Commission, Administrative Division (N1–220–09–3, 3 items, 3 temporary items). Master files of three electronic information systems that deal with such matters as invoices and billings, budget and financial operations, and payments relating to contractor background investigations.

17. National Indian Gaming Commission, Audit Division (N1–220–09–4, 2 items, 2 temporary items). Master files of electronic information system that maintains data on audits conducted at Indian gaming operations. Also included are master files of a system that contains financial statements and other financial data.

18. National Indian Gaming Commission, Office of General Counsel (N1–220–09–2, 2 items, 2 temporary items). Master files of an electronic information system that contains analyses and other records relating to Indian lands, opinions, and data concerning tribal operations. Also included are master files of an electronic tracking system that documents the status of cases assigned to the office.

Dated: April 9, 2010.

**Sharon Thibodeau,**

*Deputy Assistant Archivist for Records Services—Washington, DC.*

[FR Doc. 2010–8788 Filed 4–14–10; 8:45 am]

BILLING CODE 7515–01–P

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### National Endowment for the Arts; Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that four meetings of the Arts Advisory Panel to the National Council on the Arts will be held at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 as follows (ending times are approximate):

*AccessAbility (application review):* May 6, 2010 by teleconference. This meeting, from 2 p.m. to 4 p.m. EDT, will be closed.

*AccessAbility (application review):* May 11, 2010 by teleconference. This meeting, from 2 p.m. to 3:30 p.m. EDT, will be closed.

*Literature (application review):* May 19–20, 2010 in Room 714. A portion of this meeting, from 12 p.m. to 12:30 p.m. on May 20th, will be open to the public for policy discussion. The remainder of the meeting, from 9 a.m. to 6:30 p.m. on May 19th and from 9 a.m. to 12 p.m. and from 12:30 p.m. to 4 p.m. on May 20th, will be closed.

*Literature (application review):* May 21, 2010 in Room 714. This meeting, from 9 a.m. to 5:15 p.m., will be closed.

The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of November 10, 2009, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels that are open to the public, and if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman. If you need any accommodation due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: April 12, 2010.

**Kathy Plowitz-Worden,**

*Panel Coordinator, Panel Operations, National Endowment for the Arts.*

[FR Doc. 2010–8613 Filed 4–14–10; 8:45 am]

BILLING CODE 7537–01–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2009–0166]**

## Final Regulatory Guide: Issuance, Availability

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of Issuance and Availability of Regulatory Guide (RG) 1.65, Revision 1, "Materials and Inspections for Reactor Vessel Closure Studs."

**FOR FURTHER INFORMATION CONTACT:** Wallace Norris, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: (301) 251–7650 or e-mail *Wallace.Norris@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

RG 1.65, Revision 1, "Materials and Inspections for Reactor Vessel Closure Studs," was issued with a temporary identification as Draft Regulatory Guide, DG–1211. General Design Criterion (GDC) 1, "Quality Standards and Records," of Appendix A, "General Design Criteria for Nuclear Power Plants," to Title 10, of the *Code of Federal Regulations,* part 50, "Domestic Licensing of Production and Utilization Facilities" (10 CFR part 50), requires, in part, that "[s]tructures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety function to be performed. Where generally recognized codes and standards are used, they shall be identified and evaluated to determine their applicability, adequacy, and sufficiency and shall be supplemented or modified as necessary to ensure a quality product in keeping with the required safety function."

GDC 30, "Quality of Reactor Coolant Pressure Boundary," requires, in part, that "[c]omponents that are part of the reactor coolant pressure boundary shall be designed, fabricated, erected, and tested to the highest practical quality standards."

GDC 31, "Fracture Prevention of Reactor Coolant Pressure Boundary," requires, in part, that "[t]he reactor coolant pressure boundary shall be designed with sufficient margin to assure that when stressed under operating, maintenance, testing, and postulated accident conditions (1) the boundary behaves in a nonbrittle manner and (2) the probability of rapidly propagating fracture is minimized."

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR part 50 requires, in part, that "[m]easures be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

### II. Further Information

In April 2009, DG–1211 was issued for public comment. The public comment period closed on June 12, 2009. The staff's responses to the public comments received are located in the NRC's Agencywide Documents Access and Management System under Accession Number ML092050752. Electronic copies of RG 1.65, Revision 1 are available through the NRC's public Web site under "Regulatory Guides" at *http://www.nrc.gov/reading-rm/doc-collections/.*

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 8 day of April, 2010.

For the Nuclear Regulatory Commission.

**Andrea D. Valentin,**

*Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2010–8650 Filed 4–14–10; 8:45 am]

BILLING CODE 7590–01–P

## SMALL BUSINESS ADMINISTRATION

## Notice of Action Subject to Intergovernmental Review Under Executive Order 12372

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice of Action Subject to Intergovernmental Review Under Executive Order 12372.

**SUMMARY:** The Small Business Administration (SBA) is notifying the public that it intends to grant the pending applications of 22 existing Small Business Development Centers (SBDCs) for refunding on October 1, 2010, subject to the availability of funds. Nine states do not participate in the EO 12372 process; therefore, their addresses are not included. A short description of the SBDC program follows in the supplementary information below.

The SBA is publishing this notice at least 90 days before the expected refunding date. The SBDCs and their mailing addresses are listed below in the address section. A copy of this notice also is being furnished to the respective State single points of contact designated under the Executive Order. Each SBDC application must be consistent with any area-wide small business assistance plan adopted by a State authorized agency.

**DATES:** A State single point of contact and other interested State or local entities may submit written comments regarding an SBDC refunding within 30 days from the date of publication of this notice to the SBDC.

**ADDRESSES:**

ADDRESSES OF RELEVANT SBDC STATE DIRECTORS

Mr. Al Salgado, Region Director, Univ. of Texas at San Antonio, 501 West Durango Blvd., San Antonio, TX 78207, (210) 458–2450.

Ms. Kristina Oliver, State Director, West Virginia Development Office, 1900 Kanawha Boulevard, East Building 6, Room 504, Charleston, WV 25305, (304) 957–2087.

ADDRESSES OF RELEVANT SBDC STATE DIRECTORS—Continued

Mr. Clinton Tymes, State Director, University of Delaware, One Innovation Way, Suite 301, Newark,DE 19711, (302) 831–2747.

Mr. Michael Young, Region Director, University of Houston, 2302 Fannin, Suite 200, Houston, TX 77002, (713) 752–8425.

Ms. Liz Klimback, Region Director, Dallas Community College, 1402 Corinth Street, Dallas, TX 75212, (214) 860–5835.

Mr. Craig Bean, Region Director, Texas Tech University, 2579 South Loop 289, Suite 114, Lubbock, TX 79423–1637, (806) 745–3973.

Mr. Max Summers, State Director, University of Missouri, 1205 University Avenue, Suite 300, Columbia, MO 65211, (573) 882–1348.

Ms. Lenae Quillen-Blume, State Director, Vermont Technical College, P.O. Box 188, Randolph Center, VT 05061–0188, (802) 728–9101.

Ms. Carmen Marti, SBDC Director, Inter American University of Puerto Rico, Ponce de Leon Avenue, #416, Edificio Union Plaza, Seventh Floor, Hato Rey, PR 00918, (787) 763–6811.

Ms. Becky Naugle, State Director, University of Kentucky, 225 Gatton College of Business Economics, Lexington, KY 40506–0034, (859) 257–7668.

Ms. Rene Sprow, State Director, Univ. of Maryland @ College Park, 7100 Baltimore Avenue, Suite 401, Baltimore, MD 20742–1815, (301) 403–8300.

Ms. Leonor Dottin, SBDC Director, University of the Virgin Islands, 8000 Nisky Center, Suite 720, St. Thomas, USVI 00802–5804, (340) 776–3206.

Mr. Jim Heckman, State Director, Iowa State University, 340 Gerdin Business Building, Ames, IA 50011–1350, (515) 294–2037.

**FOR FURTHER INFORMATION CONTACT:** Antonio Doss, Associate Administrator for SBDCs, U.S. Small Business Administration, 409 Third Street, SW., Sixth Floor, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:**

### Description of the SBDC Program

A partnership exists between SBA and an SBDC. SBDCs offer training, counseling and other business development assistance to small businesses. Each SBDC provides services under a negotiated Cooperative Agreement with SBA, the general management and oversight of SBA, and a state plan initially approved by the Governor. Non-Federal funds must match Federal funds. An SBDC must operate according to law, the Cooperative Agreement, SBA's regulations, the annual Program Announcement, and program guidance.

### Program Objectives

*The SBDC program uses Federal funds to leverage the resources of states, academic institutions and the private sector to:*

(a) Strengthen the small business community;

(b) Increase economic growth;

(c) Assist more small businesses; and

(d) Broaden the delivery system to more small businesses.

### SBDC Program Organization

The lead SBDC operates a statewide or regional network of SBDC service centers. An SBDC must have a full-time Director. SBDCs must use at least 80 percent of the Federal funds to provide services to small businesses. SBDCs use volunteers and other low cost resources as much as possible.

### SBDC Services

An SBDC must have a full range of business development and technical assistance services in its area of operations, depending upon local needs, SBA priorities and SBDC program objectives. Services include training and counseling to existing and prospective small business owners in management, marketing, finance, operations, planning, taxes, and any other general or technical area of assistance that supports small business growth.

The SBA district office and the SBDC must agree upon the specific mix of services. They should give particular attention to SBA's priority and special emphasis groups, including veterans, women, exporters, the disabled, and minorities.

### SBDC Program Requirements

*An SBDC must meet programmatic and financial requirements imposed by statute, regulations or its Cooperative Agreement. The SBDC must:*

(a) Locate service centers so that they are as accessible as possible to small businesses;

(b) Open all service centers at least 40 hours per week, or during the normal business hours of its state or academic Host Organization, throughout the year;

(c) Develop working relationships with financial institutions, the investment community, professional associations, private consultants and small business groups; and

(d) Maintain lists of private consultants at each service center.

Dated: April 6, 2010.

**Antonio Doss,**

*Associate Administrator for Small Business Development Centers.*

[FR Doc. 2010–8444 Filed 4–14–10; 8:45 am]

BILLING CODE M

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12116 and #12117]**

## Rhode Island Disaster #RI–00007

**AGENCY:** Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Rhode Island (FEMA–1894–DR), dated 04/08/2010.

*Incident:* Severe Storms and Flooding.

*Incident Period:* 03/12/2010 and continuing.

*Effective Date:* 04/08/2010.

*Physical Loan Application Deadline Date:* 06/07/2010.

*Economic Injury (EIDL) Loan Application Deadline Date:* 01/04/2011.

**ADDRESSES:** Submit completed loan applications to: Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 04/08/2010, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Bristol, Kent, Newport, Providence, Washington.

The Interest Rates are:

| | Percent |
|---|---|
| *For Physical Damage*: | |
| Non-Profit Organizations With Credit Available Elsewhere ... | 3.625 |
| Non-Profit Organizations Without Credit Available Elsewhere ..... | 3.000 |
| *For Economic Injury:* | |

| | Percent |
|---|---|
| Non-Profit Organizations Without Credit Available Elsewhere | 3.000 |

The number assigned to this disaster for physical damage is 121166 and for economic injury is 121176.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2010–8615 Filed 4–14–10; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12115]**

### Oklahoma Disaster # OK–00036 Declaration of Economic Injury

**AGENCY:** Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Oklahoma, dated 04/09/2010.

*Incident:* Severe Freezing Rain, Ice and Snowstorms.

*Incident Period:* 01/28/2010 through 02/18/2010.

*Effective Date:* 04/09/2010.

*EIDL Loan Application Deadline Date:* 01/10/2011.

**ADDRESSES:** Submit completed loan applications to: Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Comanche, Greer, Jackson, Jefferson, Stephens.

*Contiguous Counties:* Oklahoma Beckham, Caddo, Carter, Cotton, Garvin, Grady, Harmon, Kiowa, Love, Tillman.

Texas Clay, Hardeman, Montague Wilbarger.

The Interest Rates are:

| | Percent |
|---|---|
| Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere | 4.000 |

The number assigned to this disaster for economic injury is 12115.

The States which received an EIDL Declaration # are Oklahoma, Texas.

(Catalog of Federal Domestic Assistance Number 59002)

Dated: April 8, 2010.

**Karen G. Mills,**

*Administrator.*

[FR Doc. 2010–8617 Filed 4–14–10; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration # 12070 and # 12071]**

### Oklahoma Disaster Number OK–00035

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 2.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Oklahoma (FEMA–1883–DR), dated 03/05/2010.

*Incident:* Severe Winter Storm.

*Incident Period:* 01/28/2010 through 01/30/2010.

**DATES:** *Effective Date:* 04/08/2010.

*Physical Loan Application Deadline Date:* 05/04/2010.

*Economic Injury (EIDL) Loan Application Deadline Date:* 12/06/2010.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** Alan Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Oklahoma, dated 03/05/2010, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Counties:* Tillman.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2010–8616 Filed 4–14–10; 8:45 am]

BILLING CODE 8025–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–61877; File No. SR–DTC–2010–06]**

### Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Elective Dividends Service

April 8, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on March 22, 2010, The Depository Trust Company ("DTC") 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 primarily by DTC. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[2] and Rule 19b–4(f)(4)[3] thereunder so that the proposal was 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 proposed rule change will provide various technical updates to DTC's Elective Dividend service.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A)(iii).

[3] 17 CFR 240.19b–4(f)(4).

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

In 1991, DTC filed a rule change with the Commission to establish the Elective Dividends ("EDS") function.[4] The EDS function allows participants to use DTC's Participant Terminal System ("PTS") or Participant Browser System ("PBS") instead of hard copy for their instructions concerning distributions on certain issues of securities.

At the request of its participants, DTC has created an automated election instruction approval process accessible through PBS ("EDS approval process").[5] The EDS approval process will provide participants with a streamlined, electronic means of internally reviewing and approving election instructions and will be used for the following EDS services: Cash-in Lieu/Round Up, Dividend Reinvestment Program, Foreign Currency Payments, Optional Dividend Distribution, and Tax Relief. Participants that chose to use the EDS approval process will be required to assign an administrator in their firm to enable or disable the EDS approval process at the firm. The EDS approval process will have three basic entitlements to allow for the creation and approval of instructions: (i) Creator, which allows the user to only create instructions, (ii) approver, which allows the user to approve instructions created by others and (iii) creator/approver, which allows the user to create its own instructions that are automatically approved. Once an instruction is created, it will appear with a status of "Pending" for the approver to approve or reject. Once approved, the instruction becomes an approved election that will appear in the election window and will be processed in the same way that DTC currently processes such elections.[6]

Additionally, DTC is making technical updates to its procedures in order to properly reflect DTC contact information and the input methods available to participants.

DTC states that the proposed rule change is consistent with the requirements of Section 17A of the Act[7] and the rules and regulations thereunder because it promotes efficiencies in the clearance and settlement of securities transactions by providing participants with a streamlined, electronic means of internally reviewing and approving election instructions.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

DTC does not believe that the proposed rule change will have any impact or impose any burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

DTC has not solicited or received written comments relating to the proposed rule change. DTC will notify the Commission of any written comments it receives.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii) of the Act[8] and Rule 19b–4(f)(4)[9] thereunder because the proposed rule change effects a change in an existing service of DTC that (i) does not adversely affect the safeguarding of securities or funds in DTC's custody or control or for which it is responsible and (ii) does not significantly affect the respective rights of DTC or persons using the service. At any time within sixty days of the filing of such rule change, the Commission may summarily abrogate 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 e-mail to *rule-comments@sec.gov.* Please include File No. SR–DTC–2010–06 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–DTC–2010–06. This file number should be included on the subject line if e-mail 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 a.m. and 3 p.m. Copies of such filings also will be available for inspection and copying at DTC's principal office and DTC's Web site at *http://www.dtc.org/impNtc/mor/index.html.* 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 No. SR–DTC–2010–06 and should be submitted on or before May 6, 2010.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[10]

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010–8614 Filed 4–14–10; 8:45 am]

**BILLING CODE 8011–01–P**

[4] Securities Exchange Release Act No. 29814 (Oct. 11, 1991), 56 FR 55563 (Oct. 21, 1991).

[5] When the EDS approval process is enabled for a given service, a participant will be required to create and update its instructions in PBS for that service; PTS may not be used.

[6] If left unapproved, the instruction will remain pending until the cutoff date. If the instruction is pending on the cutoff date, it will be deleted from the EDS system at the end of the day, and the instruction will revert to the last approved election or if one does not exist, to the default for the event.

[7] 15 U.S.C. 78q–1.

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(4).

[10] 17 CFR 200.30–3(a)(12).

## DEPARTMENT OF STATE

**[Public Notice 6955]**

### Culturally Significant Objects Imported for Exhibition Determinations: "From Xanadu to Dadu: The World of Khubilai Khan"

**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), Executive Order 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 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition "From Xanadu to Dadu: The World of Khubilai Khan," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, NY, from on or about September 28, 2010, until on or about January 2, 2011, 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 exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: April 8, 2010.

**Maura M. Pally,**

*Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2010–8638 Filed 4–14–10; 8:45 am]

**BILLING CODE 4710–05–P**

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Andean Trade Preference Act (ATPA), as Amended: Request for Public Comments Regarding Beneficiary Countries

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice; request for comments.

**SUMMARY:** In compliance with section 203(f) of the ATPA, as amended, 19 U.S.C. 3202(f)(2), the Office of the United States Trade Representative (USTR) is requesting the views of interested parties on whether the designated beneficiary countries are meeting the eligibility criteria under the ATPA. (*See* 19 U.S.C. 3203(b)(6)(B).) This information will be used in the preparation of a report to the Congress on the operation of the program.

**DATES:** Public comments are due no later than 5 p.m., May 12, 2010.

**ADDRESSES:** *Submissions via on-line: http://www.regulations.gov.* For alternatives to on-line submissions, please contact Gloria Blue, Executive Secretary, Trade Policy Staff Committee (TPSC), at (202) 395–3475.

**FOR FURTHER INFORMATION CONTACT:** For procedural questions concerning written comments, please contact Gloria Blue at the above number. All other questions regarding the ATPA should be directed to Bennett Harman, Deputy Assistant USTR for Latin America, at (202) 395–9446.

**SUPPLEMENTARY INFORMATION:**

#### 1. Background Information

The ATPA, as amended by the Andean Trade Promotion and Drug Eradication Act of 2002 (ATPDEA) in the Trade Act of 2002, 19 U.S.C. 3201 *et seq.,* provides trade benefits for eligible Andean countries. In Proclamation 7616 of October 31, 2002, the President designated Bolivia, Colombia, Ecuador, and Peru as ATPDEA beneficiary countries. In Proclamation 8323 of November 25, 2008, the President determined that Bolivia no longer satisfies the eligibility criteria related to counternarcotics and suspended Bolivia's status as a beneficiary country for purposes of the ATPA and ATPDEA. In a June 30, 2009 report to Congress the President did not determine that Bolivia satisfies the requirements set forth in section 203(c) of the ATPA (19 U.S.C. 3202(c)) for being designated as a beneficiary country. Therefore, as provided for in section 208(a)(3) of the Act (19 U.S.C. 3206(a)(3)), no duty free treatment or other preferential treatment extended under the ATPA remained in effect with respect to Bolivia after June 30, 2009.

Section 203(f) of the ATPA (19 U.S.C. 3202(f)) requires the USTR, not later than June 30, 2010, to submit to Congress a report on the operation of the ATPA. Before submitting such report, USTR is required to request comments on whether beneficiary countries are meeting the criteria set forth in 19 U.S.C. 3203(b)(6)(B) (which incorporates by reference the criteria set forth in sections 3202(c) and (d)). USTR refers interested parties to the **Federal Register** notice published on August 15, 2002 (67 FR 53379), for a full list of the eligibility criteria.

#### 2. Requirements for Submissions

Persons submitting comments must do so in English and must identify (on the first page of the submission) the "USTR Report on Operation of the Andean Trade Preference Act." In order to be assured of consideration, comments should be submitted by May 12, 2010.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *http://www.regulations.gov* Web site. Comments should be submitted under the following docket: USTR–2010–0012. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the *http://www.regulations.gov* home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the *http://www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on the "Help" tab.)

The *http://www.regulations.gov* Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment & Upload File" field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character "P", followed by the name

of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www.regulations.gov,* if at all possible. Any alternative arrangements must be made with Ms. Blue in advance of transmitting a comment. Ms. Blue should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

**Carmen Suro-Bredie,**

*Chairman, Trade Policy Staff Committee.*

[FR Doc. 2010–8629 Filed 4–14–10; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

### Marine Highway Projects

**ACTION:** Solicitation of applications for Marine highway projects.

**SUMMARY:** The Department of Transportation is soliciting applications for Marine Highway Projects as specified in the America's Marine Highway Program Final Rule, MARAD–2010–0035, published in the **Federal Register** on April 9, 2010. These applications must comply with the requirements of the referenced America's Marine Highway Program Final Rule, and be submitted in accordance with the instructions contained in that Final Rule. This application period begins immediately upon publication of this notice and is open through June 11, 2010.

**FOR FURTHER INFORMATION CONTACT:** Michael Gordon, Office of Intermodal System Development, Marine Highways and Passenger Services, at (202) 366–5468, via e-mail at *michael.gordon@dot.gov,* or by writing to the Office of Marine Highways and Passenger Services, MAR–520, Suite W21–315, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Dated: April 9, 2010.

**Christine Gurland,**

*Secretary, Maritime Administration.*

[FR Doc. 2010–8619 Filed 4–14–10; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[FHWA–KY–EIS–04–2–F, NH 65–1 (73)]**

### Notice of Availability of the Record of Decision for the I–65 to US 31W Access Improvement Final Environmental Impact Statement (FEIS)

**AGENCY:** Federal Highway Administration.

**ACTION:** Notice of Availability of Record of Decision (ROD).

**SUMMARY:** In accordance with the National Environmental Policy Act (NEPA) and Federal Highway Administration (FHWA) procedures, the FHWA announces the availability of the ROD to implement the I–65 to US 31W Access Improvement project in Warren County, Kentucky. The Division Administrator, FHWA–Kentucky Division signed the ROD on March 23, 2010.

**ADDRESSES:** The FHWA ROD for the I–65 to US 31W Access Improvement project can be viewed and downloaded from the project Web site at *http://www.transportation.ky.gov/d3/I6531w,* or viewed at public libraries in the project area.

**FOR FURTHER INFORMATION:** Mr. Anthony Goodman, Environmental Specialist, Federal Highway Administration, Kentucky Division; 330 West Broadway, Frankfort, Kentucky, 40601; normal business hours Monday–Friday, 8 a.m.–4:30 p.m. Eastern Standard Time; Phone 502–223–6742, E-mail *Anthony.Goodman@dot.gov.*

**SUPPLEMENTARY INFORMATION:** The I–65 to US 31W Access Improvement ROD was developed through preparation of the Final Environmental Impact Statement for I–65 to US 31W Access Improvement, prepared in accordance with the National Environmental Policy Act (NEPA). The decision is hereby made to implement the project that involves the construction of a new road linking I–65 and US 31W, construction of a full interchange with I–65 and a partial interchange with US 68/KY 80, and reconstruction of US 31W as it approaches the intersection of the new corridor. The project, which is approximately 3.8 miles in length, is northeast of the city of Bowling Green, in Warren County, Kentucky. The road will be six lanes with a depressed median from I–65 to US 68/KY 80, and four lanes with a depressed median from US 68/KY 80 to US 31W. The purpose of the project is to meet the existing and future transportation demands including improved access between I–65 and US 31W; and improved roadway capacity and safety conditions.

**Authority:** 23 U.S.C. 315; 49 CFR 1.48.

Issued on April 6, 2010.

**Mr. Jose Sepulveda,**

*Division Administrator, FHWA–Kentucky Division.*

[FR Doc. 2010–8437 Filed 4–14–10; 8:45 am]

**BILLING CODE M**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Notice of Final Federal Agency Actions on a Proposed New Road Connecting I–65 and U.S. 31W in Kentucky

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of limitation on claims for judicial review of actions by FHWA, Army Corps of Engineers (USACE), DoD, and other Federal agencies.

**SUMMARY:** This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed highway project: a new connector road from I–65 to US 31W in Warren County, Kentucky [Kentucky Transportation Cabinet (KYTC) Item No. 3–16.00].

**DATES:** By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 5, 2010. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

**FOR FURTHER INFORMATION CONTACT:** For FHWA: Mr. Anthony Goodman, Environmental Specialist, Federal Highway Administration, Kentucky Division; 330 West Broadway, Frankfort, Kentucky, 40601; normal business hours Monday–Friday, 8 a.m.–4:30 p.m. Eastern Standard Time; Phone 502–223–6742, E-mail *Anthony.Goodman@dot.gov.* For KYTC: Mr. David Waldner, P.E., Director, Division of Environmental Analysis, Kentucky Transportation Cabinet; 200 Mero Street, 5 Floor, Frankfort, Kentucky, 40622; regular business hours Monday–Friday, 8 a.m.–4:30 p.m. Eastern Standard Time; Phone 502–564–5655, E-mail *David.Waldner@ky.gov.*

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the FHWA has taken

final agency actions subject to 23 U.S.C. 139(0)(1) by issuing licenses, permits, and approvals for the following highway project in the State of Kentucky: The project [FHWA–KY–EIS–04–2–F, NH65–1(73)] involves the construction of a new road linking I–65 and US 31W, construction of a full interchange with I–65 and a partial interchange with US 68/KY 80, and reconstruction of US 31W as it approaches the intersection of the new corridor. The project, which is approximately 3.8 miles in length, is northeast of the city of Bowling Green, in Warren County. The road will be six lanes with a depressed median from I–65 to US 68/KY 80, and four lanes with a depressed median from US 68/KY 80 to US 31W. The purpose of the project is to meet the existing and future transportation demands including improved access between I–65 and US 31W; and improved roadway capacity and safety conditions.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on July 22, 2009 (FHWA) and July 21, 2009 (KYTC); in the FHWA Record of Decision (ROD) issued on March 23, 2010; and in other documents in the FHWA project records. The FEIS, ROD, and other project records are available by contacting FHWA or KYTC at the addresses provided above. The FHWA FEIS and ROD can be viewed and downloaded from the project Web site at [*http://www.transportation.ky.gov/d3/I6531w*], or viewed at public libraries in the project area.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to the following:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128]; Public Hearing [23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544].

4. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469469(c)].

5. *Land:* Section 4(f) of The Department of Transportation Act: 23 U.S.C. 138, 49 U.S.C. 303; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Uniform Relocation Assistance and Real Property Acquisition Act of 1970 (42 U.S.C. 4601 *et seq.,* Pub. L. 91–646) as amended by the Uniform Relocation Act Amendments of 1987 (Pub. L. 100–17); Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations, February 11, 1994.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

**Authority:** 23 U.S.C. 139(l)(1)

Issued on: April 6, 2010.

**Jose Sepulveda,**

*Division Administrator, FHWA–Kentucky Division.*

[FR Doc. 2010–8438 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–RY–M

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

### International Standards on the Transport of Dangerous Goods; Public Meeting

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice is to advise interested persons that PHMSA will conduct a public meeting in preparation for the 37th session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCOE TDG) to be held June 21–30, 2010 in Geneva, Switzerland. During this meeting, PHMSA is also soliciting comments relative to potential new work items which may be considered for inclusion in its international agenda.

Information Regarding The UNSCOE TDG Meeting:

**DATES:** Wednesday, June 9, 2010; 9:30 a.m.–12:30 p.m.

**ADDRESSES:** The meeting will be held at the DOT Headquarters, West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590.

*Conference Call Capability/Live Meeting Information:* Conference call-in and "live meeting" capability will be provided for this meeting. Specific information on call-in and live meeting access will be posted when available at *http://www.phmsa.dot.gov/hazrnat/regs/international.*

**FOR FURTHER INFORMATION CONTACT:** Mr. Duane Pfund, Acting Director, Office of Hazardous Materials Technology or Mr. Shane Kelley, International Transportation Specialist, Office of Hazardous Materials Safety, Department of Transportation, Washington, DC 20590; (202) 366–0656.

**SUPPLEMENTARY INFORMATION:** The primary purpose of this meeting will be to prepare for the 37th session of the UNSCOE TDG. The 37th session of the UNSCOE TDG is the third of four meetings scheduled for the current 2009–2010 biennium. The UNSCOE will consider proposals for the 17th Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations which will come into force in the international regulations from January 1, 2013. Topics on the agenda for the UNSCOE TDG meeting include:

- Explosives and related matters.
- Listing, classification and packing.
- Electric storage systems.
- Miscellaneous proposals of amendments to the Model Regulations on the Transport of Dangerous Goods.
- Electronic data interchange (EDI) for documentation purposes.
- Cooperation with the International Atomic Energy Agency (IAEA).
- Global harmonization of transport of dangerous goods regulations with the Model Regulations.
- Guiding principles for the Model Regulations.
- Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
- Other business.

In addition, PHMSA is soliciting comments on how to further enhance harmonization for international transport of hazardous materials. PHMSA has finalized a broad international strategic plan and welcomes input on items which stakeholders believe should be included as specific initiatives within this plan. PHMSA's Office of International Standards Strategic Plan can be accessed at: *http://www.phmsa.dot.gov/hazmat/regs/international.*

The public is invited to attend without prior notification. Due to the heightened security measures participants are encouraged to arrive early to allow time for security checks necessary to obtain access to the building. Following the 37th session of the UNSCOE TDG, PHMSA will place a copy of the Sub-Committee's report and a summary of the results on PHMSA's Hazardous Materials Safety Homepage

at *http://www.phmsa.dot.gov/hazmat/regs/international.*

**Documents**

Copies of documents for the UNSCOE TDG meeting and the meeting agenda may be obtained from the United Nations Transport Division's Web site at: *http://www.unece.org/trans/main/dgdb/dgsubc/c30.html.* PHMSA's international standards Website at *http://www.phmsa.dot.gov/hazmat/regs/international* also provides additional information regarding the UNSCOE TDG and related matters such as summaries of decisions taken at previous sessions of the UNSCOE TDG.

**Magdy El-Sibaie,**

*Associate Administrator for Hazardous Materials Safety.*

[FR Doc. 2010–8446 Filed 4–14–10; 8:45 am]

**BILLING CODE 4910–60–M**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Summary Notice No. PE–2009–18]**

### Petition for Exemption; Summary of Petition Received

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

**ACTION:** Notice of petition for exemption received.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of Title 14, Code of Federal Regulations (14 CFR). The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number involved and must be received on or before May 5, 2010.

**ADDRESSES:** You may send comments identified by Docket Number FAA–2010–0288 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy:* We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

*Docket:* To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Annette K. Kovite, ANM–113, (425) 227–1262, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98057–3356, or Brenda Sexton, (202) 267–3664, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 9, 2010.

**Pamela Hamilton-Powell,**

*Director, Office of Rulemaking.*

**Petition for Exemption**

*Docket No.:* FAA–2010–0288.

*Petitioner:* Aero Union Corporation.

*Section of 14 CFR Affected:* 14 CFR 26.47.

*Description of Relief Sought:* Exemption from the requirement to develop damage tolerance data for STCs ST00353LA and SA8009NM installed on Lockheed 188A and 188C airplanes for the purpose of dispensing firefighting materials.

[FR Doc. 2010–8594 Filed 4–14–10; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Summary Notice No. PE–2010–15]**

### Petition for Exemption; Summary of Petition Received

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

**ACTION:** Notice of petition for exemption received.

**SUMMARY:** This notice contains a summary petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petitions or their final disposition.

**DATES:** Comments on these petitions must identify the petition docket number involved and must be received on or before May 5, 2010.

**ADDRESSES:** You may send comments identified by Docket Number FAA–2009–0968 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy:* We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

*Docket:* To read background documents or comments received, go to

*http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Tyneka L. Thomas, 202–267–7626, or Ralen Gao, 202–267–3168, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC on April 9, 2010.

**Pamela Hamilton-Powell,**

*Director, Office of Rulemaking.*

**Petition for Exemption**

*Docket No.:* FAA–2009–0968.
*Petitioner:* AirMed International, LLC.
*Section of 14 CFR Affected:* 135.364.

*Description of Relief Sought*

AirMed International, LLC (AirMed) seeks relief from § 135.364 which would allow AirMed to receive extended operations approval to operate its Hawker Beechcraft on a planned route that exceeds 180 minutes flying time outside the continental United States.

[FR Doc. 2010–8579 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### Petition for Exemption From the Vehicle Theft Prevention Standard; Saab

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Grant of petition for exemption.

**SUMMARY:** This document grants in full the Saab Cars North America, Inc.'s (Saab) petition for exemption of the 9–5 vehicle line in accordance with 49 CFR part 543, *Exemption from the Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541).

**DATES:** The exemption granted by this notice is effective beginning with the 2011 model year.

**FOR FURTHER INFORMATION CONTACT:** Ms. Deborah Mazyck, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, West Building, W43–443, 1200 New Jersey Avenue, SE., Washington, DC 20590. Ms. Mazyck's telephone number is (202) 366–0846. Her fax number is (202) 493–2990.

**SUPPLEMENTAL INFORMATION:** In a petition dated March 1, 2010, Saab requested an exemption from the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541) for the MY 2011 Saab 9–5 vehicle line. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant exemptions for one vehicle line per model year. In its petition, Saab provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Saab 9–5 vehicle line. Saab will install its passive transponder-based, electronic immobilizer antitheft device as standard equipment on its 9–5 vehicle line beginning with MY 2011. Major components of the antitheft device will include a body control module (BCM), passive entry passive start module (PEPS), intrusion/inclination sensor, an immobilizer control module and a user identification device (UID). Activation of the immobilization device occurs when the ignition is turned to the "OFF" position. Saab will also install an audible and visual alarm system on the 9–5 as standard equipment. Saab's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

Saab stated that before the vehicle can operate, driver authentication must be performed by communication between the PEPS and the BCM jointly with the UID (key fob). Additionally, verification of the electronic code is required to allow the transmission shift lever to unlock. When the Engine Start/Stop button on the instrument panel is pressed, the vehicle transmits a randomly generated 32-bit challenge and identifier. If the data matches the command and response values, authorizations are sent within the BCM to allow the vehicle to operate. Saab stated that, if incorrect responses are received at any point in the process, or if a response is not received, the system will inhibit operation of the engine.

The Saab 9–5 is equipped with a vehicle alarm system (VAS). The VAS consists of an ultrasonic sensor and vehicle inclination sensor. Any attempt to enter the vehicle by means other than the key will be detected by the VAS. Saab stated that when an unauthorized person has entered the vehicle after the system has been set, the signal lights will flash, and the horn and an additional siren alarm will provide a warning. The VAS monitors the doors, engine hood and trunk lid. Additionally, Saab stated that any attempt to access any of the system components will activate the VAS.

In addressing the specific content requirements of 543.6, Saab provided a detailed list of the tests conducted and believes that the device is reliable and durable since the device complied with its specified requirements for each test. Specifically, Saab stated that the design and assembly processes of the antitheft subsystems and components were validated for climatic, mechanical and chemical environments under the General Motors Corporation validation procedures.

In support of its belief that its antitheft device will be as effective as compliance with the parts marking requirements in reducing and deterring vehicle theft, Saab referenced the American Automobile Manufacturers Association response to Docket 97–042; NHTSA Request for Comments on its preliminary report to Congress on the effects of the Anti Car theft Act of 1984 provides data supporting that the anti-theft device will be effective in reducing and deterring motor vehicle theft. Additionally, Saab stated that the 2011 9–5 antitheft device, which was introduced on the 2003 Saab 9–3, has been designed to enhance the functionality and theft protection provided by Saab's first generation antitheft system. The Saab 9–3 was formerly named the Saab 900. The antitheft device installed on the Saab 9–3 (Saab 900) was granted an exemption from the parts-marking requirements. (*See* 62 FR 55453).

Saab provided data on the effectiveness of the antitheft device installed on its 9–3 vehicle line in support of the belief that its device will be at least as effective as those comparable devices previously granted exemptions by the agency. The agency's 2007 theft data showed that the theft rate for the 9–3 vehicle line has remained consistently low. The average theft rate using three MY's data for the 9–3 is 0.4690. Based on the theft rate experience of the 9–3 vehicle line and the additional advanced technology utilized in the current 9–5 antitheft system, Saab believes that the Saab 9–5 will be more effective in deterring

theft than the parts-marking requirements of 49 CFR 541.

Based on the supporting evidence submitted by Saab on the device, the agency believes that the antitheft device for the 9–5 vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR 541). The agency concludes that the device will provide the five types of performance listed in § 543.6(a)(3): promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7(b), the agency grants a petition for exemption from the parts-marking requirements of part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts marking requirements of part 541. The agency finds that Saab has provided adequate reasons for its belief that the antitheft device for the Saab vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Saab provided about its device.

For the foregoing reasons, the agency hereby grants in full Saab's petition for exemption for the Saab 9–5 vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with the 2011 model year vehicles. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR part 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If Saab decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR Parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Saab wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the anti-theft device on which the line's exemption is based. Further, Part 543.9(c)(2) provides for the submission of petitions "to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden that Part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis,* it should consult the agency before preparing and submitting a petition to modify.

**Authority:** 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: April 12, 2010.

**Stephen R. Kratzke,**

*Associate Administrator for Rulemaking.*

[FR Doc. 2010–8660 Filed 4–14–10; 8:45 am]

**BILLING CODE 4910–59–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–1999–6480; FMCSA–2003–16564; FMCSA–2005–23238; FMCSA–2005–21254; FMCSA–2005–21711; FMCSA–2005–22727; FMCSA–2007–0017; FMCSA–2007–0071; FMCSA–2008–0021]**

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of renewal of exemptions; request for comments.

**SUMMARY:** FMCSA announces its decision to renew the 29 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

**DATES:** This decision is effective May 12, 2010. Comments must be received on or before May 17, 2010.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–1999–6480; FMCSA–2003–16564; FMCSA–2005–23238; FMCSA–2005–21254; FMCSA–2005–21711; FMCSA–2005–22727; FMCSA–2007–0017; FMCSA–2007–0071; FMCSA–2008–0021, using any of the following methods.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this Notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

*Privacy Act:* Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, *etc.*).

You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476). This information is also available at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Dr. Mary D. Gunnels, Director, Medical Programs, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

## Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

## Exemption Decision

This notice addresses 29 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 29 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Gerald L. Anderson
Leo G. Becker
Timothy W. Bickford
Stanley W. Davis
Ray L. Emert
Sean O. Feeny
Steven R. Felks
Marvin T. Fowler
Michael J. Frein
Jimmy G. Hall
Hazel L. Hopkins, Jr.
Dennis R. Irvin
Mark L. LeBlanc
David A. Miller
Rick P. Moreno
Paul D. Schnautz
Steve J. Sherar
Robert F. Skinner, Jr.
William T. Smiley
Richard M. Smith
Robert A. Stoeckle
David N. Stubbs
Edward J. Sullivan
Aaron S. Taylor
Martin L. Taylor
Gary R. Thomas
William B. Thomas
Michael J. Tisher
Kevin R. White

*These exemptions are extended subject to the following conditions:* (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provides a copy of the annual medical certification to the employer for retention in the driver's qualification file and retain a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

## Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two-year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 29 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (64 FR 68195; 65 FR 20251; 67 FR 17102; 69 FR 17267; 71 FR 16410; 73 FR 28188; 68 FR 74699; 69 FR 10503; 71 FR 6829; 71 FR 5105; 71 FR 19600; 70 FR 30999; 70 FR 46567; 72 FR 40360; 70 FR 48797; 70 FR 61493; 73 FR 6246; 70 FR 71884; 71 FR 4632; 73 FR 5259; 72 FR 67340; 73 FR 1395; 73 FR 6242; 73 FR 16950; 73 FR 15567; 73 FR 27015). Each of these 29 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the standard specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption standards. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

## Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by May 17, 2010.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 29 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was based on the merits of each case and only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all of these drivers, are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: April 6, 2010.

**Larry W. Minor,**

*Associate Administrator for Policy and Program Development.*

[FR Doc. 2010–8646 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2003–16241; FMCSA–2003–16564; FMCSA–2005–22194; FMCSA–2007–27897]**

### Qualification of Drivers; Exemption Renewals; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA previously announced its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 15 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

**FOR FURTHER INFORMATION CONTACT:** Dr. Mary D. Gunnels, Director, Medical Programs, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

#### Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The comment period ended on March 25, 2010 (75 FR 8184).

#### Discussion of Comments

FMCSA received no comments in this proceeding.

#### Conclusion

The Agency has not received any adverse evidence on any of these drivers that indicates that safety is being compromised. Based upon its evaluation of the 15 renewal applications, FMCSA renews the Federal vision exemptions for Lee A. Burke, Barton C. Caldara, Allan Darley, Robin S. England, Charles D. Grady, Richard Hailey, Jr., Robert V. Hodges, George R. Knavel, John R. Knott III, Timothy S. Miller, Roger D. Mollak, Edward D. Pickle, Ezequiel M. Ramirez, James L. Schmitt and James T. Wortham, Jr.

In accordance with 49 U.S.C. 31136(e) and 31315, each renewal exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: April 6, 2010.

**Larry W. Minor,**

*Associate Administrator for Policy and Program Development.*

[FR Doc. 2010–8648 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–1999–5748; FMCSA–1999–6156]**

### Qualification of Drivers; Exemption Renewals; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA previously announced its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 5 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

**FOR FURTHER INFORMATION CONTACT:** Dr. Mary D. Gunnels, Director, Medical Programs, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

#### Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The comment period ended on March 25, 2010 (75 FR 8183).

#### Discussion of Comments

FMCSA received no comments in this proceeding.

#### Conclusion

The Agency has not received any adverse evidence on any of these drivers that indicates that safety is being compromised. Based upon its evaluation of the 5 renewal applications, FMCSA renews the Federal vision exemptions for Dennis J. Lessard, Harry R. Littlejohn, James D. Simon, Robert J. Townsley and Jeffrey G. Wuensch.

In accordance with 49 U.S.C. 31136(e) and 31315, each renewal exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: April 6, 2010.

**Larry W. Minor,**

*Associate Administrator for Policy and Program Development.*

[FR Doc. 2010–8645 Filed 4–14–10; 8:45 am]

BILLING CODE 4910–EX–P

Federal Register

Thursday,
April 15, 2010

# Part II

# Department of Health and Human Services

## Centers for Medicare & Medicaid Services

## 42 CFR Parts 417, 422, 423, and 480

## Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 417, 422, 423, and 480**

**[CMS–4085–F]**

**RIN 0938–AP77**

# Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy.

**DATES:** *Effective Date:* These regulations are effective on June 7, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted.

**FOR FURTHER INFORMATION CONTACT:**

Alissa Deboy, (410) 786–6041, General information and Part D issues.

Sabrina Ahmed, (410) 786–7499, Part C issues.

Terry Lied, (410) 786–8973, Collection of information requirements and regulatory impact analysis issues.

Kristy Nishimoto, (410) 786–8517, Part C and D enrollment and appeals issues.

Jennifer Smith, (410) 786–2987, Part C and D compliance and sanction issues.

Frank Szeflinski, (303) 844–7119, Part C payment issues.

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## Acronyms

AO Accrediting Organization
ADS Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service—Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CCS Certified Coding Specialist
CMR Comprehensive Medical Review
CMP Civil Money Penalties

CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
ESRD End-stage renal disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration (HHS)
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FY Fiscal year
GAO General Accounting Office
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LTC Long Term Care
LTCF Long Term Care Facility
MA Medicare Advantage
MAAA American Academy of Actuaries
MAO Medicare Advantage Operations
MA–PD Medicare Advantage-Prescription Drug Plans
M+C Medicare+Choice program
MPDPF Medicare Prescription Drug Plan Finder
MIPPA Medicare Improvements for Patients and Providers Act of 2008
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan statistical area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Programs
NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-coverage
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PART C Medicare Advantage
PART D Medicare Prescription Drug Benefit Programs
PPACA Patient Protection and Affordable Care Act (Pub. L. 111–148)
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription drug plan
PFFS Private Fee For Service Plan
POS Point of service
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
SCHIP State Children's Health Insurance Programs
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSI Supplemental Security Income
TrOOP True Out Of Pocket
U&C Usual and Customary
USP U.S. Pharmacopoeia

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Part D program and made revisions to the provisions in Part C of the Medicare statute governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588–4741 and 70 FR 4194–4585, respectively). While the provisions of the final rule did not govern plan payment or benefits until January 1, 2006, given the fact that provisions relating to applications, marketing, contracts, and the new bidding process for the MA and Part D programs, many provisions in these final rules became effective on March 22, 2005, 60 days after publication of the rule.

As we have gained experience with the MA program and the prescription drug benefit program, we periodically have revised the Part C and D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. For example, in December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions impacting both the Medicare Part C and D programs, and make other policy clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881).

### *B. History and Overview*

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act) which provided for what was then called the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices. The M+C provisions in Part C were amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–111), and further amended by the Medicare, Medicaid, and State Children's Health Insurance Program SCHIP) Benefits Improvement Act of 2000 (BIPA) (Pub. L. 106–554).

As discussed above, the MMA, enacted on December 8, 2003, added a new "Part D" to the Medicare statute (sections 1860D–1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, and made significant changes to the M+C program.

Also as noted above, MIPPA, enacted on July 15, 2008, addressed a number of provisions impacting the Part C and D programs, including provisions impacting marketing under both programs which were implemented in regulations published in the **Federal Register** on September 18, 2008 (73 FR 54208), a final rule effective October 1, 2008, that paralleled provisions in MIPPA, and in the same issue of the **Federal Register** (73 FR 54226), a separate interim final rule that addressed the other provisions of MIPPA affecting the MA and Part D programs. We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407 and issued a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881).

In October 22, 2009 **Federal Register** (74 FR 54634), we published a proposed rule (file code CMS–4085–P), hereinafter referred to as the October 22, 2009 proposed rule) addressing additional policy clarifications under the Part C and D programs. As noted when issuing this proposed rule, we believe that additional programmatic and operational changes are needed in order to further improve our oversight and management of the Part C and D programs and to further improve beneficiary experience under MA or Part D plans.

Indeed, one of the primary reasons set forth in the preamble for issuing the October 22, 2009 proposed rule was to address beneficiary concerns associated with the annual task of selecting one plan from so many options. We noted that while it is clear that the Medicare Part D program has improved access to drug coverage for elderly and offered beneficiaries a wide range of plans from which to choose, some have suggested that a significant numbers of beneficiaries are confused by the array of choices and find it difficult to make enrollment decisions that are best for them. Moreover, experience has shown that organizations submitting bids under Part C and D to offer multiple plans have not consistently submitted plan benefit designs that were significantly different from each other, which can add to beneficiary confusion. In this rule, we finalize a number of proposals to the way we administer the Part C and D programs to promote beneficiaries making the best plan choice that suits their needs. Although we believe these provisions will go a long way to further that goal, we are committed to additional explorations of ways to structure choices for seniors to aid them in making better plan choices, and will continue to evaluate program changes in this area.

We also proposed additional provisions aimed at strengthening existing beneficiary protections, improving payment rules and processes, enhancing our ability to pursue data collection for oversight and quality assessment, strengthening formulary policy, and finalizing a number of clarifications and technical corrections to existing policy. Except as noted or otherwise modified, we finalize these requirements in this rule.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule has been published within the 3-year time limit imposed by section 902 of the MMA, and thus is in accordance with the Congress' intent to ensure timely publication of final regulations.

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted. Several provisions of this public law affect the Part C and D programs. In sections II.B. and II.F. of this final rule, we provide a discussion of the effects of two of these provisions on our proposed policies regarding MA cost sharing and "protected classes" of drugs under Part D, respectively.

## II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

We received approximately 114 items of timely correspondence containing comments on the October 22, 2009 proposed rule. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, researchers, and others.

In this final rule, we address all timely comments and concerns on the policies included in the proposed rule. We note that there were several comments submitted that were outside the scope of the proposals set forth in the proposed rule and, as such, we do not address them within this final rule. Generally, the commenters supported our efforts to improve plan offerings by the same sponsor that are meaningfully different from each other in order to support improved beneficiary decision making and our efforts to clarify and codify existing policy through rulemaking.

### *A. Changes to Strengthen Our Ability To Distinguish for Approval Strong Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers*

This section finalizes a number of proposed revisions designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA and initial implementation of the prescription drug programs in January 2006, we have steadily enhanced our ability to measure MAO and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MAOs and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. Additionally, this information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As set forth below, we are finalizing changes and clarifications to our regulations to make certain that all current and potential MAOs and PDP sponsors clearly understand and can reasonably anticipate how we measure sponsor performance, determine when there is noncompliance, and when enforcement actions are warranted.

These provisions are described in detail in Table 1.

TABLE 1—PROVISIONS STRENGTHENING OUR ABILITY TO DISTINGUISH FOR APPROVAL STRONG APPLICANTS AND TO REMOVE CONSISTENTLY POOR PERFORMERS

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Notice of Intent to Apply | Subpart K | § 422.501 | Subpart K | § 423.502. |
| Application Standards | Subpart K | § 422.502 | Subpart K | § 423.503. |
| Compliance Measures/Analysis | Subpart K | § 422.502 | Subpart K | § 423.503. |
| Compliance Programs | Subpart K | § 422.503(b)(4)(vi) | Subpart K | § 423.504(b)(4)(vi). |
| Network Adequacy of Coordinated Care and Network-Based Private-Fee-For-Service plans under Part C. | Subpart C | § 422.112 | N/A | N/A. |
| Clarify programmatic elements that are "deemable" | Subpart D | § 422.156(b)(7), § 422.156(f). | Subpart D | § 423.165(b), § 423.165(f). |
| Procedures for termination and Nonrenewals: Part C and D | Subpart K | § 422.510(c)(1), § 422.506(b)(3). | Subpart K | § 423.509(c)(1), § 423.507(b)(3). |
| Intermediate Sanctions: procedures for imposing civil and money penalties. | Subpart O | § 422.756 | Subpart O | § 423.756. |
| Contract Termination | Subpart K | § 422.510(a) | Subpart K | § 423.509(a). |
| Proper request for hearings | Subpart N | § 422.662 | Subpart N | § 423.651. |
| Burden of Proof, Standard of Proof, Standard of Review and Conduct of Hearing. | Subpart N | § 422.660, § 422.676(d). | Subpart N | § 423.650, § 423.658(d). |
| Postponement of effective date of determination when a request is being filed. | Subpart N | § 422.664 | Subpart N | § 423.652. |
| Extending timeframe for contract determination hearings | Subpart N | § 422.670 | Subpart N | § 423.655. |
| Appeal times: require each party provide witness list and documents 5 calendar days before hearing. | Subpart N | § 422.682 | Subpart N | § 423.661. |
| Appeal times: require request for a review by the administrator must be received with 15 days after receipt of hearing decision. | Subpart N § 422.692(a) | § 422.692(a) | Subpart N | § 423.666(a). |
| Contract redeterminations and reopening | Subpart N | § 422.696 | Subpart N | § 423.668. |
| Mutual termination of contract | Subpart K | § 422.503(b)(6) | Subpart K | § 423.504(b)(6). |

1. Require Notice of Intent To Apply Under Part C and D Within the Application Requirements (§ 422.501 and § 423.502)

Under the authority of section 1871(a)(1) of the Act, which authorizes us to prescribe such regulations as may be necessary to carry out the administration of the Medicare program, we proposed an administrative requirement in the October 22, 2009 proposed rule for both the Part C and D programs related to the application submission to qualify as MA and PDP sponsor contractors. We specifically proposed in § 422.501 and § 423.502 to codify our existing guidance that initial applicants and existing contractors seeking to expand complete a nonbinding Notice of Intent to Apply.

We noted that as a result of the fully electronic submission process and restrictions on access to the CMS Health Plan Management System (HPMS), every applicant must complete a Notice of Intent to Apply as described in the HPMS memo dated October 10, 2008. This includes both initial applicants and current contractors seeking to expand their organizations' service area and current contractors adding a Special Needs Plan (SNP) or an Employer Group/Union-Sponsored Waiver Plan (EGWP) to their existing contract.

We also noted that submitting a Notice of Intent to Apply does not bind that organization to submit an application for the following year. However, without a pending contract number and completed CMS User ID connectivity, an organization will not be able to access the appropriate modules in HPMS to complete the application materials.

In this final rule, we address comments received and finalize this provision with modification. As explained below, we modified § 422.503(b)(2) and § 423.502 (b)(2) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

*Comment:* Several commenters supported this provision.

*Response:* We appreciate the commenters support of our proposal.

*Comment:* Some commenters were concerned about the due date of the Notice of Intent to Apply and wanted exceptions to allow CMS the flexibility to accept notice of intent after the due date. Some commenters were particularly concerned about special need plans offered in conjunction with Medicaid. Commenters also urged CMS to provide organizations adequate time to make the decision whether to apply and stated that some organizations may not consider submitting an application at the time notices are due.

*Response:* As stated in the proposed regulation at § 422.503(b)(2) and § 423.503(b)(2), the Notice of Intent to Apply does not bind the organization to submit an application. For this reason, we do not believe it is necessary to be flexible with the due date of the notice of intent. Organizations are free to submit a Notice of Intent to Apply and then consider whether or not to submit an application without risking any negative consequences from CMS. We also believe that the notice of intent requirement will benefit applicants as it will serve as a 3-month advance reminder to begin preparation for their submission. We anticipate that the additional lead time will result in more successful applications.

*Comment:* One commenter questioned whether the three month lead time is necessary, particularly for existing sponsors, to ensure timely connectivity to CMS systems.

*Response:* Our preparation for the receipt of applications is a process that can take up to 3 months. We encourage interested parties to see the October 2, 2009 HPMS memo for an example of the timeline from submission of the Notice of Intent to Apply to the application submission.

*Comment:* One commenter wanted CMS to add language indicating that for those notices of intent that do not result in the submission of an application, lack of submission would not be considered as part of any punitive evaluation.

*Response:* As we stated in the October 2009 proposed rule, the Notice of Intent

to Apply does not bind the organization to submit an application. We want to make clear that the submission of a notice of intent without a subsequent application submission would present no risk of reprimand or sanction by us. For this reason, we are modifying § 422.503(b) and § 423.502 (b) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

2. Application Requirements (§ 422.501 (c) and § 423.502 (c)) and Evaluation and Determination Procedures for Determining Whether Applicants Are Qualified for a Contract Under Parts C and D (§ 422.502 and § 423.503)

In the October 2009 proposed rule, we proposed a single clarification that applies to both MA organizations and Part D sponsors related to our application evaluation procedures and appeals of our determinations regarding applications. At § 422.502 and § 423.503, we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and D program requirements.

We noted that the application process under Part C and D requires an applicant to submit for our review a combination of attestations that it will comply with stated program requirements, as well as submit contracts with organizations the applicant has contracted with to perform key Part C or D functions, evidence of the applicant's risk-bearing licenses, and data documenting that the applicant can provide its members access to Part C and D services consistent with the programs' requirements. We proposed at § 422.501(c)(1) and (2), § 422.502(a)(2), § 423.502(c)(1) and (2), and § 423.503(a)(2) to require that applicants demonstrate that they meet all requirements outlined in the MA organization and Part D sponsor applications.

We simplified the application evaluation process under § 422.502(a)(1) and § 423.503(a)(1) by limiting the evaluation of an entity's application to information contained in the application and any additional information that we obtain through onsite visits. As we noted in the proposed rule, limiting our review to this information ensures that we will afford all applicants (numbering in the hundreds each of the last 4 years) a fair and consistent review of their qualifications. Organizations can be assured that we will not consider additional sources of information regarding one applicant's qualifications that we do not consider for others.

We also proposed to clarify our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application. We clarified § 422.502(c)(2) and § 423.503(c)(2) by proposing to add a new paragraph (iii) to establish that if we do not receive a revised application within 10 days from the date of the intent to deny notice, or if after timely submission of a revised application the applicant still appears unqualified to contract as an MA organization or Part D sponsor or has not provided enough information to allow us to evaluate the application, we will deny the application.

Further, we noted that consistent with the revisions to § 422.650(b)(2) and § 423.660(b)(2), which are discussed elsewhere in this final rule, the applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. Allowing for such a submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application. In this final rule, we adopt these provisions as proposed. *Comment:* A number of commenters expressed support for all areas of this provision.

*Response:* We appreciate the commenters support of our proposal.

*Comment:* Many commenters urged CMS to be flexible and allow for unique circumstances. Several commenters noted that SNPs have only limited ability to influence the terms and timelines that State Medicaid agencies follow in executing the SNP agreements.

*Response:* We design our solicitations to ensure that all organizations have a fair opportunity to demonstrate their qualifications for an MA or PDP contract. As noted in the preamble to the October 2009 proposed rule, allowing exceptions to requirements to address unique circumstances would undermine the need for a uniform application process applied fairly to all applicants. With respect to Medicaid agency contracts, we may require that organizations submit those documents as part of an application to qualify to offer a SNP plan. When we include that requirement in a particular year's SNP application, we have determined that organizations can reasonably be expected to obtain the executed agreements in time for us to determine that it is qualified to operate a SNP during the coming contract year. We do not anticipate the need to provide any flexibility on this particular matter.

*Comment:* One commenter stated that the "all" standard is not practical given that there is not a narrative of requirements in the applications, but a series of attestations and tables (with detailed requirements stated in regulations and CMS subregulatory guidance).

*Response:* We believe the "all" standard is practical. Applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies. While we advise that applicants should be familiar with Part C and D program regulations and guidance, in most instances they are not required to describe how their organization will meet a requirement; rather they simply attest that they will meet the requirement. Therefore, an explanation of all the program requirements in the application is not necessary for organizations to submit successful Part C or D applications to us.

*Comment:* Several commenters stated that CMS has been unclear in its previous deficiency responses to applicants and that it has been difficult to obtain guidance from CMS. Commenters urged CMS to provide clear rules and be consistent. In light of the inconsistencies with which applications are reviewed, one commenter recommended using a standard that emphasizes the materiality of the requirements that sponsors must meet.

*Response:* We agree that in order for applicants to have a consistent understanding of the expectations on which we base our contract approval and denials, we must ensure the clarity and transparency of the program requirements and review criteria. Applicants receive up to three communications which explain our application requirements and provide clear instructions on how to be a successful applicant. Organizations that fail to completely and accurately apply receive a courtesy e-mail explaining the deficiencies and are given an opportunity to cure. Organizations that are still deficient after the initial opportunity to cure receive a notice of intent to deny and are given another opportunity to cure. All application communications include contact information for CMS subject matter specialists. We are always willing to work with applicants to ensure a complete understanding of program and contracting requirements.

*Comment:* One commenter stated that the applicants that have disagreed with CMS' network adequacy determinations have been reluctant to seek re-

evaluation of their network adequacy in specific counties because of the possibility that CMS will confirm its original finding and deny the entire application. A denial of one county in one state could result in the denial of an entire application. To address this problem, the commenter recommended that CMS revise its policy to provide that an applicant for a network-based plan or service area expansion (SAE) may drop a county or portion of its service area that has been identified in the intent to deny notice after receiving CMS' final decision based upon the additional information submitted by the organization.

*Response:* We afford sponsors multiple opportunities during the application review process for applicants to modify their proposed service area. However, when we conduct our final review of an application prior to the issuance of a notice of intent to deny, we must make the reasonable assumption, for the sake of consistency, that the applicant seeks approval for its entire proposed service area, not some portion that the applicant will identify at a later date. Therefore, we will not allow applicants to modify their service areas after they have received a final notice of denial of their application from us.

*Comment:* One commenter recommended that CMS explicitly provide in the regulation for a process to permit applicants to cure deficiencies identified by CMS subsequent to the issuance of the notice of intent to deny; and that if such an opportunity is not provided, CMS should base any denial notice only on issues raised in the notice of intent to deny and not on deficiencies that are identified later in the application review process.

*Response:* When we have discovered a deficiency after we have issued a notice of intent to deny, we have not disapproved that application based on the failure to correct the new deficiency. Rather, we approve the application (assuming all corrections have been made based on deficiencies identified in the Notice of Intent to Deny), but communicate to the applicant that the newly identified deficiency must be corrected prior to executing a Medicare contract. If the issue is not so corrected, it immediately becomes the subject of a CMS contract compliance action.

*Comment:* One commenter requested that we clarify the type of information gained via the onsite visits and how this information will be used in evaluation of applications.

*Response:* We clarify, that we limit our application reviews (with the exception of the past performance analysis) to the materials organizations submit in response to the annual solicitations. We would also make clear that we retain our authority to conduct site visits to conduct compliance and monitoring activities.

*Comment:* One commenter noted that it would be beneficial to sponsors if CMS provided a tool that allows sponsors to self-determine network adequacy. The commenter stated that the CMS network adequacy standards are subject to reviewer discretion and stated that this ambiguity is unfair when the sponsor must identify, negotiate, and complete contract terms, sometimes with multiple entities, within a 10-day period.

*Response:* We have developed standardized network criteria and an automated review process that we will use, starting with the contract year 2011 application cycle, to review network adequacy. Applicants may request exceptions where they do not meet the standardized criteria for individual provider types in individual counties under limited, defined circumstances. We believe these changes will increase the consistency and transparency of network reviews.

3. Deny Contract Qualification Applications Based on Past Contract Performance (§ 422.750 and § 423.750)

As described in the existing provisions at § 422.502(b) and § 423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. In the October 22, 2009 proposed rule, we proposed to modify these provisions at § 422.502(b) and § 423.503(b) to clarify that we will review past performance across any and all of the contracts held by the applicant, by specifically revising the language to refer to "any current or prior contract" held by the organization, instead of the current language referring to a "previous year's contract." We also clarified that the period that will be examined for past performance problems will be limited to those identified by us during the 14 months prior to the date by which organizations must submit contract qualification applications to CMS. Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.

In making these proposed changes, we noted that indicia of performance deficiencies that might lead us to conclude that an organization has failed to comply with a current or prior contract include, but are not limited to, poor performance ratings as displayed on the Medicare Options Compare and MPDPF Web sites; receipt of requests for corrective action plans (CAPs) unrelated to an audit (as these types of CAPs generally involve direct beneficiary harm); and receipt of one or more other types of noncompliance notices from CMS (for example, notices of noncompliance or warning letters).

Additionally, consistent with the proposed changes to § 422.503(b), § 422.508(c), § 423.504(b), and § 423.508(e), we indicated that the withdrawal of Part C or D operations from some or all of an organization's newly contracted service area prior to the start of a benefit year (through mutual termination or otherwise) is an indication of poor performance. Such a situation can arise when, for example, an organization, after it has signed its Medicare contract for the upcoming program year, loses a contract with a significant number or type of providers, jeopardizing its ability to provide its members adequate access to services. Also, an organization may suddenly face financial difficulties that threaten its ability to offer the benefit packages approved by us throughout the upcoming contract year. In such instances, we noted that we could simply leave the contract in place and take enforcement actions against the organization. However, under such an approach, we would knowingly be permitting beneficiaries to remain enrolled with an organization that cannot effectively deliver the benefit. Instead, we indicated our preference to act in the best interests of the beneficiaries by agreeing with the organization to terminate its contract and work with the organization to make certain that beneficiaries receive uninterrupted access to Medicare services through another MA organization, PDP sponsor, or original Medicare. We are adopting these proposed changes without further modification in this final rule.

*Comment:* Several commenters expressed their support for our use of the past performance review authority to ensure that underperforming sponsors are not permitted to expand their participation in the Part C and D programs.

*Response:* We appreciate the commenters' support.

*Comment:* Several commenters requested that CMS more clearly articulate the methodology it will apply to past performance reviews conducted under this regulatory provision. For example, commenters were interested in knowing the relative weights CMS will

be assigning to different types of compliance actions (such as, corrective action plan requests, warning letters) and whether we will afford organizations the opportunity to correct deficiencies before CMS makes past performance determinations.

*Response:* We expect to make past performance methodology available through publication in our manuals. We believe that the manuals provide us and sponsors with the best available avenue for providing such detailed information and making updates to it as we continue to gain more experience with conducting past performance analysis. Given that, we note that the information on which we will base our past performance analysis has already been made available to organizations. For example, at any time an organization can review its own record of compliance correspondence received from us to get a sense of the degree to which the organization should be concerned about the likelihood that CMS would deny an application for a new contract.

We believe that questions regarding corrective action opportunities are not relevant to our process for reviewing past performance in making application determinations. The purpose of the past performance review is to determine whether the sponsor has demonstrated, over a 14-month period, whether it has operated its Part C or D contract in a manner that suggests that it is generally meeting and capable of meeting program requirements and that new Medicare business would not jeopardize that status. While some organizations take corrective action to address any and all compliance issues prior to the expiration of the 14-month review period, such corrective action would not change the fact that during that period of time, the organization demonstrated a pattern of noncompliance that may raise questions about its ability to take on new Medicare business.

*Comment:* Some commenters advised that the 14-month review period is too long, while others stated that a longer period (for example, 3 years) would provide a more comprehensive view of a sponsor's contract performance.

*Response:* We believe that the 14 month look-back provides an adequate amount of time for us to review an MA organization's or Part D sponsor's performance and the choice of 14 months as the look-back period was not arbitrary. As we noted previously, and in the proposed rule, 14 months covers the period spanning the start of the previous contract year to the time we receive applications for the following contract year. To shorten that time period to, say, 12 months would leave a gap in our past performance review. Similarly, limiting the period to the 14-month timeframe gives sponsors and organizations the opportunity and incentive to promptly establish a positive compliance track record so that the next CMS past performance review will find them eligible for additional Part C or Part D business.

*Comment:* Several commenters asked that CMS indicate whether the withdrawal from all or part of a service area, non-renewal of one or more plans (on the Part C or Part D sponsor's initiative), withdrawal of an application or bid, or termination of a contract after it has been executed would be counted against an organization for purposes of past performance analysis.

*Response:* We would not consider a sponsor-initiated non-renewal of all or a portion of an MA or PDP sponsor contract as an indication of poor contract performance. (However, under separate regulatory authority sponsors that non-renew their contracts may not be permitted to reenter the program for a period of 2 years.) We would treat non-renewed plan benefit packages similarly, assuming the organization had met the Part C or D requirements for providing timely notice to us and our enrollees. We do not consider the withdrawal of an application for qualification as Medicare contractor or of a bid prior to the publication of the annual benchmark calculation as relevant to a performance evaluation.

We do look unfavorably on organizations that withdraw bids after the benchmark has been announced. Also, we consider the termination of a contract for an upcoming benefit year after the organization has executed the contract as a failure to meet Part C and D program requirements. Accordingly, organizations should expect that these occurrences would be considered against them when we evaluate their past contract performance.

*Comment:* Several commenters offered suggestions on factors CMS should take into consideration when developing and applying our past performance review methodology. These included accounting for distinctions between national and local organizations, beneficiary impact of noncompliance (or lack thereof), unique characteristics of SNP plans, and whether difficulties in an organization's operation of a contract can be attributed to an entire organization or are limited to operation of only one or more of its contracts.

*Response:* As noted previously, we plan to address issues raised by some of the commenters more fully in guidance issued through our manual update process. At this time, we can provide a general discussion of some of the principles we intend to apply to the development of our past performance methodology. We are cognizant of the variety of products offered by Medicare contractors, and when an element of our past performance evaluation is affected by the unique feature of a particular plan type, we will adjust the application of our methodology as appropriate. We also want to emphasize that we intend to be conservative in our determinations. We expect to use our authority under this provision to exclude only those organizations demonstrating a pattern of poor performance. Finally, we acknowledge that not all types of noncompliance will be given equal weight, and our methodology will assign weights to different measures based on factors such as beneficiary impact or program stability.

*Comment:* A number of commenters suggested that CMS provide the results of its past performance analysis prior to the due dates for the submission of notices of intent to apply or for the applications for contract qualification.

*Response:* We will explore the feasibility of providing a preliminary analysis in response to sponsors' requests. However, we note that such a report would not be final, and in no case would even a preliminary report be available before December of each year.

*Comment:* A number of commenters requested assurance that the past performance review described previously in this final rule and in the October 2009 proposed rule would not include information concerning a sponsor's performance under contracts other than those governing Medicare managed care and prescription drug plan operations (such as, Medicaid, QIC contracts).

*Response:* Absent extraordinary circumstances, we plan to limit our past performance review to the operations of organizations in the performance of their Part C and D contracts only.

*Comment:* One commenter objected to CMS' use of past performance analysis asserting that is equivalent to taking a second punitive action for a single instance of noncompliance.

*Response:* In this final rule, we are clarifying the scope of our existing authority and we do not believe it is equivalent to an additional compliance or enforcement action taken against any of the organization's existing Medicare contracts. Our denial of an application based on an applicant's past contract performance is a reflection of our belief that an organization demonstrating significant operational difficulties

should focus on improving its existing operations before expanding into new types of plan offerings or additional service areas. Such a determination has no impact, punitive or otherwise, on a sponsor's current Medicare contract rights and obligations.

*Comment:* One commenter requested that organizations be permitted to attest that they will meet all Part C or D program requirements as of no earlier than January 1 of the upcoming contract year, as organizations are focused on enrollment and readiness activities prior to that date.

*Response:* This comment concerns an aspect of the Part C and D application and contracting processes unrelated to our exercise of the past performance review authority. Thus, it is outside the scope of our proposal, and we will not address it here.

4. Use of Data to Evaluate Continued Ability to Act as a Qualified Sponsoring Organization Under Parts C and D (§ 422.504, and § 423.505)

In the October 22, 2009 proposed rule, we clarified our authority to find organizations or sponsors out of compliance with MA and Part D requirements. We noted that under the authority of Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, the Secretary may add terms to the contracts with MA and Part D sponsors including terms that require the sponsor to provide the Secretary "with such information * * * as the Secretary may find necessary and appropriate." Additionally, under that authority, CMS established § 422.516 and § 423.514, which support the submission of Part C and D Reporting Requirements. We clarified that the data acquired through the reporting requirements are often used for the purpose of monitoring an organization's or sponsor's continued compliance with MA and Part D requirements. We also explained that in some instances, we may use an outlier analysis to determine a MA organization's or Part D sponsor's performance relative to industry standards established by the performance of all the other organizations and sponsors as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts.

As part of the proposed rule, we added paragraphs § 422.504(m)(1) and (2) and § 423.505(n)(1) and (2) to make explicit our existing authority to find organizations or sponsors out of compliance with MA and Part D requirements when the organization's or sponsor's performance fails to meet performance standards articulated in statutes, regulations, and guidance or when an organization's or sponsor's performance represents an outlier relative to the performance of other organizations or sponsors. In this final rule, we adopt the provisions as proposed.

*Comment:* Some commenters supported this provision, specifically the development of consistent performance data evaluation processes.

*Response:* We appreciate the comments.

*Comment:* Many commenters recommended that CMS not use outlier data to make compliance determinations for a variety of reasons. Some commenters believed that CMS should only use specific, previously articulated criteria to determine non-compliance. Other commenters stated that the outlier analysis is arbitrary, inconsistent, and capricious at least in part because it would result in CMS holding sponsors to standards that are developed simply by measuring sponsors' performance relative to each other, not what is actually required to comply with Part C and D program requirements. One commenter noted that such an approach is inconsistent with the operation of a program where Medicare sponsor contracts are not awarded on a competitive basis. Still other commenters recommended that if an outlier analysis is used, it should only be used as a means by which CMS identifies plans in need of improvement not as a determination of non-compliance.

*Response:* We appreciate these comments, but we maintain our belief that outlier analysis remains a valid method for identifying non-compliant plan sponsors and a valuable tool in our efforts to monitor hundreds of contracting organizations in a timely and effective manner. Technically, the Part C and D regulations require 100 percent compliance with all program requirements. We acknowledge that it can be impractical to hold sponsors to such an absolute standard. When attempting to establish an acceptable level of noncompliance, it makes sense for us to compare a sponsor's performance to that of its peers. Such outlier analysis gives us a sense of the general performance capabilities of a set of sponsors. From such an analysis it is reasonable, in most instances, for us to conclude that organizations whose performance trails that of other similarly situated sponsors are not making reasonable efforts to provide an acceptable level of service to their enrollees. As we noted in the discussion of our proposed rule, inherent in the use of outlier analyses to evaluate compliance is the application of the well-accepted principle that we should look to evolving industry standards to establish program requirements.

We recognize our obligation, as both a business partner and a regulatory agency, to use the outlier analysis tool in a manner that is fair to sponsors and is legally supportable. For example, we want to reassure organizations that we understand that effective outlier analysis is concerned not just with which organizations' performance scores are lower than others, but also with the degree to which some sponsors may trail their peers. Therefore, an outlier analysis does not by definition and in every case result in a finding of non-compliance. Also, we remind organizations that we have adopted over the last several years, a graduated system of compliance notices, and we expect that in the large majority of instances, we will make organizations aware of their non-compliance with an outlier-based standard through the lower-level types of notice. These are the types of notices issued in the earlier stages of CMS' compliance efforts and would afford organizations reasonable opportunities to take corrective action. Finally, we are committed to publishing regularly outlier-based performance standards, as they are developed, in guidance materials, including our program manuals, HPMS memoranda, and our annual call letter, and to update these standards over time. Further, compliance communications to sponsors concerning an area of noncompliance where the basis for the finding relied on outlier analysis include an explicit description of the methodology employed to make such a determination.

*Comment:* Many commenters requested that CMS compare like plans with respect to several identifiers, including: plan types (with particular consideration given to SNPs), size, market conditions, open vs. closed formularies, and age of enrollees. Some commenters noted that meaningful comparisons across sponsors might be difficult.

*Response:* Where appropriate, we compare like sponsors and frequently take enrollment (both numbers and types of beneficiaries, such as, LIS-eligible) into consideration. Identifiers that the commenters mentioned are taken into consideration as part of our data analysis. Our goal is to do meaningful analysis that can aid us in identifying potential weaknesses.

*Comment:* Several commenters were concerned with how CMS will conduct outlier analysis and requested that CMS

define and develop standardized methods for determining outliers. One commenter recommended that CMS work with the industry to establish methods for outlier analysis. Another commenter recommended that the methodology should include different weights assigned to measures based on the magnitude of beneficiary impact and program integrity. One commenter requested that the outlier analysis be done at the contract level as opposed to the plan benefit package (PBP) level. Another commenter recommended that CMS be specific about whether compliance action would be taken for first-time outliers or only for sponsors with a history of being an outlier.

*Response:* We understand the importance of working with the industry to establish methodologies and do so where appropriate. For example, we have and will continue to share drafted or proposed plan rating (star ratings) measures and their analyses. Comments from sponsors are reviewed and considered as we finalize those measures. The Part C and D reporting requirements also undergo similar public comment periods.

The issue of assigning different weights to measures is not relevant here as the proposed change concerns the use of outlier analysis for particular, not aggregated, operational requirements. We incorporate weighting into our analysis of sponsors' overall contract performance. This analysis is typically done at the contract level at least in part because we collect data at that level, not the PBP level.

As discussed previously, we account for whether a sponsor is a first-time or repeat outlier when it determines the type of compliance notice to issue. Depending on the circumstances, organizations identified as first-time outliers may receive only a notice of noncompliance, while those that are repeat outliers may receive a CAP request or be subject to an enforcement action.

*Comment:* Several commenters urged CMS to make the outlier methodology available to all sponsors through, for example, the Call Letter or Technical Specifications. Many of these commenters requested an opportunity to review and comment on the methodology. A couple of commenters were concerned about CMS' use of outlier analysis and being able to predict how other sponsors will perform to ensure that their own performance is aligned and compliant.

*Response:* Where appropriate, we will make methodologies available to sponsors, as we discussed earlier in our response to comment on this proposal. An example of the importance we place on the need for clarity and transparency is the fact that we currently make available our methodologies in the technical specifications for the Reporting Requirements and the plan ratings (star ratings). In another example, we recently (January 2010) released an HPMS memo and incorporated into the Part D manual a comprehensive description of our outlier methodology for ensuring appropriate access to home infusion pharmacies. In an effort toward complete transparency, we also provided the underlying data and necessary information for Part D sponsors to conduct their own independent analyses on this topic.

*Comment:* Many commenters noted that there are reasons other than non-compliance that may result in a sponsor being an outlier. Outlier, by definition, means that there will always be a sponsor underperforming.

*Response:* We acknowledge that outlier status does not necessarily mean non-compliance. We review the list of statistical outliers and set thresholds on a number of factors for the purposes of identifying potential compliance problems. This is consistent with our goal to do meaningful analysis that can aid in identifying potential weaknesses. Most often, a sponsor will receive a request for information, as opposed to a compliance letter, to help us better understand why that particular sponsor was an outlier. These requests frequently result in the sponsor gaining a better understanding of our requirements and promote program improvement.

*Comment:* There were a few comments on the validity of current analyses performed by CMS. Some commenters discussed their observation that the findings resulting from some of CMS' outlier analyses methodology may penalize some organizations unfairly because—(1) the underlying data on which the analysis was based was flawed; or (2) analyses based on self-reported data may indicate that one sponsor is reporting data more accurately data than its peers. A commenter noted that the compliance letters that result from outlier analysis come months after the data has been collected and that there is little opportunity for an organization to correct its performance. A few commenters requested that CMS give sponsors the opportunity to appeal or explain the outlier status to CMS.

*Response:* We are always open to information and feedback from sponsors on our analyses and make corrections to our compliance determinations where the new information supports such a step. We also note that we are developing requirements concerning sponsors submitting audited data to address the concerns about data accuracy that the commenters raise.

*Comment:* One commenter believed that the annual audits and the outlier analyses appear to be duplicative.

*Response:* We use audits, outlier analysis, and other methods to ensure compliance with program requirements and to help identify potential compliance problems. Audits and outliers analyses are two distinct monitoring methods that utilize different sources of information and apply different types of analyses to evaluate sponsors' compliance with program requirements. Audits represent an in-depth review of selected sponsor's documentation related to the operation of their Medicare contracts. Outlier analysis, by contrast, consists of an agency review of performance data (generated by CMS or the sponsor) across all contracting organizations which results in the identification of potential noncompliance and the need for further investigation.

5. Compliance Programs Under Parts C and D (§ 422.503(b)(4)(vi) and § 423.504(b)(4)(vi))

In the October 2009 proposed rule, we proposed to modify the language at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) to explicitly provide clarification as to what constitutes an "effective" compliance program. We also proposed clarifying language for each of the required elements of an effective compliance program in order to assist sponsoring organizations with implementing more effective compliance programs and to more clearly articulate our expectations.

We proposed to add language to the first element at § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A) to require that written policies and procedures must describe a commitment to comply with all Federal and State standards, compliance expectations as embodied in the standards of conduct, implement the operations of the compliance program, provide guidance to others, identify how to communicate compliance issues to compliance personnel, describe how compliance issues are investigated and resolved and include a policy of non-intimidation and non-retaliation.

The second element requires a sponsoring organization to have a compliance officer and committee accountable to senior management. We proposed to add language at § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) that the

compliance officer must be employed by the sponsoring organization, and the compliance officer and committee must periodically report directly to the governing body and that body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program.

The third element requires the sponsoring organization to have an effective training and education program. We proposed to add language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C) to specify several key groups and individuals (the chief executive or other senior administrator, managers, and governing body members) among the sponsoring organization's employees who are required to have compliance training and education. We also proposed to add language that this training must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments of a chief executive, manager, or governing body member. The required compliance training must include training regarding the prevention and detection of fraud, waste and abuse. We proposed to add that providers who have met the requirement for fraud, waste and abuse training and education through enrollment into the Medicare program are deemed to have met that portion of the training and education requirement.

We noted that, in some instances, a particular pharmacy or other provider may contract with dozens of MA or PDP plans, each of which is required by the existing language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C), read literally, to provide the required fraud, waste and abuse prevention and detection training to the pharmacy, or other provider, and its staff. Since we did not intend to require duplicative training, we offered two options in our proposed rule. One option was that the sponsoring organization "assures" or "obtains an assurance" that the first tier, downstream, and related entity has received such training. Another option was to leave existing language unchanged, but issue interpretive guidance on this point. We requested workable suggestions to assure that our objective is met, while eliminating unnecessary duplication.

The fourth element requires a sponsoring organization to have effective lines of communication. We proposed to add language at § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D) that requires that these lines of communication be confidential and accessible to all employees and allow for compliance issues to be reported anonymously and in good faith as issues are identified.

The fifth element requires a sponsoring organization to enforce standards through well-publicized disciplinary guidelines. We proposed to add language at § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E) that more specifically described that these guidelines must be implemented to include policies that articulate expectations for reporting issues and their resolution, identify noncompliance or unethical behavior, and provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is detected.

The sixth element requires a sponsoring organization to have procedures for internal monitoring and auditing. We proposed to add language at § 422.503(b)(4)(vi)(F) and § 423.504(b)(4)(vi)(F) to more specifically describe that an effective system for routine monitoring and identification of compliance risks includes internal monitoring and audits and, as appropriate, external audits, in order to evaluate the sponsoring organization's compliance with our requirements and overall effectiveness of the compliance program. We also proposed to add language that these audits should include the sponsoring organization's first tier entities.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We proposed to add language at § 422.503(b)(4)(vi)(G) and § 423.504(b)(4)(vi)(G) to more specifically describe the implementation of a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensuring ongoing compliance with our requirements.

We are adopting all of these proposed changes into the final rule without further modification with the exception of changes made to § 422.502(b)(4)(vi)(B), § 423.504(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(C), to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and clarify that he or she may not be an employee of a first tier, downstream or related entity of the sponsoring organization and must be accountable to the governing board of the sponsoring organization. In addition, at § 423.504(b)(4)(vi)(C)(3), we adopt a new regulation for the Part D program to specify that first tier, downstream, and related entities that have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program and accreditation as a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier are deemed to have met the fraud, waste and abuse training and educational requirements.

We received the following comments on the first element, which requires written policies and procedures:

*Comment:* Two commenters raised concerns about the resources necessary to satisfy our requirements related to written policies and procedures. One commenter stated that sponsoring organizations are currently spending significant time and resources drafting and redrafting policies and procedures and are still uncertain if these policies and procedures will cover the items we expect to be covered in requisite detail. Both commenters suggested that we release our audit worksheets which outline CMS's expectations for the contents of policies and procedures, which would allow sponsoring organizations to tailor their policies and procedures accordingly. Additionally, one commenter suggested that CMS should not be dictating the scope or components of such policies and disagreed with our inclusion of more "prescriptive standards" into the regulatory text and alternatively suggested that certain requirements be issued through subregulatory guidance.

*Response:* Our proposals are intended to significantly strengthen our oversight of compliance programs, and provide more specificity and clarity to sponsoring organizations with regard to what we expect to see when we review a compliance program. We believe the proposals we have made are important changes and are necessary to maintain consistency and promote appropriate focus on these requirements and that going through the rulemaking process is the best way to promote these goals. We also believe that the proposed changes to the first element provide important information as to what we consider a framework for an effective compliance program. We do not intend to be prescriptive as to the choice of particular processes or procedures, only to provide the minimum amount of information we would expect to see in a comprehensive set of written policies,

procedures and standards of conduct. With respect to the comment regarding releasing audit materials, we must balance the goals of transparency regarding our audit program with the goals of conducting an effective evaluation of whether organizations have in fact instituted effective compliance programs (and not just "paper" compliance programs). To the extent that sponsoring organizations are looking to tailor their policies and procedures for compliance programs to materials released by us, they should be looking to our regulations, including the changes made by this final rule, and any subregulatory guidance issued by CMS, and not documents related to our audit program, as these may only be a subset of CMS' larger set of requirements.

We received the following comments regarding our proposed revisions to the second element, which addresses the designation of a compliance officer and a compliance committee who report directly to the organization's chief executive or other senior management:

*Comment:* Commenters expressed concern with CMS' proposal to require that the compliance officer, vested with day to day operations of the compliance program, be an employee of the sponsoring organization. Commenters recommended that CMS broaden this portion of the provision to permit the compliance officer to be employed by the sponsoring organization or an affiliate in its corporate group. These commenters indicated that "the entity who employs the compliance officer is a corporate structure issue that may have no effect or bearing on the issues of accountability and oversight." One commenter further insisted that in instances when related entities are MA organizations and PDP sponsors who hold separate contracts with CMS, having one centralized compliance officer is not only effective and efficient, but it also promotes consistency with respect to the implementation of the compliance program across the contracting entities. Several commenters also stated that having the compliance officer at a parent or affiliated group level would not lessen the accountability of the compliance officer with respect to each entity.

*Response:* We agree that having a compliance officer being employed at a parent company or corporate affiliate may not necessarily lessen the accountability of the compliance officer to the governing body of the sponsoring organization. Our proposal was intended to provide further clarity on how sponsoring organizations can meet the key requirement of having a compliance officer and compliance committee that is accountable to the governing body of the sponsoring organization. We have issued extensive subregulatory guidance on this issue, both in the 2007 call letter and in Chapter 9 of the Medicare Prescription Drug Benefit Manual ("Chapter 9"). This guidance was issued in part in response to us learning that sponsoring organizations were subcontracting the compliance officer function to their first tier, downstream and related entities. We do not view subcontracting that function as an acceptable alternative for a number of reasons, including the potential for conflicts of interest that would exist by virtue of the compliance function residing in a subcontracted entity that is being paid by the entity whose compliance the subcontractor is charged with monitoring. As a result of the comments received, we are modifying the language in this final rule to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and to provide that the compliance officer may not be an employee of a first tier, downstream or related entity of the sponsoring organization.

*Comment:* Proposed sections § 422.503(b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2) specify that the compliance officer and committee must periodically report to the governing body of the sponsoring organization on the activities and status of the compliance program. One commenter emphatically supported CMS' proposal to strengthen the compliance program by increasing the requirements with respect to interaction with the executive leadership and board members. One commenter recommended that CMS revise the language of this provision to state that the compliance officer and committee, "or their delegate", report directly to the governing body. Lastly, one commenter stated that although they supported CMS' goal of ensuring sponsoring organizations' senior leadership and governing body are informed of key developments, the commenter opposed CMS dictating internal reporting obligations and reporting structures.

*Response:* We disagree with the suggestion to add "or their delegate" to the language at § 422.503 (b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2), which would expand the scope of individuals who could provide periodic reports to the governing body of the sponsoring organization. The purpose of this provision is to ensure communication between the compliance officer, committee and the governing board. We do not intend that this reporting responsibility be delegated to someone other than the compliance officer as that would defeat the purpose of the proposed provision. Therefore, we will not be incorporating the commenter's suggested change into the final rule.

We also do not believe that the proposed regulatory language in this section results in CMS dictating to MA organizations and Part D sponsors their internal reporting obligations and reporting structures. The proposed language does not specify the means or manner in which the report should be communicated to the governing body, nor does it provide specific requirements as to how often such reports are made.

We received the following comments concerning our proposed changes to the third compliance program element, which—(1) states that sponsoring organizations must establish and implement effective training and education between the compliance officer and the sponsoring organization's employees, governing board, first tier, downstream and related entities; (2) specifies that this training and education must occur at a minimum annually and must be made a part of new employee orientation; and (3) provides deeming of fraud, waste and abuse educational requirements to first tier, downstream and related entities who have met the fraud, waste and abuse certification requirements though Medicare program enrollment:

*Comment:* Some commenters stated that organizations should have the flexibility to modify and tailor the training for the governing body so that it is not a replication of the training needed for front line staff, and expressed specific concern with CMS requiring training of the governing body annually. Additionally, several commenters stated that requiring sponsoring organizations to conduct compliance training at new employee orientations and annually thereafter is administratively and financially burdensome, and may even result in organizations having to conduct such training on a weekly basis. Commenters made numerous recommendations, including providing sponsoring organizations with flexibility in determining the appropriate level and timing of training depending on the audience; modifying the education and training requirements to apply to only those involved in the administration of the Medicare Advantage and Part D lines of business within the organization; clarifying that the annual education and training requirement is limited to general compliance training, and does not include the specialized

training that sponsoring organizations have to implement in accordance with Chapter 9; and the suggestion that CMS develop a Web-based compliance training tool or certify an independent industry entity to provide consistent and efficient compliance training; and finally, providing additional clarification on the required training for downstream entities.

*Response:* We believe that the proposed regulatory language allows organizations the flexibility to tailor the content of the training and many aspects of how the training is provided. We have not specified the manner in which the training would be provided at new employee orientations, or to senior leadership or members of the governing body upon their appointment to these positions. Organizations can decide to provide new employees with a copy of the organization's compliance policies and procedures and ask new employees to attest that they have been provided with a copy and have read the material. We do not believe that such a requirement is overly burdensome or difficult for sponsoring organizations to implement.

We also do not believe that it is appropriate to clarify in regulation text that we are referring to general versus specific compliance training, as discussed in Chapter 9. The proposed language makes no reference to the training being specialized and we believe that the regulatory language should be left general as the level of training and education will vary depending on the level and responsibilities of the person receiving the training. We believe that the proposal is sufficiently clear in its description of what is expected of the sponsoring organization in the implementation of its compliance training and education program and the requirements are reasonable. If we determine in the future that further guidance is necessary, we will issue subregulatory guidance.

Lastly, in response to those commenters who suggested that CMS develop a Web-based compliance training tool, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

*Comment:* Some commenters stated that requiring sponsoring organizations to conduct compliance training for all delegated entities (first tier, downstream and/or related) or insuring that all delegated entities conduct such training on their own imposes a significant burden on sponsoring organizations.

*Response:* In response to those commenters who stated that requiring that first tier, downstream and related entities to receive compliance training is overly burdensome, we would like to reiterate that this is an existing requirement, not a proposed new requirement. We agree that duplicative training is inefficient and we believe that commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

*Comment:* Commenters also suggested striking the word "effective" from the language of this section which specifies that the sponsoring organization must establish, implement and provide "effective" training and education. Alternatively the commenter requested that CMS at least clarify how we would determine if training were "effective" and clarify CMS' definition of sufficient oversight.

*Response:* The use of the term "effective" is existing regulatory language and has already gone through notice and comment rulemaking. "Effective" is not a new requirement, therefore, we do not believe it is necessary to remove the word "effective" from this regulatory provision.

*Comment:* Commenters suggested that CMS consider revising the requirement that fraud, waste, and abuse training and education occur at least annually and be a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments to chief executive, manager or governing body member. Commenters believe that CMS should require that training only at the time of initial hire or when there are significant changes in the laws and regulations related to fraud, waste, and abuse.

*Response:* We disagree and believe that annual training is a necessary component of an effective compliance program that addresses the detection, correction, and prevention of fraud, waste, and abuse in the MA and Part D programs. The intent of this regulation is to codify the existing CMS expectation that fraud, waste and abuse training be provided at a minimum on an annual basis, which is contained in Chapter 9 of the Prescription Drug Benefit Manual (Part D Program to Control Fraud, Waste, and Abuse). Chapter 9 can be viewed at: *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.* We recognize that Chapter 9 was specifically developed for Part D (prescription drug plan) sponsors. In previous guidance, we have directed MA organizations to apply the provisions of Chapter 9 to Part C (Medicare Advantage) programs as well. We are in the process of updating this document to specifically address any particular Part C measures for detecting and preventing fraud, waste, and abuse.

*Comment:* Several commenters expressed support for our proposed revisions to § 422.503 (b)(4)(vi)(C)(2), which clarify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse under this rule. One commenter disagreed with the proposed revision.

*Response:* We believe that the proposed regulatory language eliminates redundant certification made when these entities enroll in the Medicare program. We also wish to clarify that the reference to deeming in this regulation is distinct from the MA deeming and accreditation program described at § 422.156, § 422.157, and § 422.158.

*Comment:* A number of commenters recommended that CMS extend the regulatory change proposed for the Part C program at § 422.503(b)(4)(vi)(C) to the Part D program at § 423.504(b)(4)(vi)(C). The commenters noted that Part D first tier, downstream, and related entities that have enrolled in the Medicare program as a supplier of Part B covered medications or as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) go through the same application and certification process as MA providers. They contend that including Part D providers in this deeming would ensure the requirements for Part D sponsors will be identical to those for MA organizations and would reduce unnecessary additional burden.

*Response:* We agree with the commenters and have adopted a new regulation for the Part D program at § 423.504(b)(4)(vi)(C)(3) to specify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program accreditation as a DMEPOS supplier are deemed to have met the

training and educational requirements for fraud, waste, and abuse training. We wish to clarify that the reference to deeming in this regulation is distinct from the Part D deeming and accreditation program described at § 423.165, § 423.168, and § 423.171.

We received the following responses to our request for comments on whether or how to best revise the requirement that first tier, downstream, and related entities receive training in how to prevent and identify fraud, waste, and abuse to address the issue of duplication of training for providers or entities that contract with multiple MA organizations or Part D sponsors:

*Comment:* Several commenters recommended requiring MA organizations and Part D sponsors to create training materials or approve first tier, downstream, and related entity-created materials and require attestations that the training was provided to all appropriate parties. These commenters noted that in order to avoid duplicative training, all sponsoring organizations would be required to accept attestations from their first tier, downstream, and related entities that they completed training provided by any other sponsoring organization in order to fulfill this requirement. Commenters also suggested that another option to ensure consistent training content and minimize duplication is for CMS to create a standardized training and require all sponsoring organizations to use it for training their first tier, downstream, and related entities. Commenters also recommended that CMS permit first tier, downstream, and related entities to create and implement their own training programs and attest to their contracting MA organizations and/or Part D sponsors that they have fulfilled the training requirement.

*Response:* We believe the commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

*Comment:* A few commenters requested that CMS provide more specificity regarding which entities must complete fraud, waste, and abuse training. These commenters believe that CMS should limit the training requirement for first tier, downstream and related entities to only staff of those entities that are involved in patient care and/or claims submission, and should not require administrative or retail clerk/cashier staff to complete the training.

*Response:* The requirement for fraud, waste, and abuse training applies to all MA organization and Part D sponsor employees (including chief executive or other senior administrator, managers and governing body members) and first tier, downstream and related entities. We will issue additional clarification in subregulatory guidance.

The fourth element requires a sponsoring organization to have effective lines of communication. We did not receive comments regarding this element.

We received the following comment concerning the proposed revisions to the fifth compliance program element which details a sponsoring organization's obligation to ensure its compliance program has well publicized disciplinary standards.

*Comment:* The commenter requested that CMS provide guidance regarding its expectations as to sponsoring organization's enforcement of disciplinary standards, and asked for clarification as to whether a policy identifying the different types of disciplinary actions a sponsoring organization may impose would be sufficient to meet the requirement.

*Response:* We believe that our proposal is sufficiently detailed to provide sponsoring organizations with necessary guidance on how to implement an effective compliance program.

We received the following comment regarding the proposed revisions to the sixth compliance program element concerning requirements for sponsoring organizations monitoring and identification of compliance risks.

*Comment* A commenter requested that CMS specify that its reference to external audits, especially of first tier entities, does not require sponsoring organizations to hire an independent, external auditor to perform this function but rather that sponsoring organizations may undertake the auditing of these contractors through their internal audit units.

*Response:* Our expectation, when referring to a sponsoring organization conducting an external audit of itself or a first tier entity, was that that sponsoring organization would utilize an auditor who is external of both the sponsoring organization and the first tier entity being audited.

*Comment:* A commenter recommended that CMS share its preamble language that further defines the expectations for an effective compliance program with other areas of the Federal government, such as the Department of Defense, so that all government contractors will have the same compliance program expectations.

*Response:* We believe that this comment is outside the scope of this regulation.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We did not receive comments regarding this element.

6. Network Adequacy of Coordinated Care and Network-Based Private Fee-for-Service Plans Under Part C (§ 422.112)

In the October 22, 2009 proposed rule (74 FR 54644), we requested comments on proposed criteria for determining whether an MA plan network meets the network availability and accessibility requirement in section 1852(d)(1) of the Act. As we discussed in the proposed rule, we have developed an automated system for reviewing network adequacy on a continuing basis based on the elements that we have determined reasonably reflect community patterns of health care delivery. As we noted in the proposed rule, our operational experience has demonstrated that the concept of community patterns of health care delivery provides a useful benchmark for measuring a proposed provider network, because it allows for varying geographical and regional conditions to be taken into consideration in determining what constitutes "reasonable" access in a given area.

In the proposed rule, we described the elements of community patterns of health care delivery that we proposed to include in our evaluations of provider networks, and stated that our goal was to make the standard of community patterns of care more transparent and consistent across the country. Specifically, we proposed adding a new paragraph (a)(10) to § 422.112 to specify the factors comprising community patterns of health care delivery that we would use as a benchmark in evaluating a proposed MA plan health care delivery network. Under proposed § 422.112(a)(10), these factors would include, but not be limited to—

- The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans;
- The prevailing market conditions in the service area of the MA plan—specifically, the number and distribution of health care providers

contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan;

- Whether the service area is comprised of rural or urban areas or some combination of the two;
- Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties; and
- Other factors that we determine to be relevant in setting a standard for an acceptable health care delivery network in a particular service area.

We proposed providing more detail about how we would operationalize these requirements through subregulatory guidance (for example, the annual Call Letter). We solicited comment on whether our proposed regulatory provisions are sufficiently clear and whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

After considering all the timely comments we received on our proposal, we are adopting § 422.112(a)(10) without modification in this final rule.

*Comment:* Many commenters expressed concern that the proposed CMS approach to evaluating network adequacy based on community patterns of care would be too limiting, and would not allow organizations sufficient flexibility to develop networks in rural areas or areas with unique conditions. Several commenters were concerned that CMS' interpretation of what constitutes community patterns of care would result in an approach that would not adequately take into account special plan-specific factors, such as the size of a plan or the quality of its providers. Also, a number of commenters were concerned that unique characteristics of a particular community, such as provider willingness to contract, would not be captured in the CMS network adequacy standards. One commenter expressed concern that the proposed requirements for network adequacy appear to encourage a fee-for-service and fragmented care model based on geographic access rather than a defined network of high quality primary care practices, supported by a limited network of sub-specialists. One commenter was concerned that CMS would only use the prevailing community standard of care to evaluate network adequacy, citing as an example a plan with a network that did not meet the prevailing community standard of care but was nevertheless adequate or even better in terms of the access it actually provides health care services to enrollees.

*Response:* In developing standards for network adequacy we chose the overarching principle of community patterns of care because it is a robust model that allows CMS the necessary flexibility to develop standards that can be adapted to the significant variations that exist in health care delivery in the United States. Our proposed regulation outlined the broad elements that we have found from years of experience to be relevant in evaluating a particular community pattern of care. However, we are cognizant of the fact that there exist a number of unique local circumstances related to such factors as geography, market conditions, and provider availability. Accordingly, this final rule codifies an approach to determining network adequacy that builds on our experience with evaluating health plan provider networks but is also flexible enough to adapt to evolving and unique local market conditions. The automated process we have established to assess network adequacy is likely to be refined as we gain more experience, and maintaining flexibility in our regulatory requirements for network adequacy supports this goal. We also note that the automated system we are using does not specify the providers with which a plan contracts. Rather, it furnishes a benchmark so we can determine if a plan's provider network is adequate given the availability of providers in the area where the plan is being offered and the expected enrollment in the plan. In other words, our standards address the relative size and scope of an acceptable MA provider network given the community patterns of care. However, MA plans still have discretion to select the providers they contract with as long as that network is adequate to meet the health care needs of its enrollees. In addition, we will have an exceptions process by which plans can highlight special circumstances that affect their ability to meet our access standards.

*Comment:* Many commenters had very detailed, specific questions about our automated system for assessing network adequacy, and much of this feedback has already been provided to CMS through other mechanisms. For example, one commenter asked for certain adjustments to the ratio of providers to beneficiaries. Other comments questioned how CMS would implement various features of network adequacy and whether they would be codified in regulations text.

*Response:* As noted previously, we have developed and implemented automated systems to evaluate the network adequacy of MA plans. As part of that implementation, we have provided considerable subregulatory guidance regarding implementation of community patterns of care through this automated process. An example of this subregulatory guidance is the provision of time and distance standards (available on the CMS Web site) by category of health care provider for a number of rural and metropolitan counties throughout the United States. Because we did not propose to incorporate the technical specifics of our automated system into regulation text, we believe it is most appropriate to address specific technical suggestions in the context of implementing and fine-tuning the automated network adequacy system.

*Comment:* Several commenters expressed concern about how CMS would implement time and distance standards for determining network access. One commenter asked that CMS be mindful of the impact of imposing time and distance standards equally among different types of providers. One commenter stated that the prevailing 30 minute/30 mile access to services standards need to be fine-tuned specifically for urban, rural, and other medically underserved areas. Other comments included recommendations to establish separate and distinct network adequacy standards for Parts A and Part B services, as well as standard for measuring network adequacy in rural areas for services that are only in hospitals.

*Response:* As noted in the October 22, 2009 proposed rule, we have historically used the 30 minute/30 mile access to services as a rough standard for evaluating provider networks. However, we agree that this standard is not sufficiently nuanced to stand on its own, and does not fully address our needs. Our operational experience has demonstrated that the concept of community patterns of health care delivery furnishes a more useful benchmark for measuring a proposed provider network because it allows for varying geographical and regional conditions to be taken into consideration.

*Comment:* One commenter asked CMS to consider Medicaid provider networks as part of the assessment of network adequacy for dual eligible integrated products. This commenter also suggested comparing contracting rates across plans serving duals as an additional measure of network adequacy. In addition, the commenter suggested that a comparison of the plan's provider availability to those actually open to new Original Medicare enrollees might indicate the value of the plan to potential enrollees. Another

commenter asked that CMS include in its regulation defining network adequacy the following factors derived from the Medicaid access standards under § 438.206: (1) The mode of transportation used by Medicare beneficiaries, particularly those who are dually eligible and those who rely on transportation for the disabled; (2) whether the location furnishes physical access for enrollees with disabilities; and (3) delivery of services in a culturally competent manner.

*Response:* We recognize that special needs plans (SNPs) that specifically serve the dual eligible population have unique requirements. It is for that reason that in 2011, SNPs that exclusively serve the dual eligible population will be required to have contracts with State Medicaid agencies where they operate. While transportation is not a Medicare covered benefit, it is our expectation that MA plans' facilities are available and accessible to plan enrollees.

7. Deemable Program Requirements Under Parts C and D (§ 422.156(b)(7), § 422.156(f), § 423.165(b), and § 423.165(f))

In the October 2009 proposed rule, we proposed to clarify what regulatory requirements are "deemable" for MA organizations that offer prescription drug benefit programs by modifying the language at § 422.156(b)(7) to refer to the list of deemable requirements for Part D sponsors set out at § 423.165(b)(1) through (b)(3). In addition, we proposed modification to § 422.156(f) and § 423.165(f) to add language clarifying that CMS may use its statutory authority to impose intermediate sanctions and civil money penalties (CMPs), initiate contract terminations, and perform evaluations and audits of a sponsoring organization's records, facilities and operations, notwithstanding our deeming provisions. We also proposed to remove language at § 423.165(b)(4) regarding programs to protect against fraud, waste and abuse from the items listed as deemable program requirements. After considering the comments we received in response to these proposals, we are adopting all of these proposals without further modification into this final rule.

*Comment:* One commenter asked if CMS will create an avenue for accrediting organizations who are currently approved under the Medicare Advantage program to apply for deeming under the Prescription Drug program.

*Response:* Our proposal did not address the process for becoming an accrediting organization. Any organization that wishes to be an accrediting organization for the Medicare Prescription Drug program must first apply and be approved by CMS in accordance with existing requirements.

*Comment:* One commenter asked if we will define possible roles and responsibilities for accrediting organizations under the revised Part D monitoring and oversight audit program.

*Response:* Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

*Comment:* One commenter indicated that Part D plan sponsors have not been given information on accrediting organizations that could grant plans deemed status for Part D. The commenter further recommended that there be an opportunity to work with us to identify accredited organizations for pharmacy benefit manager operations in order to simplify the audit process.

*Response:* Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. However, as of the date of the publication of this regulation, CMS has not approved any accrediting organizations to grant deemed status for Part D sponsors. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

*Comment:* We received a few comments indicating that the regulatory provisions provided in this section should be further clarified either through rulemaking or subregulatory guidance.

*Response:* We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

*Comment:* One commenter suggested that we provide clarification on the criteria we would use to determine whether to perform evaluations, conduct audits, or impose sanctions or civil money penalties relative to a sponsoring organization's compliance with deemable requirements.

*Response:* Our proposal did not intend to modify or affect the manner in which CMS conducts compliance evaluations, audits or the process for imposing intermediate sanctions. These processes are not directly affected by whether the underlying subject of the deficiency is a deemable requirement.

*Comment:* One commenter encouraged us to consider adding additional deemable requirements based on differences between the Part D program and the Part C program.

*Response:* We have been granted limited statutory authority regarding what specific requirements are deemable. Our proposals reflect our current statutory authority.

*Comment:* One commenter requested that since the fraud, waste and abuse program was being removed as a deemable requirement we consider allowing "certification" from an external qualified source to serve in the deeming capacity.

*Response:* We have been granted limited statutory authority regarding what specific requirements are deemable. We proposed modifications to our regulations to mirror our current statutory authority. To the extent the commenter is proposing that CMS consider ways of assessing an organization's compliance with fraud, waste, and abuse requirements that suggestion would be outside the scope of this proposal.

8. Modify the Corrective Action Plan (CAP) Process as It Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§ 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1))

In the October 2009 proposed rule, we proposed eliminating the existing language contained in regulations at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that require corrective action plans (CAPs) to be submitted for our approval prior to us issuing a notice of intent to terminate or nonrenew a contract. Instead, we proposed that the sponsoring organization be solely responsible for the identification, development, and implementation of its CAP and for demonstrating to us that the underlying deficiencies have been corrected within the time period afforded under the notice and opportunity for corrective action.

We also proposed amending the existing language at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) which sets forth the specific timeframes afforded sponsoring organizations for the development and implementation of a CAP prior to CMS issuing a notice of intent to terminate or nonrenew. Specifically, we proposed to afford sponsoring organizations with at least 30 calendar days to develop and implement a CAP, prior to issuing the notice of intent to terminate or nonrenew. CMS is adopting the proposed language into the final rule

with a few technical changes to § 422.506(b)(3)(i) and (ii), § 422.510(c)(1)(i) and (ii), § 423.507(b)(3)(i) and (ii), and § 423.509(c)(1)(i) & (ii). First, we are deleting the phrase "that formed the basis for the determination to non-renew the contract" from the proposed revised regulations governing non-renewals at § 422.506(b)(3)(i) and § 423.507(b)(3)(i) and deleting the phrase "that formed the basis for the determination to terminate the contract" from the proposed revised regulations governing terminations at § 422.510(c)(1)(i) and § 422.509(c)(1)(i). The reason for this revision is that, upon further consideration, we have concluded that this language is superfluous and has the potential to cause confusion concerning when CMS must provide notice and reasonable opportunity to correct deficiencies.

Next, we are modifying § 422.506(b)(3)(i), § 423.507(b)(3)(i), § 422.510(c)(1)(i), § 423.509(c)(1)(i) to state that CMS will provide the sponsoring organization a "reasonable opportunity" of "at least 30 calendar days" to develop and implement a corrective action plan. This modification made the propose provision at § 422.506(b)(3)(ii), § 423.507(b)(3)(ii), § 422.510(c)(1)(ii), and § 423.509(c)(1)(i) duplicative and unnecessary, therefore we are deleting that provision.

These revisions do not alter the meaning and purpose of the proposed revised regulations and are strictly editorial changes.

*Comment:* We received numerous comments regarding our proposal to modify the overall approach and timeframe sponsoring organizations are afforded for developing and implementing a CAP prior to CMS issuing a notice of intent to terminate or nonrenew. Although almost all commenters were supportive of CMS' proposal to move to an outcome oriented approach for reviewing CAPs, some commenters believe that 30 days is not enough time for sponsoring organizations to develop and implement a CAP. Commenters provided several reasons to support this concern, including the fact that CAPs may involve complex and time consuming programming or modification of systems and that the proposed change could result in sponsoring organizations pursuing a more cursory or manual remediation rather than a fuller remediation. Other commenters recommended that rather than specifying a time period, CMS and sponsoring organizations should mutually agree on a time period that is best for completing a CAP. A few commenters expressed that 30 days was more than enough time to correct deficiencies and that the regulations need to state more clearly that the corrective action should be completed within the same 30-day period.

*Response:* Our proposal specifically stated that the time period afforded sponsoring organizations would be "at least" 30 days, thereby proposing the minimum amount of time that CMS would afford a sponsoring organization to develop and implement a CAP. We believe our proposal is reasonable and accounts for those situations where we determine that longer periods of time are warranted to demonstrate correction (for example, when corrections must be made to electronic information systems). Our proposal does not intend to limit the development and implementation of a CAP to 30 days in all cases because we agree that there are some deficiencies of a complex or technical nature that may require additional time to rectify.

*Comment:* A few commenters requested that CMS clarify how it will determine if a sponsoring organization has attained compliance (for example, what are CMS' expectations and what supporting documents would we require in such situations to demonstrate compliance).

*Response:* Our proposal to change to an outcome based approach is not making modifications in the current methodologies for assessing whether an entity is in (or out of) compliance with our requirements. For example, CMS currently conducts validation activities based on account management data and information, audit results, beneficiary complaints, sponsoring organization reporting requirements and performance data indicators to determine whether a sponsoring organization is in compliance with our requirements. We will continue to determine if the sponsoring organization in is in compliance with our statutory, regulatory and program requirements by utilizing these kinds of monitoring and oversight measures. The proposed language is only clarifying that for non-renewal and termination actions, we will not be requiring the sponsoring organization to submit its corrective action plans for approval by us, but instead the sponsoring organization must submit proof that identified deficiencies have been corrected.

*Comment:* One commenter suggested that if CMS retains the authority to reject a CAP based on the process used to fix the deficiency, the sponsoring organization should be allowed to submit its CAP to CMS for approval, and if not disapproved by CMS within a specified period, assume that the CAP is approved from a process perspective.

*Response:* The commenter has misunderstood our proposal. We are proposing to modify the current CAP process to be entirely outcome oriented and we will no longer be requiring sponsoring organizations to submit corrective action plans for approval (that is, the process for how the plan goes about correcting its deficiencies will not be approved or disapproved by CMS). Rather, the process will be independently developed and implemented by the sponsoring organization and our focus will be on determining whether the deficiencies/problems that created the need for the CAP have been corrected.

*Comment:* A commenter requested that CMS not apply the 30-day CAP timeframe to "routine or ad-hoc audits."

*Response:* The procedures governing the corrective action plan process associated with routine or ad-hoc audits are not specified in regulation. To the extent, however, that we would initiate a termination or nonrenewal action against a sponsoring organization based on a routine or ad-hoc audit CAP, we would follow the procedures outlined in this regulation.

*Comment:* A commenter recommended that sponsoring organizations, which are currently under a CAP, be allowed to engage the services of an independent auditor to evaluate whether the sponsoring organization is in compliance with CMS' requirements.

*Response:* Our proposed language was not intended to prevent a sponsoring organization from taking the initiative to use an independent auditor to help identify and correct underlying compliance deficiencies.

9. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§ 422.756 and § 423.756)

In the October 2009 proposed rule, we proposed two changes to the regulations to provide additional tools to assist us in making the determination to lift an intermediate sanction as stated in § 422.756(d)(3) and § 423.756(d)(3). First, we proposed providing CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor to provide us with additional information that we will use to determine if the deficiencies upon which the sanction is based have actually been corrected and are not likely to recur. We also proposed an alternative proposal in which we would

grant sponsoring organizations the discretion to hire an independent auditor to evaluate the sponsoring organization's compliance with our requirements and would afford the results of the independent auditor's review some weight in our determination of whether the bases for the sanction have been corrected and are not likely to recur. After considering the comments we received in response to this proposal, we are adopting the proposal without modification, which provides CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor.

Second, we proposed changes to § 422.756(d)(3) and § 423.756(d)(3) to provide CMS with the discretion to require a sponsoring organization, subject to a marketing and enrollment sanction, to go through a test period during which the organization could market and accept enrollments for a limited time in order for us to determine if the sponsoring organization's deficiencies have been corrected and are not likely to recur. Additionally, we proposed to revise these provisions to provide that following the test period, if we determine the deficiencies that formed the basis for the sanction have not been corrected and are likely to recur, the intermediate sanction will remain in effect until such time that we are assured the deficiencies have been corrected and are not likely to recur. The sponsoring organization, in these instances, would not have a right to a hearing to challenge our determination to keep the sanction in effect. We are finalizing this proposal without modification.

We also proposed deleting existing provisions at § 422.756(c) and § 423.756(c) because these provisions are duplicative of the list of sanctions at § 422.750(a) and § 423.750(a) and are unnecessary. In this final rule, we are adopting all of these proposals without further modification.

*Comment:* CMS received numerous comments regarding the engagement of an independent auditor by a sponsoring organization under sanction by CMS, with most commenters supporting the alternative proposal in which CMS may allow the sponsoring organization the discretion to hire an independent auditor. Commenters provided various rationales for their support of the alternative proposal, including the potential financial and operational burden to sponsoring organizations when required to engage an outside auditor; that sponsoring organizations may already have the internal resources available to provide the information to CMS; and that absent standards, CMS could impose this requirement in an arbitrary and capricious manner. A commenter opposing both proposals because the commenter did not believe it was necessary for CMS to grant the sponsor the discretion to hire independent auditors, and that by allowing discretion to hire an independent auditor, a sponsoring organization that did not hire the auditor would then be viewed in a negative light. Finally, one commenter expressed concern with our alternative proposal that when an independent auditor was not required by CMS, but was retained by the sponsoring organization at their discretion, CMS would merit only "some weight" in the decisionmaking process to lift the sanction. Specially, the commenter recommended that the independent auditor's evaluation should have the same standard of weight regardless of whether the independent auditor was required or was discretionary.

*Response:* When a sponsoring organization has been sanctioned, the organization's deficiencies have risen to a serious and significant level. We believe that we should have the flexibility to require the sponsoring organization to hire an independent auditor for the benefit of both us and the sponsoring organization. To ensure that the use of the independent auditor will be beneficial for the sponsoring organization and to us, we intend to consider the sponsoring organization's ability to afford an independent auditor as well as the sponsoring organization's ability to demonstrate through its own resources that it has corrected its deficiencies and they are not likely to recur. To determine whether or not we would require an independent auditor, we would check to see if the sponsoring organization was on our financial watch list as well as on the financial watch list of any of the States or commonwealths in which the sponsoring organization was licensed. Also, whenever a sponsoring organization is under sanction, we engage in ongoing discussions with its senior leaders and management. If we were considering the use of an independent auditor, we would discuss this with the sponsoring organization and solicit their feedback in order to fully comprehend the financial makeup and stability of the organization.

As the proposed regulatory language reflected, this authority will not be exercised in all circumstances because we recognize that an independent auditor may not be needed or beneficial in all circumstances. For these reasons, we are maintaining the requirement in the final rule that when a sponsoring organization has been sanctioned CMS may require that the sponsoring organization hire an independent auditor.

*Comment:* CMS received a number of comments requesting that CMS provide more clarification related to our use of the term independent auditor in our proposal, including providing a definition, minimum qualifications, and whether conflict of interest rules would apply. One commenter suggested that CMS provide a list of auditors for sponsoring organizations to choose from. Another commenter seemed to be concerned that an independent auditor is generally used in the context of a financial audit and referred to "Sarbanes Oxley" stating that it has fairly clear rules with regard to conflicts of interest. In that respect, commenters requested that CMS clarify what context it used the phrase "independent auditor."

*Response:* We intend that sponsoring organizations will choose the independent auditor. We will work with sanctioned organizations to determine if the independent auditor they are proposing is appropriate. Some basic examples, however, of standards that we will require for independent auditors are knowledge of the Part C and Part D programmatic requirements and experience evaluating an organization's performance in the areas specific to the deficiencies. To the extent that one commenter was referencing financial audits under the Sarbanes Oxley Act of 2002 (Pub. L. 107–204, 116 Stat. 745, enacted July 30, 2002), this proposal is not governed by the standards in Sarbanes Oxley. The type of audit contemplated by Sarbanes Oxley is a financial audit and not a program compliance audit. The audits proposed here would involve an independent evaluation of whether the sponsoring organization is in compliance with CMS requirements. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

*Comment:* Several commenters requested that CMS provide standards for when an independent auditor would be needed. Commenters wanted clarity on when an independent auditor would be required, what types of issues the auditor would be called to review, and the parameters under which an auditor would perform its work. One commenter requested that we limit the focus of the audit to the bases for the sanction.

*Response:* During the period of the sanction, we communicate regularly with the sponsoring organization and,

therefore, we intend to fully discuss with the sanctioned organization the basis for concluding an independent auditor is necessary prior to requiring the organization to retain the independent auditor. We intend to utilize the requirement in our proposal when we determine that an independent auditor would be beneficial, such as in situations where the deficiencies are highly technical in nature. Also, if the sanctioned organization is having difficulty demonstrating to us that its deficiencies have been corrected, an independent auditor can provide us with assurances that the deficiencies have in fact been corrected through a neutral third party evaluation. We intend to determine what areas the independent auditor should assess depending on the nature and extent of the deficiencies. We do not believe it is possible or appropriate to provide this information in regulation since each sanctioned organization may require a different assessment based on its particular deficiencies. With respect to the comment that the focus of the audit should be limited to the bases for the sanction, based on our experience, we believe the independent auditor would need the flexibility to broaden the assessment because new or related issues may arise in the period after the sanction is imposed that need to be evaluated in order to ensure that the deficiencies have been corrected and are not likely to recur.

*Comment:* Several commenters were concerned with our comparison of the independent auditor in this requirement to the Corporate Integrity Agreements (CIA) used by the HHS Office of Inspector General (OIG) because information found under the CIA is not publicly disclosed, and the commenters believe that the results should be publicly disclosed. Commenters also stated that in the case of nursing homes, experience has shown that CIAs have not been effective and that nursing homes have not improved as a result of CIAs.

*Response:* When a sponsoring organization is subjected to an intermediate sanction, this information, along with the bases for the sanction, is publicly disclosed through the CMS Web site. Additionally, the public subsequently is notified as to whether we have determined that these deficiencies have been corrected and are not likely to recur. We do not believe that there is any significant value in making the public aware of audit results related to an internal technical assessment of the correction of these deficiencies that may be relied on to make our ultimate determination. However, to the extent these documents would be required under existing law to be disclosed we fully intend to comply with those requirements.

With regard to the commenters who were concerned about the overall effectiveness of using independent auditors to assist us in evaluating compliance, correcting the deficiencies is ultimately the responsibility of the sanctioned organization. Although, the independent auditor may consult with the sanctioned organization on the best way to fix its deficiencies, the main purpose of the independent auditor is to provide evidence and additional assurances which would assist us in making the determination that those deficiencies have been corrected. We intend that independent auditor results will be weighed with a host of other validation activities conducted by us and will not be the sole source of information concerning whether deficiencies have been corrected and are not likely to recur.

*Comment:* One commenter stated that the audit findings of an independent auditor should be subject to attorney-client privilege and that they would only be subject to release to CMS if the sponsoring organization waived the privilege.

*Response:* We disagree with the commenter that results of the independent auditor are protected by attorney client privilege. The purpose of the independent auditor is to provide a neutral third party evidenced-based evaluation of whether a sanctioned organization is in compliance with CMS requirements. Attorney-client privilege is a legal concept which protects communications between an attorney and his or her client and keeps certain communications between the parties confidential. Independent audit findings are by no means necessarily subject to the attorney-client privilege and, in this case, the sole purpose of the audit being performed is to provide information to CMS.

*Comment:* One commenter stated that CMS' determination not to lift the sanction after the results of the independent audit should be appealable and such appeal is required by law.

*Response:* There is no statutory right to appeal a decision by CMS to keep a sanction in effect. Appeal rights are afforded at the time the sanction is imposed.

*Comment:* One commenter requested that we remove the language "not likely to recur" from the independent auditor requirement. The commenter stated that it was not general practice for an auditor to opine as to whether the deficiencies were not likely to recur.

*Response:* We did not propose and do not intend to require the independent auditor to opine as to whether the deficiencies are not likely to recur. The independent auditor will perform an assessment to determine if the sponsoring organization is in compliance with our requirements and we would use that evaluation, along with other information provided by the sponsoring organization, to make our determination as to whether the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. The independent auditors report is evidentiary and not dispositive as to whether the deficiencies have been corrected and are not likely to recur. We make that determination.

*Comment:* We also received a number of comments on the proposal that in instances where marketing or enrollment sanctions have been imposed, CMS may require a sponsoring organization to engage in a marketing or enrollment "test period" in order to assist CMS in making a determination as to whether the deficiencies have been corrected and are not likely to recur. Most commenters wanted more clarity regarding the parameters of the "test period," including any limitation on enrollment during the test period, the duration, when it would be required and the level of performance required during the test period.

*Response:* The details concerning implementing a test period will vary from organization to organization depending on the nature and extent of the deficiencies that formed the basis for the sanction and other factors such as the organization's size, complexity of operations, etc. We intend to work closely with any sanctioned organization prior to establishing a "test period" and the organization will receive specific notice of the standards the organization must meet to demonstrate that its deficiencies have been corrected during the test period.

*Comment*: Several commenters asserted that sanctioned organizations should be afforded appeal rights if, after the marketing and enrollment "test period," CMS determines to keep the sanction in effect.

*Response:* Under our proposed provision, the "test period" is a validation activity that will help us to determine that the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. For example, when we validate a sponsoring organization's compliance with appeals and grievances requirements, we may perform an audit to test those areas. If the audit

demonstrates that the sponsoring organization has not corrected its deficiencies or that they are likely to recur, the sanction will remain in effect and the sponsoring organization cannot appeal that determination. Appeal rights are afforded at the time the sanction is imposed.

*Comment:* Several commenters expressed concern that sponsoring organizations subject to a "test period" would be under heightened scrutiny and that CMS would have sole discretion to determine the point at which the sponsoring organization has corrected the basis for the sanction. One other commenter questioned the value of a "test period" as well as the independent auditor and seemed to equate these validation activities to a situation where the sponsoring organization has been issued a corrective action plan (CAP).

*Response:* We intend to use a "test period" as one of a host of validation activities and we intend to work closely with any sanctioned organization prior to imposing a "test period" to ensure the sponsoring organization receives specific notice of the standards it must meet to demonstrate that its deficiencies have been corrected and are not likely to recur. We fully intend to subject all sponsoring organizations placed under a sanction to heightened scrutiny both during the sanction period and for some period afterwards to ensure that the deficiencies that formed the basis for the sanction are corrected and are not likely to recur. The "test period" requirement simply provides organizations under marketing/enrollment sanctions the same opportunity other organizations would have to demonstrate compliance with our standards for releasing the organization from the sanction during an established enrollment test period. The provision is not applicable to an organization that has been asked to implement a CAP and has not had a marketing and enrollment sanction imposed. This provision is limited to sponsoring organizations subject to intermediate sanctions.

*Comment:* One commenter requested that CMS adopt alternative approaches for evaluating whether it is appropriate to lift a marketing and enrollment sanction imposed on a sponsoring organization when the deficiencies that led to the sanction are ones where CMS cannot appropriately evaluate the extent of remediation through a trial enrollment and marketing period.

*Response:* We fully intend to continue to explore other ways to effectively validate whether deficiencies have been corrected while a sponsoring organization is under sanction. The test period proposal was intended to address the specific dilemma faced by CMS and the sponsoring organization when a sanctioned organization cannot market and enroll during the sanction period so as to demonstrate that the deficiencies have been addressed.

*Comment:* One commenter suggested that CMS specify that any decision not to lift an intermediate sanction at the end of such "test period" is a separate decision from, and shall not automatically result in, an action to terminate a contract.

*Response:* We do not intend to use the decision not to approve a sponsoring organization's request to release the sanction, in and of itself, as a basis for reaching a determination to terminate a contract. Termination determinations must always meet our specific statutory and regulatory requirements.

10. Termination of Contracts Under Parts C and D (§ 422.510(a) and § 423.509(a))

In the October 2009 proposed rule, we proposed to delete the enumerated bases for termination contained at § 422.510(a)(5) through (12) and § 423.509(a)(5) through (11). We proposed to modify language at § 422.510(a) and § 423.509(a) to separate the language into two paragraphs with the first paragraph, (a)(1), listing the statutory bases for termination and the second paragraph, (a)(2), clarifying that a sponsoring organizations (i) failure to comply with our regulations, (ii) failure to meet performance standards; and/or (iii) participation in false, fraudulent, or abusive activities, may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1).

Based on the comments we received on the proposed rule, we have decided not to finalize our proposal and as an alternative to slightly modify existing regulations. First, we are finalizing the proposed modified language in provisions § 422.510(a)(1)–(3) and § 422.509(a)(1)–(3) so that the regulatory text mirrors the statutory language. Second, we are finalizing proposed modified language for § 422.510(a)(4) and § 423.509(a)(4), which states that CMS may now terminate under this provision when Medicare, Medicaid, or other State or Federal health care programs are affected. Next we are finalizing our proposed deletion of existing § 422.510(a)(5) and § 423.509(a)(5) because we believe that the provision is a basis for expedited termination and therefore inappropriately located in this part. We have decided to retain the remaining enumerated bases for termination that we previously proposed to delete at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11). We are, therefore, redesignating § 422.510(a)(6)–(12) and § 423.509(a)(6)–(11) as § 422.510(a)(5)–(11) and § 423.509(a)(5)–(10) respectively. Finally, we are adding the two new proposed bases, with modified language, to the existing enumerated list at § 422.510(a)(12) and § 423.509(a)(11) (failure to comply with regulatory requirements) and § 422.510(a)(13) and § 423.509(a)(12) (failure to comply with performance standards). The discussion of these revisions is set forth in more detail below.

*Comment:* A number of commenters expressed specific concerns about our proposed changes to § 422.510(a) and § 423.509(a), namely our proposal to remove the enumerated standards for termination and proposal to mirror the statutory language. Commenters stated that the proposed language is too broad and vague, gives CMS unprecedented discretion and authority and invites arbitrary or inconsistently applied determinations by CMS. One commenter suggested that CMS maintain the existing language.

*Response:* We disagree that the proposed changes to § 422.510(a)(1) through (3) and § 423.509(a)(1) through (3) provide CMS with unprecedented authority and discretion. The proposed language merely mirrors the authority provided to CMS through statute. We have, however, after considering all of the comments, decided to retain the existing provisions from § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11) into the final rule. These examples of substantive bases are now redesignated as § 422.510(a)(5) through (11) and § 423.509(a)(5) through (10) respectively.

*Comment:* A number of commenters expressed concern with the proposed language at § 422.510(a)(12) and § 423.509(a)(11) (formerly § 422.510(a)(2)(i) and § 423.509(a)(2)(i)) which provided that CMS may determine that a basis exists to terminate a sponsoring organization's contract if the sponsoring organization fails to comply with *any* regulatory requirement contained in parts 422 or 423. While one commenter strongly supported the proposed change, many commenters believed that the revision removed the "substantiality" or "materiality" tests explicit or inherent in each of the existing requirements, and in effect it would allow CMS to terminate on the basis of a single instance in which a particular requirement is not met.

*Response:* We have considered the comments and have decided to remove the word "any" from the proposal to avoid confusion and have modified the regulatory text in the final version of the regulation to reflect this change. Adherence to all our regulatory requirements is important and necessary, but we acknowledge that in making a decision to terminate a contract, we would take into account the nature and extent of the failure to meet our regulatory requirements and the materiality of the requirement as compared to other requirements.

*Comment:* A number of commenters also expressed concern about the proposed language at § 422.510(a)(13) and § 423.509(a)(12) (formerly § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii)) supporting the use of outlier analysis to reach a termination decision. These commenters opposed this proposal and argued that it is inconsistent with law and unfair to equate outlier status to noncompliance. Another commenter stated that it was improper to make contract termination decisions based on a determination that a sponsoring organization is the lowest performer among a cohort when the organization may still be performing adequately. Some commenters stated that they needed more clarity on the specifics associated with the outlier standards and access to the data underlying these standards. Additionally, commenters asserted that the outlier standards are too vague of a standard to serve as a basis for contract terminations, particularly when CMS has not disclosed the relevant standards or methodology and organizations have not be notified in advance of these standards in order to be afforded an opportunity to improve. Two commenters recommended that CMS allow sponsoring organizations to appeal CMS findings as a result of outlier analysis.

*Response:* Outlier analysis is an oversight mechanism by which we can more effectively focus our limited resources in determining which sponsoring organizations to target for further compliance analysis and assessment. We do not intend to use this analysis in and of itself as a basis to terminate a contract. Therefore, we have decided to remove this outlier language from the final rule, to avoid misunderstandings and confusion among sponsoring organizations concerning the use of this data to take termination actions.

*Comment:* CMS proposed to modify language at § 422.510(a)(4) and § 423.509(a)(4) (formerly § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii)) to revise the agency's existing regulatory authority to allow CMS to terminate a sponsoring organization when there is credible evidence that shows that the sponsoring organization has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs. Two commenters on this proposed provision, one in support and the other opposing the provision, stated that CMS should not terminate contracts in cases where the employees committing the fraudulent acts have no involvement with the administration of the Medicare lines of business offered by the sponsoring organization.

*Response:* Our proposal was not intended to indicate that we will terminate a contract in the case of employee fraudulent acts unrelated to Medicare, Medicaid, or other State or Federal health care programs.

11. Request for Hearing Under Parts C and D (§ 422.662 and § 423.651)

In the October 2009 proposed rule, we proposed to modify the language at § 422.662(a) and § 423.651(a) stating that the sponsoring organization must file a request for a hearing in accordance with the requirements specified in the notice of the contract determination or intermediate sanction. This proposed change would ensure that the proper officials within CMS receive the request and are able act upon it in a timely manner. Current regulations at § 422.662(a) and § 423.651(a) governing the hearing procedures require sponsoring organizations to file a request for a hearing on contract determinations with the Hearing Officer and to also file it with "any CMS office." As we stated in the preamble to the proposed rule, we believe this procedure is ineffective and inefficient because it is likely to result in a request for hearing not being received by the appropriate officials within CMS.

We also proposed a conforming change at § 422.662(b) and § 423.651(b) which governs the timeframes for filing the request for hearing to provide that the request must be filed within 15 calendar days after receipt of the notice (versus the existing language which states 15 calendar days from the "date CMS notifies" the sponsoring organization of its determination). This proposed change was made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

Since we received no comment on these sections, these changes are adopted without modification in this final rule.

12. Burden of Proof, Standard of Proof, Standards of Review, and Conduct of Hearing (§ 422.660, § 423.650, § 422.676, and § 423.658)

In the October 2009 proposed rule, we proposed to delete the references to "substantial compliance" as a standard of review at hearing and delete the existing regulations which provide for an "earliest of" test from § 422.660 and § 423.650. We also proposed to explicitly state that the preponderance of the evidence is the standard of proof that we believe applies during the appeal of a contract determination or intermediate sanction. We also proposed to delete the existing language contained at § 422.660(b) and § 423.650(b) and replace it with language that provides that the sponsoring organization has the burden of proving by a preponderance of the evidence that our determination was inconsistent with the requirements of the applicable part. Additionally, we specified in our proposal that the applicable requirements are § 422.501 and § 422.502 for the processes and standards for applicants for the MA program, § 423.502 and § 423.503 for applicants for the Part D program, § 422.506 or § 422.510 for MA contract determinations, § 423.507 or § 423.509 for Part D contract determinations, and § 422.752 or § 423.752 for intermediate sanctions.

We proposed to modify § 422.660(c) and § 423.650(c), which specified that the notice of any decision favorable to a Part C or D applicants appealing a determination that it is not qualified to enter into a contract with us must be issued by July 15th for the contract in question to be effective on January 1st of the following year. We proposed a change from the July 15th deadline to September 1st.

Finally, we proposed to modify existing regulations at § 422.676(d) and § 423.658(d) governing the conduct of the hearing to provide that, consistent with the burden of proof, during the hearing the sponsoring organization bears the burden of being the first to present its argument to the Hearing Officer according to any briefing schedule determined by the Hearing Officer.

We are adopting all of the proposed changes as the final rule without further modification.

*Comment:* Several commenters opposed CMS' removal of the "substantial compliance" standard

asserting that this standard was well established and well understood as opposed to the new language that CMS proposed, which these commenters stated was vague and unclear.

*Response:* We disagree that the "substantial compliance" standard is clear and easy to apply in making a determination. As explained in the preamble to the October 2009 proposed rule, the "substantial compliance" language has led to confusion among parties to the hearing, has been difficult for the Hearing Officer to apply, and does not reflect the nuances of the different legal standards provided in the Act for making contract determinations and imposing intermediate sanctions. Our proposal, which provided that the standard of review is whether CMS' determination is inconsistent with the regulatory requirements for taking the underlying action (for example, application denial, non-renewal, termination or intermediation sanction) provides the requisite specificity to be applied by the hearing officer and the parties to these actions. We also believe the proposal properly focuses the hearing officer and all parties to the hearing on the correct standard, and the pertinent issue under review at the hearing.

*Comment:* Several commenters expressed concern that the proposed changes result in the sponsoring organizations bearing the burden of proof in appeal proceedings and one commenter added that CMS' proposal is inconsistent with the general rule articulated by the Supreme Court that the party seeking to take action ordinarily bears the burden of persuasion and cited to *Schaffer* v. *Weast,* 546 U.S. 49 (2005).

*Response:* The commenters have misunderstood the scope of our proposals because we did not propose a change as to which party bears the burden of proof. Existing regulations explicitly state that the sponsoring organization bears the burden of proof. Also, we believe that the commenter is mistaken in its reading and interpretation of the ruling in *Shaffer* v. *Weast.* In that case, the Supreme Court held that the burden of proof in an administrative hearing is properly placed upon the party seeking relief ("[T]he burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion.") In our appeal proceedings, the party seeking relief is the sponsoring organization, thereby making it appropriate for that party to bear the burden of proof. Thus, existing regulations which require that the sponsoring organization bear the burden of proof are consistent with the legal precedent cited by the commenter.

*Comment:* One commenter requested that CMS provide a definition for the "preponderance of the evidence standard."

*Response:* The preponderance of the evidence standard is a well established and defined legal standard. To make a showing by the preponderance of the evidence, one must show that it is more likely than not that the fact that the claimant seeks to prove is true.

*Comment:* Some commenters opposed changing the notification date from July 15th to September 1st. Some commenters noted that notification by September 1 of a favorable determination would not leave a sponsor with sufficient time to prepare for the upcoming year given that sponsors are permitted to start marketing for the upcoming year on October 1. One commenter recommended moving the application deadline to March to allow for adequate preparation of the application and suggested that adequate preparation may reduce the number of appeals.

*Response:* In most cases, we do not believe a favorable determination issued by the CMS hearing officer will be rendered as late as September 1st. However, moving the notification date of the favorable determination from July 15th to September 1st affords applicants that receive a favorable decision the opportunity to be sponsors in the contract year for which they applied. In all instances, this regulatory change works to the benefit of sponsors.

We believe that sponsors are given adequate time and instruction to complete the application. We believe changing the application due date would not significantly impact the number of appeals.

13. Expedited Contract Terminations Procedures (§ 422.510, § 423.509, § 422.644, § 423.642, § 422.664, and § 423.652) Under Parts C and D

In the October 2009 proposed rule, we proposed to delete the references to expedited terminations based on false, fraudulent or abusive activities and severe financial difficulties contained in the termination procedures at § 422.510(b)(2)(i), § 423.509(b)(2)(i), § 422.510(c)(2) and § 423.509(c)(2) and in the appeal procedures at § 422.644(c)(2), § 423.642(c)(2), § 422.664(b)(2) and § 423.652(b)(2). We proposed to modify these provisions instead to reflect the more general statutory language concerning our ability to take an expedited termination when we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We are adopting our proposal to include this statutory language, and based on the comments we have decided to retain and amend the two existing bases for expedited termination currently located at § 422.510(a)(4) & (a)(5) and § 423.509(a)(4) &(a)(5).

*Comment:* We received several comments on our proposals. Commenters were concerned that our proposal was overly broad, lacked specificity and that there were no examples of situations where we would pursue an expedited termination. Additionally, a few commenters were concerned that a sponsoring organization might be subjected to an expedited termination for a single, isolated incidence of non-compliance and that sponsoring organizations would not be afforded the opportunity for a hearing before the termination took effect.

*Response:* After considering all of the comments we received, we have decided to retain the two existing examples for when CMS may pursue an expedited termination as well as incorporate the statutory language into the final rule.

The existing regulation references § 422.510(a)(5) and § 423.509(a)(5) as one example of a situation where CMS would pursue and expedited termination, but it is also listed as a basis for termination. In the proposed regulation, we proposed removing this instance as a basis for termination, thereby removing its associated reference in expedited termination. We believed that this language created some confusion because it intertwines a basis for termination (that is, failure to make services available) with the statutory standard for making an expedited termination. Based on the comments we received, however, we see that the reference to this basis provided sponsoring organizations with a clear example of the instances under which CMS may decide to take an expedited termination. In order to resolve this issue, we have decided to add the language from § 422.510(a)(5) and § 423.509(a)(5) to the regulatory provisions on expedited terminations in the final rule. We have decided to finalize our proposal to delete this language as a basis for termination because we maintain that the circumstances in this provision would

lead CMS to pursue an expedited termination.

The second example in the existing regulation references § 422.510(a)(4) and § 423.509(a)(4) which concerns situations where there is credible evidence that a sponsoring organization committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including the submission of false or fraudulent data. Based on the comments we received, this reference also provided sponsoring organizations with a clear example of the circumstances under which CMS may decide to take an expedited termination. Therefore, we have decided to retain the reference to § 422.510(a)(4) and § 423.509(a)(4) as a basis for expedited termination.

Finally, we are moving forward with our proposal to incorporate the statutory language in the revised regulations governing expedited termination, thereby permitting CMS to expedite a termination if we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We do not agree that our proposal to include the statutory language is overly broad or vague, and believe that by retaining the two existing examples, it provides sponsoring organizations with some guidance on the types of issues that might lead CMS to pursue an expedited termination while still allowing us the flexibility we need to ensure we can act quickly in situations where adherence with the standard termination procedures would pose an imminent and serious risk to the health of Medicare beneficiaries.

14. Time and Place of Hearing Under Parts C and D (§ 422.670 and § 423.655)

In the October 2009 proposed rule, we proposed adding new language to § 422.670(b) and § 423.655(b) to state that either the sponsoring organization or CMS may request that a hearing date be postponed by filing a written request no later than 5 calendar days prior to the scheduled hearing, and that when either the sponsoring organization or CMS requests an extension, the Hearing Officer must provide a one-time 15-calendar day postponement, and additional postponements may be granted at the discretion of the Hearing Officer. We also proposed revising the language in § 422.670(a) and § 423.655(a) to provide that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days after the "receipt of the request for the hearing." This change was made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes). We are adopting all the proposed changes into the final rule without further modification with the exception of the timeframes outlined in § 422.670(b) and § 423.655(b) as set forth below.

*Comment:* Several commenters questioned CMS' proposal to allow sponsoring organizations or CMS to request an extension for the hearing by filing a written request no later than 5 calendar days prior to the scheduled hearing. Most commenters believed that allowing requests for extensions until 5 days prior to the scheduled hearing would not allow enough time for sponsoring organizations to change travel arrangements and commenters proposed different timeframes they thought would be more suitable.

*Response:* We agree with the commenters concerns and have decided to extend the timeframe for requesting an extension to the hearing date from 5 calendar days to 10 calendar days prior to the scheduled hearing in our final rule.

*Comment:* One commenter raised concerns that there may be times when an automatic, 15-day extension may not be workable due to previous commitments on the part of the Hearing Officer or non-requesting party and suggested CMS add language to the requirement to allow for an alternate, mutually agreed upon hearing date if the Hearing Officer or the non-requesting party is not available on the hearing date that would otherwise result from postponement.

*Response:* We believe that the addition of such language is not necessary because current regulations at § 422.670(b)(1) and (2) and § 423.670(b)(1) and (2) already provide that the Hearing Officer has the authority on his or her own motion, to change the time and place for the hearing.

15. Discovery Under Parts C and D (§ 422.682 and § 423.661)

In the October 2009 proposed rule, we proposed to delete the formal discovery process contained in § 422.682 and § 423.661. In the December 5, 2007 **Federal Register** (72 FR 68700), we published a final rule with comment period that finalized our revisions to § 422.682 and § 423.661 to provide for a formal discovery process prior to hearing. However, based on our experience since the promulgation of this rule, we do not now believe a formal discovery process is necessary or appropriate for these kinds of proceedings. In addition, the existing timeframe in which the hearing normally must take place, 30 calendar days after request for a hearing, does not easily accommodate a formal discovery process. We also proposed to amend § 422.682 and § 423.661 to require that witness lists and documents be identified and exchanged at least 5 calendar days prior to the scheduled hearing. We are adopting § 422.682 and § 423.661 without further modification into this final rule.

*Comment:* Several commenters opposed CMS' removal of the formal discovery process from regulations. Commenters specifically stated that deleting discovery is a violation of their due process rights, and would deny sponsors the only opportunity they have to obtain the full breadth of information they are entitled to for a fair hearing. One commenter stated that the discovery process is the appropriate forum for the sponsoring organization to learn of the criteria CMS used in reaching its decision and that sponsoring organizations have a statutory right under 5 U.S.C. 552 to this information.

*Response:* We disagree with the commenters who stated that the removal of discovery from regulations is a violation of their due process rights and a violation of their statutory right to obtain information in this manner. Our hearings are informal administrative proceedings and as the court held in *Lopez* v. *U.S.,* "[t]here is no general constitutional right to discovery in administrative proceedings" *Lopez* v. *U.S.,* 129 F.Supp.2d 1284 (2000). Also, we do not believe that finalizing our proposal to remove discovery will create unequal or prejudicial treatment that will lead to a violation of due process. Both CMS and sponsoring organizations will be equally limited to producing and receiving witness lists and documents that must be exchanged at least 5 calendar days before the hearing. Also, we do not believe that full discovery for sponsoring plans is required to receive the necessary information from us for adequate and proper preparation for the hearing. Prior to the hearing, we will have already provided sponsoring organizations the specific information relied upon by CMS in reaching the determination which they are appealing. In cases of contract terminations or intermediate sanctions, we will have previously provided the specific basis for the determination within the notice

of intent to terminate or impose intermediate sanctions. Therefore, we believe that a witness list and documents are sufficient to meet the evidentiary needs of the parties. Additionally, any prior decisions of hearing officers are public record, and therefore, obtainable by sponsoring organizations. Sponsors have numerous statutory rights under 5 U.S.C. 552 which govern the agency's disclosure of public information; agency rules, opinions, orders, records, and proceedings. The removal of the discovery process does not circumvent the rights provided to the public under 5 U.S.C. 552.

*Comment:* One commenter also requested that if CMS moves forward with the proposal to eliminate the formal discovery process that we revise our proposal to include a list of the specific documents to be shared and to indicate the action that will result when the required documents are not shared prior to the hearing.

*Response:* Appeal proceedings will vary dependent on what type of determination is being appealed and we cannot possibly specify which documents would be necessary in each and every type of case. Also, if documents are not shared prior to the hearing, it is within the discretion of the hearing officer to determine what the consequences of that action or inaction for the parties to the hearing.

16. Review by the Administrator Under Parts C and D (§ 422.692(a) and § 423.666(a))

In the October 2009 proposed rule, we proposed revisions to the language at § 422.692(a) and § 423.666(a) to provide that the sponsoring organization may request review by the Administrator within 15 calendar days after "receipt of the hearing decision." In addition, we revised the language at § 422.692(c) and § 423.666(c) governing the notification of Administrator determination to state that the Administrator must notify both parties of his or her determination regarding review of the hearing decision within 30 calendar days after "receipt of the request for review" (versus the existing language which provides within 30 calendar days of "receiving the request for review"). These changes were made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes). We received no comment on this section, and are adopting these changes without modification.

17. Reopening of an Initial Contract Determination or Decision of a Hearing Officer or the Administrator Under Parts C and D (§ 422.696 and § 423.668)

In the October 22, 2009 proposed rule, we proposed revising the regulations governing the reopening of an initial contract determination or decision of a Hearing Officer or the Administrator under Parts C and D by replacing the language "initial determination" with "contract determination" in the section headings of § 422.696 and § 423.668 and in the text of § 422.696(a) and § 423.668(a). We noted that the term "initial determination" is not used elsewhere in Subpart N (Contract determinations and appeals). We received no comment on our proposals and are adopting these changes without modification.

18. Prohibition of MA and Part D Applications for 2 Years After a Mutual Termination (§ 422.503(b)(6) and § 423.504(b)(6))

In the October 22, 2009 proposed rule, we proposed prohibiting an MA organization or Part D sponsor, as a condition of the consent to a mutual termination, from applying for new contracts or service area expansions for a period of 2 years, absent circumstances that warrant special consideration as provided under section 1857(c)(4)(A) of the Act. Specifically, under Part D, we proposed modifying § 423.508 by adding paragraph (e), which states that as a condition of the consent to a mutual termination, CMS requires as a provision of the termination agreement language prohibiting the Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in § 423.504(b), we proposed adding a new paragraph (b)(6) stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the Part D sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 423.508(e). We also proposed redesignating the current § 423.504(b)(6) to § 423.504(b)(7).

Similar modifications were proposed for the MA regulations. Specifically, we proposed modifications to § 422.508 by adding paragraph (c), which states that as a condition of the consent to a mutual termination, we require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in section § 422.503(b), we added a new paragraph (b)(7), stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c).

In proposing these changes, we noted that in practice, a voluntary nonrenewal of a contract by a Part D sponsor or MA organization is not dissimilar from an organization requesting and being granted a mutual termination of their contract under § 422.503 and § 423.508. Under § 422.506(a)(4) and § 423.507(a)(3), if a sponsor voluntarily nonrenews a contract, we cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. The primary difference between a nonrenewal and a mutual termination is often timing. For a nonrenewal request to take effect at the end of the current contract year, it must be received by us on or before the first Monday in June (the bid deadline), as specified in § 423.507(a)(2)(i) and § 422.506(a)(2)(i). However, once an organization submits a bid, it can no longer voluntarily nonrenew its contract for the following year. Rather, the Part D sponsor or MA organization must request a mutual contract termination. The later in the year the organization requests such a mutual termination for the following contract year, the more disruptive and difficult the process becomes. In the October 2009 proposed rule, we noted that this is particularly true if a request for a mutual contract termination occurs once plan information has become publicly available, marketed to beneficiaries, and beneficiaries have been given the opportunity to enroll. These late terminations create significant disruption for beneficiaries and for us. Similarly, even greater disruption results from mutual terminations requested to take effect during the course of a contract year.

In light of the disruptions that may occur, we proposed that a termination by mutual consent, which involves a termination by an MA organization or a Part D sponsor as well as by us, be considered a termination of a contract for purposes of the 2-year ban on entering into new contracts under section 1857(c)(4)(A) of the Act, which

is incorporated for Part D under section 1860D–12(b)(3)(B) of the Act.

After considering the comments we received in response to these proposals, in this final rule, we are adopting our proposals without modification.

*Comment:* One commenter stated that it is important to inform beneficiaries immediately when—(1) their plan is not in compliance with CMS requirements; (2) sanctions have been implemented; or (3) a plan is prohibited from applying for new contracts or service area expansions for a 2-year period. By notifying beneficiaries immediately of these situations, they will be afforded more time to plan. Immediate notification will increase the likelihood that the information will not be lost in the extraordinary amount of information given during the open enrollment period. The commenter recommended that CMS strengthen compliance in general in order to hold plans accountable through CMS monitoring and oversight.

*Response:* Although mutual terminations are often requested when a contract is, or will soon be, out of compliance with CMS requirements, a mutual termination can occur even when there is no current or expected compliance violation. Our proposed revision to this portion of the regulation only addresses the period of time during which a mutually terminated sponsor would be precluded from applying for a new or expanded contracts. As a result, this comment addressing the issue of beneficiary notice concerning Part C and D plan performance is outside the scope of the proposed regulatory change.

*Comment:* One commenter stated that it did not support the proposal for a 2-year ban because market conditions can create the need for contract terminations and service area reductions. The commenter requested that CMS allow flexibility on market re-entry based on environmental conditions and appropriate negotiations with and approval by the agency.

*Response:* Terminations can cause beneficiary confusion and disruption. Additionally, if a sponsor responds to market conditions through the nonrenewal process, a 2-year application ban would apply. Accordingly, we believe it is reasonable and appropriate to apply the same 2-year application ban in situations when a sponsor terminates a plan after the nonrenewal deadline. We also note that, the proposed regulation changes preserve our authority to permit affected organizations to submit applications in less than 2 years when special consideration is warranted.

*Comment:* One commenter stated that it did not oppose the proposed changes, but requested that CMS clarify that the 2-year moratorium is based on a sponsoring organization terminating all of its MA or Part D contracts, not a subset of each line.

*Response:* The regulation as proposed would apply to a licensed legal entity that mutually terminated any of its MA or PDP contracts. A complete exit from either program by an organization is not required for CMS to invoke the 2-year application prohibition.

*Comment:* One commenter requested additional clarity regarding "nonrenewal" and "mutual termination." The commenter urged CMS to be especially cautious about any presumption by CMS that termination may be due to some type of poor performance. The commenter stated that it is possible that after the first week in June a plan will determine that it is not feasible to continue with the contract. The commenter included the example of a State-initiated dramatic midyear reduction in payment for Medicaid services in a dually integrated product. The commenter also stated that the references in § 422.508 to § 422.510 seem to imply some type of failure to perform. The commenter supported providing adequate notice of terminations to beneficiaries, but suggested that a 60-day timeframe may be adequate for end-of-year terminations. The commenter indicated that the 2-year prohibition against applying for new contracts or services areas is reasonable given the language "absent circumstances warranting special consideration." The commenter stated that an example of such a circumstance should include the situation of when a plan is trying to be responsive to state purchasing initiatives on behalf of dual eligibles.

*Response:* With this proposal, we were not addressing whether a sponsor is a poor performer. Rather, the proposal was intended to make the consequences to a sponsor of a mutual contract termination the same as that for a non-renewal. Without this change, a plan might opt for a mutual termination rather than the less disruptive non-renewal in order to avoid the 2-year ban. Additionally, the existing 2-year ban on non-renewing sponsors is not meant to address those sponsors' performance, although it may help us to identify good business partners. The 2-year application ban, as it has been applied to non-renewing organizations and, once this proposed change is adopted by CMS, to mutually terminating organizations, is intended to ensure continuity in the Part C and D programs by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

*Comment:* A commenter asked CMS to clarify that this change applies only to mid-year mutual terminations and not to a plan electing to non-renew with ample notice to CMS (such as at the time of bid submission or per non-renewal guidance).

*Response:* Consistent with § 422.506(a)(4) and § 423.507(a)(3), the 2-year ban already applies to sponsors electing to nonrenew. The proposed regulatory change is an effort to extend the application of that rule to the analogous situation of a mutual contract termination, regardless of the effective date of that termination.

*Comment:* Commenters stated that while they understood the importance of the change, they would encourage CMS to be flexible as there may be instances where an MAO will conduct the right level of due diligence on its providers, yet a provider may experience a disruption that causes the organization to withdraw. The commenters stated that there is significant merit in those instances of an MAO acting in the best interest of Medicare beneficiaries and not effectuating the new plan or contract.

*Response:* Regardless of the degree of due diligence performed prior to contracting, the sponsor assumes all risks associated with complying with an MA or PDP contract, including a 2-year ban on new contracting resulting from a mutual termination. Also, as indicated in the proposed rule, CMS will retain the authority to accept applications where special consideration is warranted.

*Comment:* A commenter asked how this provision would be applied if an acquisition or merger is pending.

*Response:* The acquiring sponsor should assume that it is acquiring all the Medicare contract assets and liabilities of the selling organization, including a 2-year ban on new applications.

*Comment:* A commenter stated that plans should be allowed to terminate prior to the start of the benefit year if an adequate network cannot be obtained. The commenter also stated that if the termination occurs after the start of open enrollment, CMS should wait 30 days and allow beneficiaries to make their own elections before assigning them to an alternate plan. Additionally, it was suggested that there should be a mechanism in place to make sure that a plan cannot use termination as a tool to shift beneficiaries into a higher cost plan offered by the terminating sponsor.

*Response:* This comment does not concern the proposed application of the 2-year ban on mutually terminated sponsors. We will not address the comment as it is outside the scope of the proposed change.

*Comment:* A commenter stated that there are a variety of circumstances, including but not limited to the loss of an adequate network that may be beyond the control of the plan but force it to withdraw a contract. Such withdrawal may be in the best interest of the beneficiaries. Therefore, overall plan performance should not be judged on this one factor. If a plan can remedy the issue for the following contract year it should be allowed to re-contract. The commenter suggests that this issue be looked at on a case-by-case basis.

*Response:* This provision does not address whether a sponsor is a poor performer. Rather, the provision is intended to make the consequences of a mutual contract termination the same as those for a nonrenewal. The 2-year ban on nonrenewing sponsors is not meant to address those sponsors' performance; rather, it is intended to ensure continuity in the Part C and D programs by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

*Comment:* One commenter asked if CMS intends to apply this provision to all types of applications regardless of plan type or geographic location.

*Response:* In the context of voluntary nonrenewals, our policy has been to apply this prohibition based on plan type and service area (for example, non-renewal of a PFFS contract does not prohibit the same organization from applying immediately for an MA–HMO contract for the same service area). We anticipate applying the same policy to mutual terminations.

*B. Changes To Strengthen Beneficiary Protections*

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. Under Part D, we address proposals in the area of eligibility and enrollment policy, transition period requirements, coordination of benefits policy, retroactive claims adjustment reimbursements and recoveries, and use of standardized technology. We also finalize Part D rules regarding timeframes and responsibility for making redeterminations. Under Part C, we finalize rules to—

- Authorize us to annually establish limits on member cost sharing;
- Prohibit PPO, PFFS, and MSA plans from using compliance with voluntary prior notification procedures in determining cost-sharing amounts;
- Establish new requirements for organization determinations; and
- Offer two definitional revisions.

We also finalize Part C and D marketing requirements by distinguishing marketing materials from enrollee communications materials and mandating the use of standardized marketing material language and format to ensure clarity and accuracy among plan documents. We also clarify notice requirements, and require that sponsoring organizations disclose information concerning the organization's performance and compliance deficiencies to enable beneficiaries to make informed choices. This information is detailed in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Broker & Agent Requirements under Parts C and D. | N/A | N/A | N/A | N/A. |
| Beneficiary Communications Materials under Parts C and D. | Subpart V | § 422.2260, § 422.2262. | Subpart V | § 423.2260 § 423.2262. |
| Required Use of Standardized Model Materials under Parts C and D. | Subpart V | § 422.2262 | Subpart V | § 423.2262. |
| Extend the mandatory minimum grace-period for failure to pay premiums. | Subpart B | § 422.74 | Subpart B | § 423.44. |
| Maximum allowable out-of-pocket cost amount for Medicare Parts A and B services. | Subpart C | § 422.100 | N/A | N/A. |
| Maximum allowable cost sharing amount for Medicare Parts A and B services and prescription drugs. | Subpart C | § 422.100 | Subpart C | § 423.104. |
| Prohibition on prior notification by PPO, PFFS, and MSA plans. | Subpart A | § 422.2 § 422.4, § 422.105. | N/A | N/A. |
| Requirements for LIS eligibility: expand the deeming period for LIS-eligible beneficiaries to cover at least 13 months. | N/A | N/A | Subpart P | § 422.773(c)(2). |
| Expand auto-enrollment rules to entire LIS-eligible population. | N/A | N/A | Subpart B | § 423.34. |
| Special Enrollment Period (SEP) Policies | N/A | N/A | Subpart B | § 423.38. |
| Transition Process | N/A | N/A | Subpart C | § 423.120(b)(3). |
| Sponsor responsibility for retroactive claims adjustment reimbursements and recoveries. | N/A | N/A | Subpart J | § 423.464. § 423.466. § 423.800. |
| Time Limits for Coordination of Benefits | N/A | N/A | Subpart J | § 423.466. |
| Pharmacy use of Standard Technology (ID cards) under Part D. | N/A | N/A | Subpart C | § 423.120. |
| Allow members in stand-alone Part D plans to be temporarily out of area for up to 12 months. | N/A | N/A | Subpart B | § 423.44. |
| Prohibit mass SPAP reenrollments during plan year. | N/A | N/A | Subpart J | § 423.464(e). |
| Non-Renewal Public Notice 60-day non-renewal beneficiary notification requirement. | Subpart K | § 422.506 | Subpart K | § 423.507. |

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS—Continued

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Notice of Alternative Medicare Plans | Subpart K | § 422.5(a)(2)(ii) | Subpart K | § 423.507(2)(ii). |
| Timeframes and Responsibility for making Redeterminations under Part D. | N/A | N/A | Subpart M | § 423.590. |
| Requirements for Requesting Organization Determinations. | Subpart M | § 422.568 | N/A | N/A. |
| Organization Determinations under Parts C | Subpart M | § 422.566 & § 422.568 | N/A | N/A. |
| Refine/clarify definitions related to authorized representatives. | Subpart M | § 422.561, § 422.574 & § 422.624. | N/A | N/A. |
| Sponsors may be required to disclose to enrollees compliance and performance deficiencies. | Subpart C | § 422.111(g) | Subpart C | § 423.128(f). |
| Revise definition of "service area" to exclude facilities in which individuals are incarcerated. | Subpart A | § 422.2 | N/A | N/A. |

1. Broker and Agent Requirements Under Parts C and D

In the preamble to our October 22, 2009 proposed rule, we recognized the important role that agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we also stated our continuing concern about the inherent financial incentives independent agents and brokers have when selling Medicare products. For this reason, while not proposing any specific changes in the October 2009 proposed rule, we solicited comments suggesting ideas for effectively providing Medicare health plan and drug plan information and enrollment assistance that ensures beneficiaries select the plan that best meets their needs, including whether additional changes are needed in recently established requirements relating to plan sponsors' use of agents and brokers. We specifically requested comments regarding the tools we currently use (for example, our print publications and our online resources) to assist beneficiaries with their health care decisions; whether State Health Insurance Assistance Programs (SHIPs) have the capacity to serve significantly more Medicare beneficiaries; and the effectiveness of limiting the use of independent agents and brokers by MA organizations and PDP sponsors to certain times of the year, specifically, the open enrollment period (OEP) and annual enrollment period (AEP), or to selected groups of beneficiaries.

*Comment:* Several commenters provided very specific suggestions for an enrollment broker demonstration. Comments we received on an enrollment broker demonstration included suggestions for guiding principles that should govern such a demonstration as well as recommendations on specific features that should be included. Some commenters expressed the concern the proposed enrollment broker demonstration would prevent plans from continuing to use plan-employed agents. Other commenters recommended that independent agents and brokers be permitted to make referrals and receive a referral fee, with the enrollment broker merely assisting with actual enrollment. One commenter suggested that the demonstration initially focus on one State that already uses a third party enrollment assistance approach for Medicaid managed care plan enrollment as a pilot. The same commenter provided a very detailed plan for how the commenter believed an enrollment broker demonstration should work. Under this suggested plan, the enrollment broker would receive applications, record oral scope of appointment confirmations, conduct third-party enrollment verification calls, and conduct general marketing activities providing high-level, standardized general information on plan options. The enrollment brokers would refer beneficiaries with detailed questions or needing more tailored plan presentations to plan-employed agents. The commenter also expressed concerns about the enrollment broker demonstration, suggesting that coordination and communication between the enrollment broker, plans, and beneficiaries would be crucial to the success of the demonstration; the ability to assure the quality of information provided to beneficiaries would be important; and enrollment broker training would also be a critical component of the program. This commenter suggested that CMS solicit additional input from MA plans on operational and information issues involved with effective communication, coordination, and training. The commenter also had concerns about the role an enrollment broker would play in the disenrollment process.

*Response:* We thank the commenters for this feedback and will consider it as we continue to improve our tools for assisting beneficiaries with their health care decisions and as we continue to assess the impact of our current rules regarding independent agents/brokers.

*Comment:* A number of commenters provided us with responses to our request for comments on the idea of limiting the use of agents and brokers to the AEP and OEP, or to selected groups of beneficiaries. The majority of these commenters expressed concerns that limiting the use of agents and brokers in this way could disadvantage age-ins, dual-eligibles, and those eligible for the low-income subsidy. They believe strongly that these limits would decrease the service and support that beneficiaries depend on to understand plan benefits and make enrollment decisions. They also indicated that CMS' current support tools are not sufficient to replace the function that agents and brokers serve.

Commenters also indicated that limiting the use of agents and brokers to certain times of the year is not feasible given that plans use agents and brokers throughout the year and that current CMS oversight of agents and brokers is sufficient. Along these same lines, one commenter supported the view set forth in the proposed rule preamble that sufficient time has yet not passed to fully evaluate the impact of the new marketing requirements codified by CMS following enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Several commenters suggested that limiting the use of agents and brokers to the AEP

and OEP or to select beneficiary groups would, in fact, result in increases of the marketing abuses we are trying to eliminate and would force good agents out of business, leaving behind agents only interested in short-term gains.

Several commenters provided alternatives to limiting the use of agents and brokers to the OEP and AEP or with selected groups. The suggested alternatives can be grouped into three categories—(1) Recommendations to strengthen current rules, processes, and oversight of agents and brokers; (2) Recommendations to require better collaboration among stakeholders; and (3) Recommendations that may require regulatory changes.

Recommendations for strengthening current rules, processes, and oversight of agents and brokers included—

- Strengthening agent and broker education/training;
- Creating a Medicare license and industry designation that all agents must have in order to sell Medicare products; standardizing agent compensation by geographic area;
- Creating and requiring the use of a "replacement/suitability" form that agents would use when moving a beneficiary to a new plan;
- Strengthening CMS surveillance efforts;
- Stabilizing CMS' guidance in this area by limiting the frequency of future policy changes; and
- Tightening our current rules regarding the use of independent agents and brokers.

Commenters' recommendations for requiring better collaboration with stakeholders included—

- Working with plans, advocates, and associations to develop alternatives;
- Creating a list of agents/brokers prohibited from selling Medicare plans that would be shared with all stakeholders;
- Providing more support to and coordination with the States; and
- Periodically publishing best practices.

Additional recommendations that may require regulatory or statutory changes included—

- Requiring plans to share information on agent misconduct and terminations;
- Creating uniform compensation rates for MA plans and PDPs;
- Requiring agents and brokers to register with the National Insurance Producer Registry (NIPR);
- Precluding agents from selling MA plans or PDPs or selling to LIS beneficiaries;
- Allowing a one-time "new enrollment payment"; and
- Renewal compensation for all subsequent moves (regardless of plan type change).

Commenters also recommended—

- Rescinding "lock-in";
- Limiting agent/broker involvement in marketing, but not limiting their involvement to certain periods during the year;
- Shortening the AEP; and
- Eliminating the additional three month OEP for MA plans at the beginning of the year and applying the enrollment period uniformly to MA plans and PDPs.

A number of commenters also provided recommendations with respect to our question about whether and how to expand the role of SHIPs. Almost all of these commenters expressed concerns about SHIP funding, capacity, and capability. They expressed concern about—

- Inadequate funding;
- The fact that SHIPs' reliance on volunteers limits their ability to fully replace the role of independent agents and brokers;
- The lack of capacity of existing SHIP networks to service entire States; and
- The lack of knowledge by SHIP volunteers about plans in every local market within a State.

Several commenters suggested that by limiting plan options and standardizing benefits, SHIP counselors would be better able to handle questions from beneficiaries about plan differences. Other commenters suggested that by strengthening SHIP networks, their capacity could also be expanded.

*Response:* While we did not propose any changes to our regulations governing plans' use of independent agents and brokers to sell Medicare plans in our October 22, 2009 proposed rule, we appreciate the thoughtful ideas and recommendations commenters offered. We recognize the important role agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we still have concerns about the inherent financial incentives independent agents and broker have when selling Medicare products. We recently implemented regulations (§ 422.2274 and § 423.2274) intended to reduce agent and broker incentives to enroll beneficiaries in plans inappropriately. We continue to agree with the commenter that suggested it is still too soon at this time to fully evaluate whether these new rules have achieved MIPPA's goal of creating incentives for agents and brokers to assist beneficiaries with selecting plans based on their health care needs. As we continue to monitor and evaluate our marketing rules and oversight activities, we will evaluate the need for any future notice and comment rule making.

2. Beneficiary Communications Materials Under Parts C and D (§ 422.2260, § 422.2262, § 423.2260, and § 423.2262)

In the October 22, 2009 proposed rule, in implementing sections 1851(h) and 1860D–1(b)(1)(vi) of the Act, we proposed narrowing the definition of the term "marketing materials" at § 422.2260 and § 423.2260 to exclude a new proposed category of "current enrollee communications materials," which we proposed defining to include either situational materials or beneficiary specific customized communications. We proposed this change in order to streamline the review and approval of beneficiary communication notices to current members.

Specifically, we proposed revising § 422.2260 and § 423.2260 to exclude from the definition of marketing materials communications targeted to current enrollees that are customized or limited to a subset of enrollees or a specific situation, or that involve claims processing or other operational issues. In the preamble to the proposed rule, we cited the following examples of the types of materials that would be excluded from our proposed revised definition of "marketing materials": Part D explanations of benefits (EOBs); notifications about claims processing changes or errors; and other one-time or situational, beneficiary specific letters to current enrollees.

In addition, we proposed to revise § 422.2262 and § 423.2262 to specify that, while the current enrollee communications excepted from the definition of marketing materials would not be subject to the statutory requirement that they be submitted to CMS for review and approval prior to use, we retained the right to review such materials, and their use could be disapproved (or disapproved subject to modification) by CMS.

In this final rule, we adopt these provisions with some modification. For reasons discussed below, we have in this final rule revised paragraph § 422.2260(5) (vii) to retain materials about membership rules and procedures, which we are calling "membership activities" (for example, materials on rules involving nonpayment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in

the definition of marketing materials subject to CMS prior approval. In addition, we have added a new paragraph § 422.2260(6) to expressly exclude from the definition of marketing materials ad hoc customized or situational enrollee communications.

*Comment:* A number of commenters supported our proposal to modify the definition of the term "marketing materials" to distinguish materials used to market to new potential enrollees from current enrollee communication materials. However, these commenters raised an ambiguity in our proposed revision to the definition of marketing materials at § 422.2260(5)(vii) and § 423.2260(5)(vii). These commenters noted that, as written, the revised paragraph (5)(vii) merely defines "current enrollee communications materials" without making it clear that such materials are excluded from the revised definition of marketing materials.

*Response:* We agree that, as written, the proposed revisions to the definition of marketing materials did not make it sufficiently clear that we were excluding customized or situational current enrollee communications from the definition of marketing materials, and that certain materials directed at current members should still be included in the definition. Accordingly, as noted above, in response to these comments, we have revised paragraph § 422.2260(5) (vii) to retain materials about "membership activities" (such as, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in the definition of marketing materials. In addition, we have added a new paragraph § 422.2260(6) to specifically exclude from the definition of marketing ad hoc customized or situational enrollee communications from the definition of marketing materials.

*Comment:* Several commenters suggested that, in the absence of a clear definition of claims processing or operational issues, we should define the terms "situational" and "beneficiary specific" narrowly. Several commenters requested that we specify those situations where beneficiary communications would be considered current enrollee communications materials and be excluded from the proposed revision to the definition of marketing materials. These commenters also suggested that we allow operational letters that pertain to enrollment, disenrollment and appeals issues to be excluded from the definition of marketing materials. Some commenters suggested that we specify that any materials excluded from the definition of marketing materials are not subject to the Medicare Marketing Guidelines' requirements that plans include certain plan mailing statements on envelopes regarding the contents of the materials enclosed within. In addition, these commenters requested additional guidance regarding how we intend to operationalize the process for review and approval of situational enrollee communications that would, if the proposed provisions were finalized as proposed, be outside CMS's current marketing review and approval processes.

*Response:* We disagree that it is necessary, and do not believe it would be appropriate, to attempt to specify in the regulations text an exhaustive listing of enrollee communications that are not considered marketing materials per our revised definition of the term "marketing." Our intent is to define these exclusions from the definition of marketing materials narrowly to include communications that are either customized or intended for a subset of current enrollees and which deal with specific situations or cover member-specific claims processing or other operational issues. Our intent was not to exclude from the definition of marketing materials communications that are used more broadly or that convey information about plan benefit structures. As noted previously, in response to earlier comments and this comment, we have revised our proposed definition of current enrollee communications materials in the final rule to add a new § 422.2260(6) to better describe our intent in the proposed rule, and now refer to these materials as "ad hoc enrollee communications materials." The final definition encompasses materials that are targeted to current enrollees; are customized or limited to a subset of enrollees; do not include information about the plan's benefit structure; and apply to a specific situation or cover member-specific claims processing or other operational issues. We envision that ad hoc enrollee communications materials could include the following types of materials;

- Communications about a shortage of formulary drugs due to a manufacturer recall letter.
- Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments.
- Letters describing member-specific claims processing issues.

Although we mentioned the Part D EOB in the preamble to the October 2009 proposed rule as an example of a customized current enrollee communications material in the preamble to our proposed rule, in light of the comments we received on the scope of the exemption from the marketing definition, we no longer believe that example was appropriate, particularly given the importance of our review of EOB templates. Thus, under this final rule, we will continue to require submission and approval of EOB templates through the CMS marketing review and approval process as part of the new definition of marketing materials, and distinguish this general, regularly issued notice from documents pertaining to the processing of an individual claim. We intend to provide further guidance on the types of marketing materials that would be considered ad hoc enrollee communications materials, as well as any alternate processes for their review and approval, in the Medicare Marketing Guidelines.

*Comment:* One commenter suggested that all prospective and current member materials be submitted to CMS as file and use materials so that there is a centralized and consistent place for beneficiary communication to be housed within CMS. This commenter suggested, as an alternative, that the plan develop internal processes to monitor materials for consistency with CMS requirements rather than filing those materials with CMS. We note that MA organizations and PDP sponsors already have the responsibility to ensure, from a monitoring and compliance perspective, that their marketing materials are complete, accurate, and consistent with marketing rules. A few commenters suggested that we require plans to submit a report on beneficiary communications and audit these communications periodically to ensure that plans are not engaging in inappropriate beneficiary marketing practices, and that we retain oversight responsibilities for these materials.

*Response:* As stated previously, we have revised the definition of "customized current enrollee communications materials" in this final rule such that it covers a narrow class of ad hoc, customized beneficiary communications materials. We will provide more information about alternative review and approval processes for customized current enrollee communications materials in the Medicare Marketing Guidelines. We note that we periodically audit marketing materials. We will also ensure that ad hoc enrollee communications materials meet all relevant requirements and are reviewed, approved, and used appropriately.

*Comment:* One commenter recommended that we extend our

current waivers of marketing review and approval requirements for employer group waiver plan marketing materials to employer group waiver plan enrollment materials. Some other commenters requested that our current regulations concerning review and approval of marketing materials be expanded to apply to third party entities, as these commenters believe third party entities tend to send inaccurate or incorrect information to beneficiaries.

*Response:* These comments address our exercise of employer group waiver authority, and accordingly are outside the scope of this rulemaking, and not addressed in this final rule.

3. Required Use of Standardized Model Materials Under Parts C and D (§ 422.2262 and § 423.2262)

In order to reduce variability of marketing materials and to ensure documents are more accurate and understandable to beneficiaries, we proposed, under the authority of sections 1851(h) and 1860D–1(b)(1)(vi) of the Act, to move toward greater standardization of the information provided in plan marketing materials. Specifically, we proposed revising § 422.2262 and § 423.2262 to require that MAOs and PDP sponsors use standardized marketing material language and format, without modification, in every instance in which we provide standardized language and formatting. We noted that we will provide MAOs and PDP sponsors with standardized marketing materials through the annual Call Letter, Health Plan Management System (HPMS) memoranda, or other guidance documents. We believe this change will ensure beneficiaries receive more accurate and comparable information to make informed decisions about their health care options, as well as lead to increased efficiencies and greater consistency in our marketing material review protocols and processes. In this final rule, we adopt these provisions as proposed. For the upcoming 2011 plan year, we plan to update some of our current standardized documents later this spring through guidance, but we are unlikely to standardize new types of documents. For 2012 and future years, we will consider and explore standardizing additional forms and materials.

*Comment:* Several commenters strongly supported our proposed rule to require MAOs and PDP sponsors to use standardized language and formats in marketing materials in instances where we provide them. Other commenters supported this proposal but urged CMS to use consumer research and testing to determine the terms and features consumers want and the best ways to disclose that information to assist beneficiaries with making informed decisions about their health care options.

Several commenters suggested we collaborate with the industry, advocates, and State agencies to develop standardized models, or convene a workgroup to explore ways of improving the wording of model materials. In addition, some of these commenters suggested, as an alternative, that we solicit document examples and suggestions from plans regarding the creation of standardized materials and establish from these examples best practices for model language, content, and format.

*Response:* Given the support for our proposed requirement, we are adopting it as set forth in the proposed rule. We agree with the commenters' recommendations that CMS should research and consumer test standardized model marketing materials, when practical, as well as engage in dialogue with the industry, advocates and State agencies as part of our efforts to standardize more marketing model materials. As we did when we reissued the standardized annual notice of change/evidence of coverage (ANOC/EOC) models for contract year 2010, we intend to continue to consumer test our marketing materials, as practical, to ensure that they accurately describe plan benefits and assist beneficiaries with making the best health care decisions for their particular needs. As part of the process of revising the standardizing ANOC/EOC models, we also conducted listening sessions with the industry to solicit input on improving standardized documents. We received a great deal of useful information as a result of those sessions, which we believe was critical to improving the consumer friendliness of those models. In addition, we will continue to provide opportunities for external stakeholders to comment on draft versions of model documents prior to finalizing them.

*Comment:* Many commenters requested clarification on whether, in developing standardized model marketing materials, we will continue to allow plans the flexibility to modify model documents to accurately convey specific or unique plan information. Many commenters argued that our existing models do not adequately capture the range of variation in plan types and benefits and that standardizing additional models could impede effective communications with members and potentially lead to beneficiary confusion.

These commenters also expressed concern that without such flexibility and space for free form text, plans will be unable to adequately capture the nuances and unique features of the various plan types. Commenters specifically indicated that it was imperative for us to allow flexibility within standardized models for special needs plans (SNPs), cost plans, point-of-service (POS) plans and employer group plans. A few commenters requested the option to waive standardized language for SNPs, or to develop separate standardized documents for these plans if we do not provide sufficient flexibility within standardized models. A commenter suggested that CMS develop documents specifically for low-income subsidy (LIS) eligible beneficiaries and that we provide documents translated into non-English languages, as well as documents in Braille.

*Response:* We agree that standardized materials should be sufficiently tailored to the intended recipients to relay plan information as clearly as possible. Accordingly, we intend to continue to allow plans flexibility to accurately convey specific plan information. As with the current ANOC/EOC standardized models, we will permit plans to capture the unique features and nuances of their various plan types and plan benefits through variable text, as appropriate. Our requirement to use standardized models when we make them available does not change this practice; we are simply moving toward standardizing more marketing documents.

We will consider how best to provide information to LIS-eligible individuals as we standardize models. With regard to providing translated materials, our Medicare Marketing Guidelines currently require plans to provide translated and alternative format documents to beneficiaries. Specifically, plans are required to translate materials in service areas where at least ten percent of the population speaks a non-English language as its primary language. In addition, plans must make basic enrollee information available to individuals with disabilities (for example, visually impaired beneficiaries) and must ensure that information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

To ensure that beneficiaries understand materials translated into a non-English language, we require that plans translating their marketing materials into other languages use

standardized language. For example, plans translating materials into Spanish or Cantonese should use a standard Spanish or Cantonese language resource (such as, "Real Academia Española" [Royal Spanish Academy], the most widely-recognized institution responsible for regulating the Spanish language).

*Comment:* Several commenters suggested we clearly identify the documents we intend to standardize, while two commenters suggested we limit the documents we intend to standardize. One commenter wanted clarification on what "when specified by CMS" means. In addition, many commenters urged us to release standardized documents to plans early in the year to allow plans sufficient time to disseminate plan information to beneficiaries.

*Response:* In addition to the ANOC/EOC, we indicated in the 2009 Call Letter that we intended to standardize the Part D explanation of benefits (EOB), pharmacy directory, provider directory, plan formulary, and transition notice. We are currently in the process of consumer testing and revising some of these models to include plain language.

With regard to the comment about what "when specified by CMS" means, as with the ANOC/EOC, CMS will specify which documents must be used without modification through guidance documents such as the annual Call Letter or HPMS memoranda. Finally, we are committed to releasing final standardized models as early as possible in the year in order to permit plans sufficient time to prepare and disseminate those documents to beneficiaries for the following contract year.

*Comment:* A commenter suggested that, as an alternative to our proposed requirement that plans use standardized documents as specified by CMS, we should allow for review of requested changes to standardized language similar to our review of hard copy change requests for the Summary of Benefits.

*Response:* We disagree with the commenter's suggestion. As stated elsewhere in this preamble, we believe standardization leads to improvements in accuracy, comparability, and understandability, as well as increased efficiencies and greater consistency in our marketing material review protocols and processes. Permitting hard copy changes would undermine our efforts to reduce variability in marketing materials. In addition, we believe that we can address the commenter's concerns by permitting plans to use variable text fields throughout standardized documents so that they accurately reflect unique plan information.

*Comment:* One commenter understood and appreciated the need to standardize models but was concerned that requiring a standardized format limits options, may expand the length of current model documents, and could potentially drive up costs of printed materials.

*Response:* We believe the benefits of increased standardization outweigh the commenter's concerns. The move toward standardizing more documents will reduce the variability and errors in marketing materials, and will ensure that standardized documents provide more accurate, understandable, and comparable information across plans, thereby helping beneficiaries to make the best possible health care decisions for their particular needs.

4. Involuntary Disenrollment for Failure To Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)

We proposed to amend the regulations at § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any involuntary disenrollment occurs, in order to provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. Furthermore, we proposed to codify existing subregulatory guidance regarding the beginning of the grace period for Part D. In this final rule, we adopt these provisions as proposed.

*Comment:* Several commenters supported our proposed regulatory revision to increase the length of the minimum grace period and further requested that CMS exempt beneficiaries from having to pay plan premiums if the organization fails to request payment of the premiums in a timely manner. Another commenter supported this change and further recommended that CMS also require plans to provide for exceptions in cases of financial hardship or other special circumstances.

*Response:* We appreciate the support for this proposal and are adopting it as proposed. Although we do not believe that it is appropriate to exempt beneficiaries from paying premiums for periods of coverage based on late notification, we strongly encourage plans to work with such individuals to implement payment plans where financial hardship could be involved. Also, we note that a change in policy with respect to an individual's eventual obligation to pay his or her premiums is not within the scope of this rulemaking.

*Comment:* Another commenter who supported the proposed regulatory revision further requested that CMS develop a method for beneficiaries to engage CMS in resolving premium payment disputes, such as whether individuals who qualify for the Part D low income subsidy or are enrolled in a state pharmaceutical assistance program (SPAP) owe plan premiums, in addition to disputes regarding individuals who experience problems with premium withhold from their Social Security benefits.

*Response:* Although there is no formal CMS administrative process for dealing with these issues, we do play an important role in resolving premium payment disputes through our existing casework procedures. CMS caseworkers often deal directly with individuals who have their premiums withheld from their SSA benefit payment, and we also work with plans to resolve both premium issues involving individuals or groups of enrollees, such as the LIS population in a plan. We also facilitate discussions between plans and SPAPs about such payment issues. We will continue to look at ways to better address these issues.

*Comment:* One commenter supported the change and recommended that the 2-month grace period begin the first of the month for which the enrollee is delinquent and not from the point of notification.

*Response:* Current regulations state that the grace period begins the first day of the month for which the premium is unpaid. Subregulatory guidance (§ 50.3.1 of Chapter 2 of the Medicare Managed Care Manual and § 40.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual) further clarifies that the premium is "unpaid" only after the member is notified of, or billed for, the actual premium amount due. We clarified that the grace period not begin prior to the member being notified of the delinquency was established to ensure that members have the full grace period in which to resolve the premium payment issue. We agree with the commenter that the grace period should begin the first day of the month for which the enrollee is delinquent, but only if the organization has previously requested payment of the premium and has provided the member an opportunity to pay. Accordingly, in this final rule, we are revising § 422.74(d)(1) and § 423.33(d)(1) to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day

of the month following the date on which premium payment is requested, whichever is later.

*Comment:* Several commenters representing plans opposed the proposed change. One commenter contended that the change would not result in a reduction in disenrollments and requested that CMS instead maintain the minimum 1-month grace period and allow organizations to offer a longer grace period at their discretion. Another commenter cited the potential costs that may be incurred by organizations to make systems enhancements and to modify current administrative processes, policies, and procedures. Another commenter feared lengthening the minimum grace period from 1 month to 2 months would potentially expose the organization to increased financial liability.

*Response:* We believe that providing additional time for individuals to pay their premiums will assist a great number of individuals in meeting their financial obligations and avoid disenrollment. As discussed in the preamble to the October 22, 2009 proposed rule (74 FR 54657), under current rules, individuals may have less than a month a resolve payment delinquencies. Thus, we believe this proposal will provide a valuable beneficiary protection, particularly in view of the significant potential gap in coverage that could result from such a disenrollment, given that in many cases an individual may not be able to re-enroll until the following annual election period. It will also help to reduce the number of situations where individuals pay their premiums shortly after their disenrollments take effect but the plan has already submitted a disenrollment transaction.

Many organizations currently offer a grace period in excess of the one month minimum that is currently required. As such, the impact of the proposed change is limited to those organizations that have chosen to implement the minimum requirement. For these organizations, we believe any administrative costs that may result from changing from a one month to a two month grace period are fully justified by the benefits to be gained by both the organization and its members by providing a more reasonable time frame for all parties to resolve premium payment issues and avoid disenrollment. With respect to the financial liability issue, we also note that the proposed change would not affect an organization's ability to pursue collection of past due premium payments from current and former members.

*Comment:* One commenter requests that CMS change the requirement for issuing disenrollment notices, stating that a timeliness standard of 5 or 7 days would be more manageable than the current three business day requirement.

*Response:* The 3-day requirement referred to by the commenter is not for provision of the disenrollment notice; rather, it is the deadline for organizations to submit the ensuing disenrollment transaction to CMS. This timeframe was established to provide adequate time for data to be transmitted to CMS to ensure the timely processing of any necessary auto-enrollments for those individuals who receive the Part D low income subsidy. Therefore, we are not adopting this suggestion.

*Comment:* One commenter requested that CMS clarify that the grace period applies only to members for whom CMS makes payment to the organization.

*Response:* Our interpretation of this comment was that it was intended to address situations where a plan's enrollment records may not immediately match CMS records, and thus there is some question as to whether an individual is enrolled in the plan. Given that the plan has determined the beneficiary eligible for the plan, has notified the beneficiary of the enrollment, has submitted the enrollment to CMS and the discrepancy in the enrollment record is not caused by any action of the beneficiary but instead is an issue to be resolved between CMS and the plan, we believe it would be appropriate for the same grace period policies to apply to such a beneficiary as to a confirmed plan enrollee.

5. Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§ 422.100)

In our October 22, 2009 proposed rule, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, we proposed to amend § 422.100(f)(3) by adding a new paragraph (f)(4) to specify that all local MA plans must establish a maximum out-of-pocket (MOOP) liability amount inclusive of all Medicare Parts A and B services, the amount of which would be set annually by CMS. We also noted that, under our proposal to require that a MOOP amount be established for local MA plans, the MOOP limit for local preferred provider organization (PPO) plans would be inclusive of all in-network and out-of-network beneficiary cost sharing. As discussed in the proposed rule, we believe that requiring the inclusion of such a limit in plan design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act).

In the preamble to our October 22, 2009 proposed rule, we generally described the process we have established to comprehensively review the proposed cost sharing of each plan benefit package and determine if MA plans' cost sharing designs—both in terms of aggregate expected out-of-pocket cost-sharing and particular cost-sharing amounts for certain health care services—discriminate against those beneficiaries with higher than average health care needs. We noted in the preamble to the proposed rule that we have annually established, through subregulatory guidance, a voluntary maximum out-of-pocket limit on Parts A and B services that, if adopted by an MA plan, would allow the plan greater cost sharing flexibility than it would otherwise receive absent the voluntary MOOP. We also noted that we have identified certain health care services that beneficiaries with higher than average health care needs are likely to need (for example, in-patient hospital, dialysis, skilled nursing facility (SNF), mental health services, Part B drugs and home health care) and described our process for conducting outlier analyses by which we consider the distribution of cost sharing levels submitted by MA organizations to identify levels in the upper end of the range for the purpose of reviewing whether cost sharing levels for submitted benefit designs are discriminatory. We believe these efforts have resulted in reduced discriminatory cost sharing and improved the transparency of plan design. For example, in contract year 2010, about 39.2 percent of all non-employer MA plans representing about 3 million MA enrollees adopted the voluntary MOOP limit on beneficiary cost sharing.

In the preamble to the proposed rule, we stated our intent to use a similar method for establishing a mandatory MOOP amount for Parts A and Part B services for all local MA plans as we used to establish the voluntary MOOP limit for contract year 2010. Therefore, the MOOP would be set by CMS at a certain percentile of fee-for-service (FFS) beneficiary out-of-pocket spending. We also noted that we set the voluntary MOOP limit at the 85th percentile of FFS spending for contract year 2010 but could set the limit at a different percentile or through a modified approach as determined by us in future years. We also proposed to continue to furnish information to MA organizations on our methodology and

the amounts for acceptable MOOP amounts on a timely basis through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach.

After considering the comments we received on this issue, we are finalizing § 422.100(f)(4) largely as proposed but, as discussed in greater detail below, are adding a new paragraph (f)(5) to address concerns raised by commenters about applying our proposed MOOP amount to PPO out-of-network services. Specifically, we are specifying in paragraph (f)(5) that the mandatory MOOP amount under paragraph (f)(4) would only apply to PPO network services, while a higher catastrophic maximum would apply to both in- and out-of-network liability. In setting a higher catastrophic maximum, we will take into consideration standard practices in commercial benefit design as well as protecting beneficiaries who use out-of-network providers.

*Comment:* Several commenters noted that a MOOP amount protects beneficiaries from catastrophic medical costs and supported our proposal. Another commenter noted that it was important that all Parts A and B services be included in the MOOP amount. Another commenter supported our proposal on the grounds that it will bring an element of standardization to the MA program.

A number of Medicare Advantage organizations (MAOs) expressed concern that Original Medicare does not have a MOOP and argued that it would therefore not be equitable to require one for MA plans. These commenters were also concerned that a mandatory MOOP would increase plans' costs and result in increased premiums for beneficiaries, particularly if the dollar limit is too low. Some commenters were also concerned that a mandatory MOOP amount would result in adverse selection, with "sicker" Medicare beneficiaries dropping out of Original Medicare and selecting MA plans. One commenter advocated that we continue our current process of allowing voluntary MOOP limits with a more stringent review for plans that do not adopt the voluntary MOOP limit.

*Response:* As discussed in the proposed rule, we believe that requiring the inclusion of a MOOP limit is an important step to ensure that individuals who utilize higher than average levels of health care services are not discouraged from enrolling in MA plans that do not have such a limit in place. Given that regional PPO plans are required by statute to have such a liability limit in place, and a substantial number of local plans have adopted one voluntarily, we were concerned that high cost enrollees would be discouraged from enrolling in MA plans that did not include a MOOP limit. We believe that requiring a mandatory MOOP limit does not unduly disadvantage MA plans relative to original Medicare. We note that beneficiaries in original Medicare have the option of selecting between two Medigap policies, K and L, that afford them an annual cap on out-of-pocket expenses (currently at $4,600). In addition, enrollees in the original Medicare program can select among other Medigap polices that limit their cost-sharing liability for Parts A and B services. As noted previously, a significant number of MA plans have already successfully designed benefit packages that include MOOP limits and have continued to effectively compete in the marketplace.

We agree, however, that retaining a voluntary MOOP amount that is lower than the mandatory maximum we have proposed would preserve current incentives for further reducing enrollee out-of pocket liability. Therefore, in addition to establishing a mandatory MOOP amount, we also plan to continue our current policy of offering MA plans the option of establishing a lower voluntary MOOP amount in exchange for more flexibility in cost-sharing thresholds than available for plans that adopt the higher mandatory MOOP for contract year 2011. Under this approach, the voluntary MOOP amount would be set at an amount lower than the mandatory MOOP, and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. We would in effect establish two sets of Parts A and B service cost-sharing thresholds under this approach, one applicable to plans selecting the higher, mandatory MOOP amount, and the other applicable to those choosing the lower, voluntary MOOP. To incent plans to adopt the lower MOOP amount, we would allow plans greater cost sharing flexibility for Parts A and B services if they adopt the lower, voluntary MOOP. We plan to articulate this voluntary MOOP policy through subregulatory guidance such as the annual Call Letter or a similar document.

*Comment:* Several commenters were concerned that a mandatory MOOP amount should not be set so high as to discourage low income individuals from joining MA plans. Other commenters recommended that we ensure that the MOOP amount is low enough to benefit low income individuals. One commenter also expressed concern that a MOOP limit may disadvantage smaller local plans compared to larger plans, potentially resulting in those smaller plans being priced out of the MA market. One commenter recommended that we use a fixed benchmark for the MOOP amount, rather than the 85th percentile of expected FFS spending cited in the preamble to our proposed rule, as the cut-off established for contract year 2010, which they believe would still be too high an amount for low income enrollees. Another commenter supported a cut-off at a higher percentile of FFS to ensure that plans do not have to increase their premiums or, alternatively, that the MOOP amount be set no lower than $7,500 in order not to affect the sustainability of the MA program. Another commenter supported a mandatory MOOP amount, but argued that plans should be allowed to establish their own MOOP amounts.

*Response:* In establishing the mandatory MOOP amount, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the MOOPs we establish, annually adjusting the limit as necessary based on the previous year's experience, as well as other factors as appropriate, to ensure that this balance is maintained. As noted previously, we believe the approach of establishing a higher, mandatory MOOP amount and a lower, voluntary MOOP amount will allow us to better strike this balance.

*Comment:* A couple of commenters did not believe their systems would support tracking of out-of-pocket expenses relative to a mandatory MOOP limit, and that the imposition of one would therefore introduce a significant new administrative burden. One commenter argued that we should furnish additional funding to MA plans due to the costs of implementing a mandatory MOOP amount.

*Response:* We recognize that those plans that have not already voluntarily introduced a MOOP may need to invest resources in ensuring their systems are designed to implement this requirement. We believe, however, these costs need to be weighed against the benefits of ensuring that MA plan designs without a MOOP limit do not discourage enrollment by high cost individuals.

*Comment:* Several commenters requested clarification regarding the applicability of our proposed

requirement to establish a mandatory MOOP amount to MA plans.

*Response:* Because a statutory MOOP requirement is already in place with respect to regional PPO plans, we proposed applying the new mandatory MOOP requirement only to local MA plans in our proposed rule. While we now believe regional PPOs should be subject to the same requirements with respect to a MOOP as local MA plans, since our proposed rule did not give MA organizations offering regional PPOs an opportunity to comment on such a proposal, we will need to address this discrepancy in future notice-and-comment rulemaking. However, we note that regional PPOs will have the option of implementing any mandatory or voluntary MOOP amounts we establish for local MA plans.

*Comment:* A number of commenters recommended that we announce the mandatory MOOP amount, and the methodology we use to set it, as early as possible in the year preceding the contract year in which we will apply that amount (for example, in the Advance Notice of Methodological Changes). Another commenter recommended that this information be provided in our annual Call Letter.

*Response:* As specified in the preamble to the proposed rule, we intend to continue to furnish information to MA organizations on our methodology and the amounts for acceptable out-of-pocket caps on a timely basis through the annual Call Letter or a similar guidance docunent.

*Comment:* Two commenters were concerned that the mandatory MOOP would apply to all in- and out-of-network PPO services, and contended that such an arrangement could lead to a reduction in the number of PPOs offered given the potential increase in plan costs that would result. One of these commenters believed including cost-sharing applicable to out-of-network plan covered services will undermine incentives to use preferred providers that are central to the design of a PPO.

*Response:* As stated in the proposed rule, we believe that some protection against out-of-pocket liability should apply to enrollee cost-sharing for both in- and out-of-network services covered by PPOs. However, we agree with the concerns of the commenter highlighting the effect a single MOOP applying to all services would have on incentives to use preferred providers. In addition, for reasons of beneficiary transparency and consistency, we believe that local PPOs should be subject to the same type of MOOP requirements as regional PPOs, which have a different MOOP for out-of-network cost-sharing than that which applies to use of PPO in-network services. Therefore, we are revising § 422.100 by adding a new paragraph (5) that specifies that, in addition to the MOOP for Medicare Parts A and B services that all local MA plans will be subject to—which would apply only to the use of network providers—all local PPO plans must also establish a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services consistent with the requirements applicable to regional PPOs at § 422.101(d)(3). This total catastrophic limit will be no greater than an annual limit set by CMS. In addition, we will also offer local PPO plans the option of implementing any voluntary MOOP amount CMS establishes for local MA plans.

*Comment:* One commenter requested clarification regarding whether all Medicare Parts A and B services would be included in the MOOP amount.

*Response:* As noted in the preamble to our proposed rule, cost-sharing for all Parts A and B services would be included in the MOOP amount. Such cost-sharing includes any plan deductibles applicable to Parts A and B services, but excludes monthly plan premiums.

*Comment:* A commenter argued that since States pay cost sharing for members of dual-eligible special needs plans (SNPs), there is no need to apply a MOOP to these plans. Another commenter contended that dual-eligible SNPs cannot charge their enrollees a premium as a practical matter, which would further disadvantage this plan type if they were required to implement our MOOP limit. Another commenter recommended that we provide guidance on how the MOOP will apply to SNP enrollees, particularly those in dual-eligible SNPs. This commenter was specifically interested in guidance regarding what States' obligation would be with respect to premiums and cost sharing, as well as the actual out-of-pocket liability for a dual-eligible SNP enrollee. Additionally, this commenter was concerned that dual-eligibles may experience an unnecessary reduction in supplemental benefits if our final requirement does not clearly distinguish what these individuals actually pay as out-of-pocket costs versus what Medicaid should pay.

*Response:* We disagree with comments recommending that SNPs be exempted from MOOP requirements. Dual-eligible individuals entitled to have their cost sharing paid by the State and enrolled in a SNP may experience midyear changes in their Medicaid eligibility. In those cases, these individuals may be required to directly pay the plan cost sharing that otherwise would be the obligation of the State. Accordingly, we will not exempt SNPs from the requirement that they implement a MOOP amount as established annually by CMS.

*Comment:* Another commenter recommended exempting employer plans from our MOOP requirements because such a benefit design would be inconsistent with the benefits employer plans currently offer.

*Response:* We disagree with this commenter that such a regulatory exception is warranted. The same considerations involving discrimination against high cost enrollees could also apply in the employer plan context, particularly if the employer allows more than one plan option. In exceptional cases in which CMS agrees that a waiver of this rule would be in the interest of Medicare beneficiaries served by an employer group, CMS could consider waiving the regulations through the employer group waiver authority under section 1857(i) of the Act. Employer plans will therefore be subject to the regulatory MOOP requirement finalized in § 422.100(f)(4) that applies to all MA plans.

6. Maximum Allowable Cost Sharing Amount for Medicare Parts A and B Services and Prescription Drugs (§ 422.100, and § 423.104)

In our October 22, 2009 proposed rule, we proposed to amend our regulations on the general requirements related to Medicare Advantage (MA) benefits and qualified prescription drug coverage to expressly authorize us to establish cost sharing thresholds for individual services below which cost sharing will be considered non-discriminatory.

For Part C plans, we proposed to annually review bid data to determine specific cost sharing levels for Medicare A and B services below which we would not consider there to be a discriminatory effect, and therefore may be approved in an MA benefit package. Specifically, we proposed amending § 422.100 by adding a new paragraph (f)(5) to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by us to be discriminatory.

Similarly, for Part D plans, we proposed to annually review bid data to determine acceptable cost sharing tiers for benefit packages offering non-defined standard prescription drug coverage. To this end, we proposed revising § 423.104(d)(2) by adding a new paragraph (iii) to specify that tiered cost

sharing for non-defined standard benefit designs may not exceed levels annually determined by us to be discriminatory.

We also explained in the preamble to the proposed rule that we would furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year based on the prior year's bids, and on a timely basis either through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach, including the extent to which we provided sufficient clarity on how we would determine whether cost-sharing levels are discriminatory.

After considering comments we received on this issue, we are adopting proposed § 422.100(f)(5) (which, in light of the new subparagraph (f)(5) discussed above, is recodified as subparagraph (f)(6)) and § 423.104(d)(2) with minor revisions made in response to comments discussed below that are intended to clarify that limits will only be established for those Parts A and B services specified by CMS. We note that section 3202 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) "Benefit Protection and Simplification" will apply to MA plans offered in 2011. Section 3202 of PPACA specifies that, unless a specified exception applies, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Where these new limits apply, they will constitute an absolute limit on cost-sharing for the service in question by operation of statute, and we will not set limits under this final rule. After the publication of this rule, we will issue clarifying guidance concerning section 3202 and other provisions of PPACA that impact this regulation.

*Comment:* A number of commenters supported our proposed requirement to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by us to be discriminatory. One of these commenters supported us in continuing our current approach to applying a discrimination test.

A number of commenters opposed our proposed requirement to establish individual Parts A and B service category cost-sharing thresholds, suggesting that individual service category thresholds would result in higher premiums. Other commenters believed that cost-sharing limits would present significant additional administrative costs for plans. A number of commenters contended that individual service category thresholds would limit the availability of unique benefit designs and, consequently, limit beneficiary choice. One commenter argued that we should not limit plans' ability to use cost sharing as a tool to encourage beneficiary choice of cost effective and clinically appropriate services. Another commenter recommended that, rather than adopting cost-sharing thresholds, we should evaluate other options for identifying and preventing discriminatory benefit designs, such as evaluating the prevalence of utilization control mechanisms (for example, prior authorization) on services frequently used by patients with a particular high-cost conditions.

*Response:* We believe establishing individual service cost-sharing thresholds is necessary to ensure that beneficiaries who utilize higher than average levels of health care services will not be discouraged from enrolling in MA plans with cost-sharing in excess of thresholds set by CMS and that our proposal to set specific amounts in advance improves the transparency of, and comparability between, plan choices for beneficiaries.

We are therefore finalizing our proposal to allow us to annually set cost sharing thresholds for Medicare Parts A and B services.

In establishing service category cost-sharing thresholds, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses that could discourage enrollment and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the cost-sharing thresholds we establish, annually adjusting the limits and the particular Parts A and B services that are subject to such limits as necessary based on the previous year's experience and other factors as needed, to ensure that this balance is maintained. As we have in previous years, we plan initially to establish cost-sharing thresholds for those Parts A and B services that we have, through a number of years of experience with plan benefit reviews, identified as particularly likely to have a discriminatory impact on sicker beneficiaries. Specifically, under our current cost sharing review process which has developed from our past experience in reviewing benefit packages we focus our review on 14 service categories we have identified a particularly likely to have discriminatory impact on "sicker" beneficiaries: inpatient catastrophic (90) days, inpatient short stay (10 days), inpatient mental health (15 days), SNF (42) days, home health (37) days, physician mental health visits, renal dialysis (156) visits, Part B drugs, chemotherapy, radiation, DME, equipment, prosthetics, supplies and diabetes tests.

As discussed elsewhere in this preamble, in addition to establishing a mandatory maximum out-of-pocket (MOOP) limit on overall cost-sharing for Parts A and B services, we also plan to continue our current policy of offering MA organizations the option of adopting a lower voluntary MOOP with greater flexibility in Parts A and B cost sharing than available for MA plans that meet only the higher mandatory MOOP. Under this approach, the voluntary MOOP would be set at an amount lower than the mandatory MOOP and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. In implementing thresholds for discriminatory cost-sharing for individual services, we plan to establish two sets of Parts A and B service cost-sharing thresholds, one applicable to plans choosing the higher, mandatory MOOP, and the other applicable to those choosing the lower, voluntary MOOP. We plan to articulate the cost-sharing thresholds associated with the lower, voluntary MOOP through subregulatory guidance such the annual Call Letter or similar guidance document.

In establishing cost-sharing thresholds, we will consider an MA organization's need to use cost-sharing as a tool for preventing overutilization of services. While we have not been provided evidence that this requirement would increase plans' administrative costs, we also note that MA organizations will be able to account for any increased administrative costs in their annual bids. Finally, with respect to the comment about reviewing prior authorization, we believe that establishing cost-sharing thresholds is a more efficient and effective method for eliminating discriminatory MA plan designs.

*Comment:* One commenter questioned our authority to impose individual service category thresholds, and urged us to withdraw our proposal.

*Response:* We disagree with this commenter. As discussed in the preamble to the October 22, 2009 proposed rule, our proposal relies upon the authority in section 1852(b)(1) to ensure that an MA plan would not substantially discourage enrollment by certain MA eligible individuals and our authority under section 1857(e)(1) of the

Act, under which we may add "necessary and appropriate" contract terms; and, with respect to MA plan cost sharing, the authority in section 1856(b)(1) of the Act, under which we may establish MA standards by regulation.

*Comment:* Some commenters sought clarification on how we will address cost sharing thresholds with regard to dual-eligible special needs plans (SNPs). These commenters specifically asked whether we would exempt dual-eligible SNPs from our proposed establishment of mandatory Parts A and B service thresholds, since States pay dual-eligibles' cost sharing. These commenters argued that our proposed requirement could force dual-eligible and chronic care SNPs to charge a premium, thus making their plans unattractive to dual-eligibles and other low-income enrollees.

*Response:* We disagree with commenters recommending that dual or chronic care SNPs should be exempted from our service category cost-sharing thresholds. As long as a plan has at least some enrollees subject to all of a plan's cost-sharing amount, those enrollees could still be discouraged from enrolling or continuing their enrollment in the plan given particularly high cost-sharing for specific services. Even those SNPs that exclusively serve dual-eligible enrollees entitled to have their cost sharing paid by the Medicaid program can include some individuals who lose their Medicaid status midyear and become subject to plan cost sharing which would no longer be paid by the Medicaid program. Plans should not establish excessive cost-sharing regardless of whether the State is responsible for beneficiaries' cost-sharing. We are therefore not exempting SNPs from the mandatory MOOP and cost sharing limits that apply to other MA plans.

*Comment:* One commenter asked us to consider exempting employer plans from our cost-sharing threshold requirements, arguing that such a requirement would complicate their efforts to offer their current and retired employees parallel coverage.

*Response:* We disagree with this commenter. The nature of employer arrangements varies greatly. In some cases, an employer may offer more than one MA plan option, and one or more of those plans may still discourage enrollment by certain beneficiaries through their benefit design. Also, in the case of an employer plan, if a compelling reason exists for an exemption from the limits in this final rule, and if we determine an exemption would be in the best interests of beneficiaries, employers could request a waiver of these limits under the employer waiver authority.

*Comment:* Some commenters recommended that we establish cost sharing thresholds for Parts A and B services as soon as possible prior to the bid submission deadline (for example, in the Call Letter or Advance Notice of Methodological Changes) and provide stakeholders with an opportunity to provide comments regarding the thresholds and the methodology used to arrive at those thresholds. Some commenters representing non-plan stakeholders also requested that we provide this information via means other than the HPMS, since only plans have access to HPMS and advocates and other non-plan entities would like to receive the information we share with plans via HPMS. Another commenter recommended that we permit MA organizations to resubmit a bid and benefit package if the initial bid is rejected due to a finding by CMS of discriminatory cost sharing.

*Response:* As stated in the preamble to the proposed rule, we intend to furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year on a timely basis either through the annual Call Letter or similar guidance document. We will consider ways of disseminating this information through other means to ensure that all stakeholders have an opportunity to comment and note that we generally post draft Call Letters to the CMS Web site to ensure broad public availability. With regard to opportunities to resubmit bids and benefit packages, given that we expect to provide guidance regarding cost-sharing thresholds prior to bid submission, we do not anticipate the need to allow plans to resubmit bids or benefit packages if their submissions are inconsistent with published guidance. As part of our review of submitted bids and benefit packages, we may contact plans to give them the option of modifying their bids and benefit packages if we have made a determination that the proposed plan benefit package or cost sharing contains discriminatory amounts not outlined in published guidance.

*Comment:* One commenter recommends that cost-sharing limits, and the service categories to which they apply, remain stable from year-to-year.

*Response:* We intend to implement cost-sharing thresholds carefully to ensure the right balance of ensuring against discriminatory effects of high cost-sharing and continued viability of the MA program. While we believe stability in the thresholds and the particular services to which those thresholds are applied is important, we also believe it is necessary to allow ourselves the flexibility to build on "lessons learned" each year, and to reevaluate both the thresholds and the Parts A and B service categories to which they apply, to account for any statutory changes in Original Medicare cost-sharing limits as well as other changes to the MA program, and refine our approach accordingly to maintain such a balance.

*Comment:* Some commenters believed that we were not clear in the proposed rule regarding whether we would set cost sharing thresholds for all Parts A and B service categories, or only for selected categories identified as potentially discriminatory. These commenters requested further clarification on our intended approach.

*Response:* As we have done in the context of benefits review in previous years, we intend to focus on service categories particularly likely to have a discriminatory impact on sicker beneficiaries. Initially, we will focus on the service categories we have targeted historically in our benefit review. We expect to refine our approach over time in order to achieve the right balance between plan choice and protection from high out-of-pocket costs. We intend to build on our experience, and potentially make modifications to the list of Parts A and B service categories to which we would apply cost-sharing thresholds.

*Comment:* A couple of commenters recommended that, in setting cost-sharing limits, CMS consider enrollees' cost-sharing both before and after members reach any deductible that may apply.

*Response:* We will consider whether to take plan deductibles into account as part of our methodology to establish cost-sharing thresholds.

*Comment:* One commenter requested clarification on how we will establish cost sharing thresholds based on the previous year's experience. One commenter urged that the thresholds not be adjusted based on current year data.

*Response:* As described in the preamble to our proposed rule, we intend to review the prior year's bid data, as well as actuarial equivalency relative to Original Medicare, to identify cost sharing outliers and establish a reasonable threshold. With this information, and other factors we may identify as we gain experience in establishing these thresholds, we will annually set cost-sharing thresholds as described in this preamble. We do not

anticipate that these levels will need to be changed after bids have been submitted. However, as previously noted, we will conduct a review of submitted bids and we reserve the right to address discriminatory cost sharing or benefit design we identify in these post bid reviews by asking the plan to either modify or withdraw its bid to resolve discriminatory cost sharing.

*Comment:* One commenter recommended that service category thresholds be set at fixed dollar amounts.

*Response:* We understand that copayment amounts are more transparent and predictable for beneficiaries than coinsurance, and will attempt to establish thresholds as copayment amounts rather than coinsurance percentages where appropriate. Given the fact that original Medicare employs coinsurance percentages in its cost-sharing, there may be cases, in which we may limit the coinsurance percentage that can be imposed.

*Comment:* One commenter recommended that we not set a cost sharing maximum for routine services, such as physician visits and lab services, where there is limited financial liability, or for durable medical equipment (DME), where they argue that any particular cost-sharing maximum would invariably penalize one subset of enrollees. One commenter recommended that we establish thresholds on a per day, per stay, and per benefit period basis for SNF and inpatient services. Another commenter recommended that any threshold for Part B drugs apply to all Part B covered drugs.

*Response:* We disagree that physician visits and lab services should necessarily be exempt from cost-sharing maximums, though we currently do not contemplate imposing limits in such cases, and would only do so to the extent that we saw cost-sharing imposed that had a discriminatory effect. As stated previously, we initially will focus on those service categories we have historically identified as particularly likely to have a discriminatory impact on sicker beneficiaries and will refine our approach as needed and in line with our ultimate goal of eliminating discriminatory benefit designs. We welcome the feedback provided by other commenters with regard to DME, SNF and Part B drug copayments and will consider these recommendations as we finalize our methodology and thresholds.

*Comment:* Several commenters supported the proposal to review Part D plan bids to determine acceptable cost-sharing tiers for benefit designs that deviate from the standard benefit package. One commenter indicated that this would bring a level of standardization to plans and make it easier for them to compare out-of-pocket expenses.

*Response:* We appreciate the comments.

*Comment:* Several commenters wanted to limit Part D cost sharing to a total maximum out-of-pocket amount.

*Response:* We do not believe that a regulatory overall liability limit for Part D would be practical or appropriate given the current design of Part D benefits (such as, the coverage gap). We also note that, under the Part D benefit, there is protection afforded to a beneficiary once they enter into the catastrophic phase of the benefit where there is nominal cost sharing.

*Comment:* One commenter wanted us to establish clear and definitive limits on cost sharing. Another commenter wanted us to consider the overall affordability of cost sharing that is imposed on non-low-income (LIS) Medicare beneficiaries. The commenter argues that this is particularly important when considering a plan design in which preferred formulary tiers do not include equally safe and effective drugs for the beneficiary's medical condition. Another commenter wanted us to take into account separate rules for cost contracts with HMOs under section 1876. Additionally, another commenter wanted clarification on how we will review plans with more than or fewer than a three tier benefit design. This commenter suggested that all tiers may not exceed levels determined by CMS to be discriminatory.

*Response:* We appreciate these comments. It is important to note that we review both formularies and benefit designs to ensure that a sponsor's prescription drug offering under Part D is not discriminatory. We have designed our yearly formulary reviews to ensure that all Part D plan formularies include a wide representation of drugs used to treat the Medicare population. As part of this review, we focus on identifying formularies with drug categories that may substantially discourage enrollment of certain beneficiaries, for example if the formulary places drugs in nonpreferred tiers without including commonly used therapeutically similar drugs in more preferred positions. As part of our yearly review of submitted benefit designs, we compare like plans to each other for the purpose of ensuring non-discriminatory cost-sharing. Specifically, we perform an analysis of cost sharing at the tier level, to look for outliers. The outlier analysis considers plan type (basic versus enhanced), tiering structure (for example, the number and type of tiers), and any differences among MA–PDs (including cost plans) and between MA–PDs and PDPs. When outliers are identified, we conduct negotiation calls with the relevant plan sponsors to ensure the cost sharing outliers are reduced prior to bid approval. We also require cost sharing levels for preferred tiers to be lower than cost sharing levels for nonpreferred tiers.

*Comment:* A commenter expressed concern that when coverage of a nonformulary drug is secured on appeal, the cost sharing under the nonpreferred tier can approximate, or even exceed, the negotiated price of the drug.

*Response:* The price charged to the beneficiary cannot exceed the negotiated price. The requirements related to qualified prescription drug coverage at § 423.104(g)(1) make clear that Part D sponsors are required to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount.

*Comment:* Several commenters opposed setting cost sharing maximums, claiming that this will result in higher premiums for beneficiaries. One commenter asserted that CMS' proposal will limit the ability of Part D sponsors to design plans that provide choices for additional or richer benefits in other areas important to beneficiaries. For example, they argue that establishing maximum Part D brand cost-sharing levels will impact the ability to offer $0 copayment for generic drugs; therefore, ultimately inhibiting the greater affordability and access. A commenter contended that our proposal fails to consider a plan design that is associated with a robust formulary. The commenter believes that such a plan should have the flexibility to impose higher member cost sharing, particularly for nonpreferred drugs, compared to a formulary that meets minimum requirements and, coupled with low premium which may be attractive to those with minimal drug utilization who seek protection from potential future changes in health status.

*Response:* In determining a maximum cost sharing amount for a tier above which we will view the plan's benefit design as discriminatory, we attempt to strike a balance between appropriate coverage under the benefit and the potential affect on the premium. As part of our benefit design review, and consistent with previous reviews, we consider all beneficiaries under the plan, and not just those beneficiaries expected to have limited utilization. Therefore, any actuarially-equivalent

cost sharing arrangement is reviewed, along with the rest of a plan's benefit design, to ensure that it does not discriminate against certain Part D eligible individuals. This sometimes results in a sponsor not being able to support higher member cost sharing amount under a robust formulary design for nonpreferred drugs or being able to support zero dollar generics. However, these cases are usually the exception since our review is designed to ensure the maximum utility of the benefit design for potential enrollees.

*Comment:* One commenter wanted CMS to prohibit the use of both copayment and coinsurance tiers under nonstandard Part D benefit designs.

*Response:* We disagree with the commenter and believe such a prohibition would unnecessarily limit plan design. Moreover, we believe that such a proposal is beyond the scope of this proposed rule, which addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. Our proposal did not address whether nonstandard benefit designs utilizing coinsurance are discriminatory.

*Comment:* One commenter wanted us to require that at least one drug within each therapeutic class be on each tier.

*Response:* We believe that such a proposal is beyond the scope of this proposed rule, which only addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. We also note that due to the varying number of drugs that may be available in a therapeutic class, this proposal may require many exceptions and be impractical to implement.

*Comment:* Several commenters expressed concern about our specialty tier policy. A few commenters want us to eliminate the exemption from tiering exceptions for specialty tiers. Another commenter asserted that drugs in the specialty tier are so expensive, an argument could be made that specialty tier coinsurance above 25 percent is excessive. Another commenter argues that the use of specialty tiers is a discriminatory practice that targets individuals who have medical conditions that necessitate use of expensive medications.

*Response:* We appreciate the commenters' concern in this area, which is one we will continue to study. Any revisions to the specialty tier policy will be done in future rulemaking. We note specifically that the commenters' request for us to eliminate the exemption from tiering exceptions for specialty tiers is outside of the scope of this proposal. We also note that we have only allowed a higher coinsurance percentage greater than 25 percent for specialty tiers under alternative prescription drug coverage designs with decreased or no deductibles. Thus, overall, consistent with statutory and regulatory requirements, a basic alternative design must be actuarially equivalent to the defined standard benefit design.

*Comment:* One commenter wanted us to study the effects of high out-of-pocket costs, improve drug pricing disclosure, prohibit plans from changing the price of drugs, notify beneficiaries when a drug price is going to increase, ensure that Part D plan sponsors inform beneficiaries how to get medications free or at lower prices, and end discriminatory practice cost sharing.

*Response:* We appreciate the commenter's concerns over price fluctuations that may result in changes in cost sharing under a Part D plan benefit design that includes coinsurance and the effects that these changes may have on beneficiaries enrolled in these plans. However, several of these comments are outside of the scope of the proposed rule, which addresses our ability to establish threshold levels for cost sharing above which we would determine such cost sharing to be discriminatory. Moreover, we note that under section 1860D–11(i) of the Act, commonly known as the "Non-interference provision," we are prohibited from interfering in the negotiations among drug manufacturers, pharmacies, and sponsors of prescription drug plans (PDPs), and from requiring a particular formulary or price structure for the reimbursement of a covered Part D drug. Therefore, we do not have the authority to prohibit plans from changing the price of drugs.

*Comment:* Several commenters wanted information on discriminatory cost sharing made available through Call Letter and other public means, and want such information to be made available timely so that it can be taken into account prior to bidding.

*Response:* We appreciate the commenters' concern that we be as transparent and timely as possible with our guidance in this area. We will strive to make this information available as early as possible for sponsors to begin constructing their bids for the 2011 contract year.

*Comment:* One commenter stated that if a plan sponsor offers a plan design with zero co-payment amounts for certain mail order prescription drugs, it should be required to offer the same cost sharing at retail pharmacies.

*Response:* This comment is outside the scope of the proposed rule, which does not revise our level playing field policy between mail and retail drug offerings. We refer the commenter to section 50.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf* for our current policy in this area.

7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§ 422.2, § 422.4, and § 422.105)

In our October 22, 2009 proposed rule, we stated that we have become increasingly concerned about the use of prior notification by PPO and PFFS plans as a condition for lower cost sharing. Program experience has demonstrated that such prior notification provisions are confusing to beneficiaries, misleading in terms of cost-sharing transparency, and in some instances, are used inappropriately as a form of prior authorization. In the GAO report titled "Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans (GAO–09–25)," the GAO stated that some PFFS plans it reviewed "inappropriately used the term prior authorization rather than pre-notification in the informational materials they distributed to beneficiaries, which may have caused confusion about beneficiaries' financial risks." We have determined that the complexity of cost-sharing designs using prior notification has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. Therefore, in order to reduce the complexity of MA plans' cost sharing designs and improve transparency for both enrollees and providers, we proposed to prohibit PPO plans (for out-of-network services) and PFFS plans from providing for lower cost sharing where prior notification rules have been satisfied. Specifically, we proposed to revise § 422.4(a)(1)(v) and (a)(3) to provide that PPO and PFFS plans will be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished. We are adopting § 422.4(a)(1)(v) and (a)(3) without further modification in this final rule.

In our October 22, 2009 proposed rule, we also proposed to prohibit MSA plans from establishing prior notification rules. We believe that prior notification rules established by MSA

plans are also confusing to enrollees of those plans and have similar negative effects as those described above for PPO and PFFS plans. Accordingly, we proposed to modify § 422.4(a)(2) such that MSA plans will also be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished. We are also adopting § 422.4(a)(2) without further modification in this final rule.

Finally, the October 22, 2009 proposed rule discussed similar concerns about beneficiary confusion in connection with PPO plans that included a POS-like benefit. As we noted in the October 22, 2009 proposed rule and the Medicare Program entitled Establishment of the Medicare Advantage Program, published in the January 28, 2005 **Federal Register** (70 FR 4617 through 4619), we had stated that PPOs could offer a POS-like benefit under which beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but still might be greater than it would be for in-network provider services, provided an enrollee follows preauthorization, pre-certification, or prenotification rules before receiving out-of-network services. For the same reasons discussed above, we determined that this approach is confusing, and is subject to abuse as a prior authorization mechanism for non-network services. Therefore, in order to reduce the complexity of PPO plans' cost sharing designs and improve transparency for both enrollees and providers, we proposed in our October 22, 2009 proposed rule to prohibit PPO plans from offering such a POS-like benefit. Specifically, we proposed to revise the definition of POS in § 422.2 and § 422.105(b), (c), and (f) to indicate that only HMOs may offer a POS benefit. The proposed change is consistent with section 1851(a)(2)(A)(i) of the Act, which states that an HMO may include a POS option. We are adopting § 422.105 without further modification in this final rule and revising § 422.2 as described below.

*Comment:* Several commenters supported our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Some of the commenters indicated that these practices are confusing and misleading and penalize members who are not able to give prior notification or who were unaware of the option. Some commenters also indicated that they found several plans that charge exorbitant cost-sharing (up to 75 percent) for expensive items such as durable medical equipment when prior notification requirements have not been met. A number of commenters opposed our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Other commenters stated that these practices permit plans to alert the enrollee in advance of receiving a service that it may not be covered; reduce enrollees' cost sharing obligations when obtaining covered services from out-of-network providers; enable plans to better monitor and oversee members' use of out-of-network providers, thus allowing plans to assess and expand their provider networks; and identify those plan members who may qualify for plan disease management and case management programs. One commenter indicated that MA plan premiums likely would increase if this cost control technique were eliminated. Commenters opposed to CMS' proposals provided several recommendations for addressing our concerns about prior notification rules and POS-like benefits. Commenters' recommendations included retaining existing policies; enforcing the existing requirement (for example, requiring greater clarity in enrollee materials) to address concerns raised in the proposed rule; requiring PPO plans with POS-like benefit to better describe the cost-sharing amounts under each set of circumstances that may arise; requiring plans to more clearly describe the distinction between prior authorization and prior notification, and expressly identify those covered services subject to each process; and encouraging providers' outreach to plans to confirm prior authorization/notification provisions and members' cost sharing obligations.

*Response:* We agree with the commenters supporting our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. As we stated in the October 2009 proposed rule, we believe that prior notification is confusing to beneficiaries, misleading in terms of disclosure of cost-sharing, and in some instances, used inappropriately as a form of prior authorization. Also, the complexity of cost sharing designs using prior notification and POS-like benefits has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services.

We acknowledge the concerns raised by commenters who opposed our proposals. However, we believe that most of these concerns can be addressed if the plan takes an active role to educate enrollees and providers about their right to request a written advance coverage determination from the plan, in accordance with Subpart M of Part 422, before an enrollee receives a service in order to confirm that the service is medically necessary and will be covered by the plan. These MA plans should clearly explain the process for requesting a written advance determination in member materials and respond to requests from enrollees and providers on a timely basis. Plans may also encourage enrollees and providers to request advance coverage determinations prior to receiving costly services. These MA plans can also use requests for advance coverage determinations as a tool to identify enrollees who may qualify for disease management and case management programs or who require further care coordination. Plans can use the claims data submitted by non-network providers to expand their provider networks as well as identify those enrollees who would benefit from disease management and case management. We do not believe that prohibiting prior notification rules and POS-like benefits will lead to higher MA plan premiums. We believe that prohibiting PPO plans (for out-of-network services), MSA plans, and PFFS plans from creating prior notification rules and PPO plans from offering a POS-like benefit will reduce the complexity of these plans' cost-sharing designs and improve transparency for both enrollees and providers. Accordingly, we are adopting the proposals as set forth in the October 2009 proposed rule.

We are making a technical correction to the definition of point-of-service (POS) in § 422.2 in this final rule. We are deleting the word "additional" from the definition since it no longer applies to the definition of a POS benefit option.

8. Requirements for LIS Eligibility Under Part D (§ 423.773)

In the October 22, 2009 rule, we proposed amending the length of the period for which individuals are re-deemed eligible for the full low income subsidy to conform § 423.773(c)(2), with guidance we issued in section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual. As we noted in the October 2009 proposed rule, we review data from State Medicaid

Agencies and the Social Security Administration (SSA) every year to determine whether individuals currently deemed eligible for the subsidy should continue to be deemed (that is, "re-deemed") eligible for the subsidy. These data, which are sent in July and August every year, allow us sufficient time to update individuals' records in our systems, if necessary, and to make appropriate notifications if an individual is losing deemed status for the subsequent calendar year.

We also noted that when we review data in July and August, we also identify individuals who are newly eligible for Medicaid, a Medicare Savings Program, or SSI, and deem them eligible for LIS for the remainder of the current calendar year. In addition, we also re-deem these individuals for the subsidy for the next calendar year, because we do not have sufficient time in the final months of the year to conduct a separate re-deeming process for them. Moreover, if we waited to re-deem these beneficiaries after the start of the next calendar year, they could incur greatly increased premium liability and cost sharing amounts at the start of the new calendar year than they would have otherwise.

To address these issues, we proposed to amend § 423.773(c)(2) to indicate that the deeming will be, at a minimum, for the following periods: If deemed status is determined between January 1st and June 30th of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year. If deemed status is determined between July 1st and December 31st of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year and the next calendar year. We have found that this policy promotes effective administration of the LIS benefit and decreases the administrative burden on CMS, the Social Security Agency, and State Medicaid agencies, as well as on subsidy eligible individuals. In this final rule, we adopt this provision as proposed.

*Comment:* Several commenters expressed support for our intent to put in regulation the minimum time periods for which beneficiaries are deemed eligible for the LIS.

*Response:* We appreciate this support for our intent to outline the minimum time periods of LIS eligibility.

*Comment:* One commenter urged us to consider making LIS deemed status permanent, or granting a 3-year period of presumptive eligibility. The commenter noted that while income and assets may fluctuate, most low-income Medicare beneficiaries are unlikely to experience increases that are enough to affect their eligibility. The commenter also noted that making eligibility permanent would eliminate the need for redeterminations of eligibility, thus reducing administrative costs for the program and inconvenience and stress for beneficiaries.

*Response:* We understand the potential benefits to the LIS population of extending or making permanent their eligibility for the subsidy, and reducing the inconvenience and stress to beneficiaries is an ongoing goal of our administrative processes. Currently, approximately 95 percent of LIS-eligible beneficiaries are re-deemed for the following year prior to the end of the current calendar year, and half of those who are not initially re-deemed (that is, another 2.5 percent) are re-deemed within next 6 months. In addition to this, the number of beneficiaries who actually receive the annual Loss of Subsidy Letter, also known as the gray notice, has been decreasing over the last 4 years. This suggests that CMS and State efforts to improve the administrative process are working, and that individuals who continue to qualify for the low income subsidy are being identified appropriately, while the small proportion of individuals who may no longer qualify for the subsidy also are being identified. We believe that the approach being adopted here strikes a balance between making the re-deeming process as efficient as possible while still ensuring that beneficiaries receiving the subsidy are truly LIS-eligible. For these reasons, we are not adopting the suggested modifications.

*Comment:* A few commenters recommended that we require States to continue providing Medicaid coverage to a dual-eligible until the individual's Part D enrollment actually takes effect.

*Response:* Section 1935(d) of the Act specifically precludes Federal medical assistance for Medicaid payments for prescription drugs for those Medicaid-eligible individuals who are also eligible for Part D, regardless of whether the person is enrolled in a Part D plan. Therefore, no modification to the regulations will be made.

*Comment:* One commenter requested additional regulatory changes to require improvements to the way we administer the LIS benefit, including improving the Web site, notices to encourage appropriate actions, and putting in place better "Best Available Evidence" policies and procedures to ensure that LIS status discrepancies are corrected.

*Response:* As noted previously, we continually consider ways to improve the administration of the LIS benefit and beneficiaries' understanding of it. We believe we have the authority to make the additional improvements the commenter suggested, as appropriate, without further modifying the regulation.

9. Enrollment of Full Subsidy Eligible Individuals and Other Subsidy Eligible Individuals Under Part D (§ 423.34)

We proposed to codify in regulation the enrollment procedures that we use for LIS individuals, which are similar to those specified in the regulation for the dual-eligible population. We believe that our regulations would be more accurate and complete if they specifically addressed this population. Therefore, we proposed to include information on how we enroll all LIS-eligible individuals, including full benefit dual-eligible individuals, through the following changes:

- In § 423.34(a), we expanded the general rule to refer to all LIS-eligible individuals, so that the rest of that section applies not only to full benefit dual-eligible individuals, but also to all LIS-eligible individuals.
- In § 423.34(b), we retained the definition of full benefit dual-eligible individual, and added a definition for "low-income subsidy eligible individual." We have identified the need for a technical correction to the definition of "low-income subsidy eligible individual." The proposed definition could be read to specify that the definition of full-benefit dual eligible—who are identified as a specific group of LIS eligibles—is that in § 423.722, which is limited to such individuals already enrolled in a Part D plan. However, the enrollment rules in § 423.34(b) applies to full-benefit dual eligibles not yet enrolled in a Part D plan. We made a technical correction to the regulation text to specify that the definition of full dual eligible individual is that in § 423.34.
- We amended the paragraph heading of § 423.34(c) to indicate that this paragraph describes the process we use to reassign LIS-eligible individuals during the annual coordinated election period. We indicate that the reassignment process applies to certain LIS eligible individuals (that is, not just full-benefit dual-eligible-individuals).
- We revised the paragraph heading of § 423.34(d) from "Automatic Enrollment Rules" to "Enrollment Rules." We made this change to reflect the inclusion of full subsidy and other subsidy eligible groups in the enrollment process, in addition to full benefit dual-eligible individuals. In our guidance, we refer to the process of enrolling full benefit dual-eligible individuals as "automatic enrollment,"

and the process for other LIS eligibles as "facilitated enrollment." (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.)

- We amended § 423.34(e) to indicate that the rules regarding declining enrollment and disenrollment also apply to all LIS-eligible individuals.
- In § 423.34(f), we clarified that the paragraph heading and contents of this paragraph are limited to the effective date of enrollment for full benefit dual-eligible individuals. We also amended § 423.34 (f)(3) to specify that, for individuals who are eligible for Part D and subsequently become eligible for Medicaid on or after January 1, 2006, the effective date of enrollment would be the first day of the month the individual becomes eligible for both Medicaid and Medicare Part D.
- In § 423.34(g), we added a new paragraph to specify that the effective date for LIS eligibles who are not full benefit dual-eligibles would be no later than the first day of the second month after we determine that the individual meets the criteria for enrollment into a PDP under this section. This change conforms to section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Unlike full benefit dual-eligible individuals who may have retroactive Part D coverage, these individuals have only prospective Part D coverage.

In the proposed rule, we also acknowledged concern expressed by some commenters about auto-enrolling beneficiaries on a random basis. For example, focus groups of seniors suggest the possibility that some auto-enrolled beneficiaries may not realize they have been enrolled in a drug plan or that they have been reassigned to a different drug plan. We noted that we are committed to taking appropriate steps to improve this process and welcomed comments related to all aspects of these procedures. In this final rule, we adopt these provisions as proposed.

*Comment:* Several commenters expressed support for expansion of auto-enrollment and reassignment to all individuals with LIS.

*Response:* We appreciate the support for this policy and are adopting the proposal without change.

*Comment:* Commenters urged us to shorten the time period for a plan enrollment so that it would take effect as of the date the person becomes subsidy eligible. The current time period can leave an individual who has applied and qualified for the subsidy with a gap of over 2 months between the time they express an interest in getting help with drug costs (via the application for the LIS) and the time they are actually enrolled into a plan and receive that assistance. This timeframe may have made sense initially, since it was not clear that nondually eligible LIS recipients would have an ongoing SEP. Now that they have been extended that protection, there is less of a need to wait for their selection. Instead, the enrollment should happen quickly to ensure access to prescription drugs.

*Response:* Facilitated enrollment constitutes a passive enrollment process that requires advance notice of the opportunity to make an active election before the enrollment is effective. We have been unable to find a way to ensure that individuals who are facilitated at the end of the month can receive the required advance notice and have an opportunity to make an election on their own before that enrollment takes effect (though it is possible to do so for those at the beginning of the month). It is important to keep in mind that this population consists of individuals who have applied for LIS, are notified of their approved LIS eligibility, and informed via their LIS approval notice that they need to elect a plan in order to avail themselves of the subsidy. Thus, we believe they are likely to follow through on their previous actions and choose a plan on their own, leading to possible confusion if they receive a facilitated enrollment notice after they have already made an active election. Finally, we note that all individuals whose facilitated enrollment into a PDP has not yet taken effect may obtain coverage for immediate drug needs through the Limited Income NET demonstration.

We are committed to continue exploring ways of shortening the facilitated enrollment process without infringing on an individual's ability to make a choice, or adding to the possibility of beneficiary confusion. However, it is important to note that proposed regulation text that we are now finalizing specifies that the enrollment effective date is "no later than" the first day of the second month" after we determine that they meet the necessary enrollment criteria. Therefore, although we are declining to amend the regulation as requested while we continue to address a number of operational issues that remain unresolved, the regulation language does provide the flexibility to shorten the timeframe if warranted and feasible.

*Comment:* One commenter noted that plans and beneficiaries would benefit from us specifying for both plans and beneficiaries any premium liability in instances when the beneficiary has a 25, 50, or 75 percent premium subsidy, in the process of conducting facilitated enrollment. As part of this, the commenter suggested revising of the facilitated assignment letter to include that portion of premium for which the beneficiary is liable.

*Response:* When we notify plans of new facilitated enrollees, we do identify those beneficiaries who are partial versus full subsidy beneficiaries, both on the Transaction Reply Report confirming enrollments, as well as on the LIS History report. In addition, the individuals' subsidy level is fully explained in the LIS approval letter from the Social Security Administration. However, we appreciate the suggestion for modifying the facilitated enrollment letter to reference a partial subsidy beneficiary's premium liability, and will explore whether this is feasible. We believe the latter does not necessitate a regulation change since notification details are generally an operational issue, so we will not modify the regulation to reference this.

*Comment:* A few commenters requested that we require that plans notify dual-eligibles in advance of potential involuntary disenrollments. They noted that we conduct a special auto-enrollment early each month—

- To identify full benefit dual-eligibles who are disenrolled from their previous plan;
- Who have not chosen a new one; and
- Where there continues to be a risk of a coverage gap if the plan submits the disenrollment request to CMS after the special auto-enrollment occurs.

*Response:* Section 423.36(b) of the regulation and section 40.2 of Chapter 3 of the Medicare Prescription Drug Manual already require plans to provide advance notice of potential disenrollment, so there is no need for a regulation change to that effect. The special process we run each month to capture recently disenrolled individuals already represents a significant advance in our auto-enrollment procedures. However, we will continue to look at ways to modify auto-enrollment to more quickly place auto-enrolled beneficiaries in a new plan. Note that under any circumstances, full benefit dual-eligibles who are disenrolled will not encounter any coverage gap—instead their subsequent enrollment will be made retroactive to the date of the loss of coverage from the preceding plan.

*Comment:* One commenter suggested adding in § 423.34(f)(3) the phrase "unless the individual is not a full benefit dual-eligible as identified in § 423.34(g)" to the end of the sentence that comprises this subsection. The commenter believes this addition would

clarify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles who have LIS.

*Response:* Section 423.34(f), including subparagraph (f)(3), is already limited to full benefit dual-eligibles by virtue of the introductory regulation text before subparagraph (f)(1). Given this, we see no need to further specify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles, so we decline to amend the regulation as suggested by the commenter.

*Comment:* Several commenters suggested that we expand the PDPs to which it assigns or reassigns LIS beneficiaries to include enhanced benefit plans. One commenter further clarified that reassignments should include enhanced plans whose portion of the basic premium falls below the LIS benchmark, as this would be no more costly to the government and would give LIS beneficiaries the same options as available to other beneficiaries to enroll in enhanced benefit plans.

*Response:* While enhanced benefit plans may offer supplemental benefits, they always create a premium liability for the beneficiary, including those who are eligible for the 100 percent premium subsidy. This is because, by statute, the LIS does not cover the portion of the premium attributable to the enhanced benefit, even if the total premium is under benchmark, meaning that the beneficiary is liable for the enhanced portion of the premium. The statute clearly limits initial auto enrollments to plans where an individual has zero premium liability, and we have adopted the same policy approach for purposes of reassignments. Therefore, we decline to modify the regulation as requested. We note that LIS beneficiaries are always free to elect an enhanced benefit plan if they wish to access the enhanced benefits, but they would incur some premium liability.

*Comment:* Several commenters urged us to move away from random reassignment of LIS eligible individuals to a system of beneficiary-specific reassignment in which beneficiaries are matched with plans that include their current drugs and preferred pharmacy. They believe this would result in less disruption to beneficiaries, and increased adherence to currently-prescribed drug regimens, while potentially providing the LIS benefit at the lowest total cost to beneficiaries.

*Response:* We continue to explore alternatives to random reassignment that would minimize the potential for disruptions to continuity of care, and appreciate the commenters' support for a beneficiary-specific process. While we believe there is merit to beneficiary-specific reassignment, we decline to amend the regulation to require it, given that § 423.34(c) currently provides CMS the discretion to implement such changes if our ongoing exploration of such an approach indicates that revisions to the current reassignment methodology are warranted.

*Comment:* A few commenters suggested that instead of reassigning LIS beneficiaries from plans whose premiums are going above the LIS benchmark, we should permit them to stay in the plan and be held harmless. They recommended a number of ways to do so, including giving affected beneficiaries a grace period of one year to remain in the plan, with no additional premium payment; letting the plan "absorb" any premium difference between the benchmark and the bid amount (up to $2.00 per one commenter); or waiving the requirement that plans attempt to collect delinquent premiums.

*Response:* While we have discretion to determine which beneficiaries are subject to reassignment, we believe that section 1860D–13(a)(1)(F) of the Act, which requires uniform premiums, precludes us from adopting these recommendations (absent a demonstration such as the 2006–2008 "de minimis" demonstration, where premiums of "de minimis" amounts were waived). We note that we have already implemented a demonstration for the 2010 plan year that increased the LIS benchmark, which had the effect of substantially decreasing the number of beneficiaries who needed to be reassigned.

*Comment:* One commenter suggested that CMS should allow the plan (rather than CMS) to move the LIS members in to a zero-dollar premium plan offered by the same sponsoring organization.

*Response:* As outlined in section 30.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, when we reassign a beneficiary, we first attempt to reassign to a PDP offered by the same organization. Only when that is not possible do we reassign to plans outside of the organization. Our experience has been that CMS-initiated actions are much easier to implement on a timely basis, and to monitor for accuracy and completion, than are actions that depend on sponsors to identify and submit enrollment transactions for the affected population. Therefore, we believe there is little or no benefit to delegating this responsibility to PDP Sponsors, and we decline to make the requested change.

*Comment:* One commenter urged us to let plans communicate sooner with LIS enrollees they may lose to reassignment. The commenter suggested such communication be permitted earlier than is currently permitted in the reassignment process, to ensure affected beneficiaries understand their options.

*Response:* Plan sponsors are already permitted to communicate with current enrollees, subject to Part D marketing guidelines; the reassignment regulations under discussion here do not contain additional constraints on these rules, and we make every effort to involve sponsors in the reassignment communications process as early as possible. Thus, we believe there is no need for changes to the regulation to address this issue.

*Comment:* One commenter recommended that we include LIS recipients with partial premium subsidy as opposed to only full premium subsidy recipients in the annual reassignment process. The commenter noted that while it is true that recipients with partial premium subsidy will pay some premium no matter which plan they select, the amount they pay is lower if they are enrolled in a plan with the premium at or below the benchmark.

*Response:* We acknowledge that a partial subsidy beneficiary's premium would be somewhat lower in a zero-premium plan versus a plan with a premium over the benchmark, but in either case, these beneficiaries would still have to pay some portion of the premium. As always, our policies with respect to reassignment are intended to strike a fair balance between our dual goals of limiting beneficiary exposure to premium costs and also avoiding any potential negative impact on an individual's prescription drug coverage (such as changes to a pharmacy network or drug regimen). Since reassignment cannot eliminate the premium liability for such individuals under any circumstances, in this situation, we believe that potential for disruption to the prescription drug coverage outweighs the potential financial risks associated with paying a higher premium. Therefore, we do not believe that there is sufficient benefit to reassigning these beneficiaries, and we decline to adopt the commenter's suggested change to our existing approach.

*Comment:* A few commenters asked us to reconsider our decision not to include beneficiaries who elect their current plan ("choosers") in the reassignment process. Our reconsideration of this issue should begin with an evaluation of how choosers have been affected by the current process. In particular, the

Agency should identify the number of choosers who—

- Affirmatively switch plans every fall;
- Affirmatively switch plans during the year; and
- Are involuntarily disenrolled due to nonpayment of premium.

*Response:* We share the commenter's interest in this issue, and recently solicited input on whether we should reassign choosers who will face a premium liability of $10.00 or more in the following year (*please see* page 84 of the Advance Notice of Methodological Changes for Calendar Year 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, issued February 19, 2010). We will continue to assess choosers' experience in Part D plans above the benchmark, including the extent to which they subsequently elect another plan and the extent to which they experience problems with premium payments. As noted previously, the regulations do provide the flexibility to change the existing process should our reconsideration of our approach show it to be warranted.

*Comment:* Two commenters recommended that we send a notice to LIS choosers who have chosen to join or remain in plans in which they would incur a premium liability. The commenters suggested notifying them of their zero-premium options (including an analysis of drug utilization to determine most appropriate plan). The beneficiary would be permitted to respond to the mailing in an efficient manner (for example, via postcard, telephone call, or online) to indicate his or her choice.

*Response:* We continue to assess the experience of LIS choosers who face premium liability, and as noted above, have solicited input on whether we should reassign choosers who have a premium liability of $10.00 or greater for the following year. We remain committed to reaching out to choosers whom we do not reassign to let them know about their options for zero premium prescription drug plans.

*Comment:* A few commenters urged us to require State Medicaid Agencies to increase the frequency of state submission of MMA data exchange files, which is the primary vehicle for notifying CMS of new dual-eligible beneficiaries. This would further minimize enrollment delays for new dual-eligibles.

*Response:* We believe this comment is outside the scope of this regulation, so we decline to amend the regulation in this manner. However, we continue to encourage states to submit these files more frequently, and provide technical assistance on how to do so.

*Comment:* One commenter urged us to ensure that dual beneficiaries receive clearer information about all the options available to them, including information about Medicare Special Needs Plans that can provide their Part D benefits. The commenter was especially concerned about the new Limited Income NET demonstration, which will automatically enroll LIS-eligible individuals who fail to elect a plan and are in immediate need of drugs in one Part D plan. This could create obstacles to seamless conversion from a Medicaid-only managed care plan to a Medicare Special Needs Plan offered by the same organization. The commenter encouraged us to establish more effective procedures to find and transition new duals into their Medicare benefits, especially those who are becoming Medicare-eligible because they are reaching the end of their 24-month disability waiting period.

*Response:* We appreciate the commenter's concern about ensuring dual-eligible beneficiaries receive information about all their options, and the need for ensuring a smooth transition for these beneficiaries between Medicaid and Medicare drug coverage. We have taken several steps to do so, and believe the Limited Income NET demonstration is an important step in further improving that transition. With respect to the concerns about the Limited Income NET demonstration, we note that the Limited Income NET process only involves auto enrollment to a single Part D plan for a short, retroactive period. For all prospective periods, the long-standing process of random enrollment among all PDPs with a premium at or below the LIS benchmark would continue to apply. Further, we do not believe the Limited Income NET demonstration specifically, or auto enrollment generally, creates obstacles to seamless conversion. In both cases, our processes are designed to ensure that new dual-eligibles have access to Medicare drug coverage on the first day of their eligibility for it. However, both those processes are also designed to ensure that any beneficiary election will trump a CMS-generated auto enrollment.

*Comment:* One commenter expressed support for the Limited Income NET demonstration program, but raised other concerns that the commenter believes the demonstration will not address: enrollment delays, LIS recipients in non-benchmark plans, and the need for accurate, LIS-specific information in plan mailings.

*Response:* We appreciate the support for the Limited Income NET program, and will continue to work on improving other areas of the program referenced by the commenter.

10. Special Enrollment Periods Under Part D (§ 423.380)

In the October 22, 2009 rule, we proposed to expand the SEP described in § 423.38(c)(4), which currently applies to full benefit dual-eligible individuals, to all LIS-eligible individuals. This proposed change is consistent with our authority in section 1860D–1(b)(3)(C) of the Act and will conform our regulations to current practice as reflected in CMS guidance in section 20.3.8, item 7, of chapter 3 of the Medicare Prescription Drug Benefit Manual. In this final rule, we adopt the provision as proposed.

*Comment:* Several commenters expressed support for putting the continuous Special Enrollment Period (SEP) for non-full benefit dual-eligible beneficiaries that is currently in operational guidance into regulation.

*Response:* We appreciate the comments that support placing the SEP for non-full benefit dual-eligibles into the regulation.

11. Transition Process Under Part D (§ 423.120(b)(3))

In the October 22, 2009 proposed rule, under the authority of section 1860D–11(d)(2)(B) of the Act, we proposed to codify in regulation certain plan transition policies at § 423.120(b)(3) previously established through subregulatory guidance. We specifically proposed to codify in regulation that a Part D sponsor must provide for a transition for the following—

- New enrollees into PDPs following the annual coordinated election period;
- Newly eligible Medicare enrollees from other coverage;
- Individuals who switch from one plan to another after the start of the contract year; and
- Current enrollees remaining in the plan who are affected by formulary changes from one contract year to the next.

We also proposed, consistent with our current guidance, that a Part D sponsor's transition process be applicable to nonformulary drugs, meaning both—

(1) Part D drugs that are not on a sponsor's formulary; and

(2) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules. Additionally, consistent with our current guidance, we proposed to codify the timeframes for the transition process

and the days' supply limit for a transition fill of an enrollee's medication. Specifically, we proposed to codify the transition process timeframe to apply during the first 90 days of coverage under a new plan.

In addition, noting that our existing guidance directs Part D sponsors to provide a temporary supply we proposed that Part D plan sponsors be required to ensure that the one-time temporary supply of nonformulary Part D drugs requested during the first 90 days of coverage in an outpatient setting be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days, in which case the Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication. For a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. In addition, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens. For these reasons, we proposed to require sponsors to honor multiple fills of nonformulary Part D drugs, as necessary during the entire length of the 90-day transition period. Further, we proposed requiring up to a 31-day transition supply for enrollees in an LTC facility given that many LTC pharmacies and facilities dispense medication in 31-day increments. Thus, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan at least a 31 day supply of a prescription when presenting in the first 90 days of enrollment (unless the prescription is written for less) with refills provided, if needed, up to a 93 day supply.

In addition to proposing to codify the preceding requirements, we also clarified our expectations of sponsors with respect to providing transition notices. Consistent with our guidance that specifies that Part D sponsors send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill, we proposed to codify the guidance that directs sponsors to send this notice to each affected enrollee within 3 business days of the temporary fill. In addition to this codification, we also proposed requiring plan sponsors to make reasonable efforts to notify prescribers, via mail, electronic or verbal communication, that the affected enrollees' prescription cannot be refilled, either because of utilization management requirements such as prior authorization or step therapy, or because the prescribed medication is not on the plan sponsor's formulary. All of these proposals were addressed by adding paragraphs (i) to (v) to our general transition policy requirement at § 423.120(b)(3). We are adopting paragraphs (i), (ii), and (v) as proposed without further modification. As explained below, we are modifying proposed paragraph (iii) by clarifying the existing language to state that the temporary supply of nonformulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 93 days in 31 day supply increments, with refills provided, if needed, unless a lesser amount is actually prescribed by the physician, and paragraph (iv) by clarifying that transition notices must be sent to beneficiaries within 3 business days after adjudication of a temporary fill.

*Comment:* A number of commenters supported our proposal of requiring an extended transition supply be given to enrollees residing in a LTC facilities. However, commenters requested that CMS provide the same protections to individuals requiring LTC in community-based settings as provided to those in institutions.

*Response:* While we appreciate that there are community-based enrollees who have nursing facility level of care and may experience access to multiple pharmacies, we are not persuaded that we should extend the LTC extended transition requirement to such individuals. We believe that residents of LTC institutions are more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary products. We believe that community-based enrollees, in contrast, are less limited in their access to prescribing physicians and do not require an extended transition period to work with their physicians to successfully transition to a formulary product.

*Comment:* Several commenters disagreed with the proposed timeframe in which to send out the transition notice of 3 business-days and recommended 3 calendar days. The commenters argue that a requirement of 3 calendar days is clearer and easier to enforce, particularly during holiday periods, when holidays delaying U.S. mail combined with the normal delays in mail delivery can severely cut into the time a beneficiary needs to try a different drug and request a formulary exception.

*Response:* We disagree with these commenters that the proposed timeframe be changed to 3 calendar days, which includes weekends and holidays when standard businesses are closed. We do not believe that a calendar day timeframe will allow sponsors an acceptable period in which to mail out a transition notice. Rather, we believe that the 3 business day turnaround time for notice to be sent is consistent with current transition policy and it permits a beneficiary sufficient time to work with his/her prescriber to change to a therapeutically equivalent drug on a plan's formulary or begin the exceptions process.

*Comment:* Several commenters supported the proposed requirement that sponsors notify the prescriber when a transition fill has been made. One commenter stated that the proposal is a positive that allows consistency across the MA population and it provides protection of certain vulnerable populations. Many commenters requested that we develop a standardized transition format for notices and explanations to be provided to plans. Another commenter requested our review notices that sponsors provide to ensure that beneficiaries are not unknowingly being steered to mail order pharmacies.

*Response:* We appreciate the comments. We note that we have developed a model transition notice for plans to send beneficiaries and are considering for the future whether or not to make that model standardized. In addition, we have prepared model notices for sponsors to ensure that beneficiaries are not unknowingly being transferred to mail order pharmacies. Model transition notices may be found at *Part D Marketing Model Materials.*

*Comment:* Many commenters opposed the requirement to send the transition notice within 3 business days of the temporary fill being dispensed. These commenters requested changing the proposal to notice being sent within 3 business days after a temporary fill is processed. The commenters argue that this is consistent with the current language in Section 30.4.10 of Chapter 7 of the Prescription Drug Benefit Manual, where the phrase "within 3 business days of the temporary fill" has been understood by the industry to refer to the date the temporary fill is processed, since it is only when the claim is processed that a plan learns about it and can act on it.

*Response:* We agree and note that industry practice standards have interpreted the language to mean within

3 business days of a temporary fill being processed. Therefore, we are revising the language of § 423.120(b)(3)(iv) to read "within 3 business days of adjudication of a temporary fill."

*Comment:* Some commenters expressed concerns with our proposal that Part D plan sponsors make reasonable efforts to notify the prescriber of the transition fill, with some commenters recommending that we make the prescriber notice requirement optional so that plans may exercise discretion to determine whether it is warranted. Another commenter stated that for the notification to be successful their master DEA file would need constant updating and that the requirement does not take into account emergency room or urgent care physicians covered by a blanket DEA number from the hospital. Another commenter suggested we should dialogue with the industry to review operational challenges to the prescriber notification. Yet another commenter suggested that we not implement the requirement unless we provides plan sponsors with access to databases with complete and accurate physician contact information cross-referenced with physician identifiers.

*Response:* We disagree with the commenters' request to make the prescriber notice optional and leave it to the plan's discretion whether such notification is warranted. The prescriber notification is a means of further strengthening beneficiary protections when dealing with formulary changes or utilization management protocols for necessary medications because the prescriber is in the best position to advise the beneficiary on the benefits or risks of switching to a different medication. Prescriber notification is an additional step to ensure a beneficiary is receiving optimal medication therapy outcomes with little to no delay in their drug regimen. As a result of this provision, sponsors and network pharmacies will need to ensure that they update their databases on a more consistent basis. We intend to provide additional guidance on what constitutes "reasonable notification efforts" in the future, but we do not envision providing plans with a comprehensive database of physician contact information as this is not information that we keep track of, and therefore it is not feasible for plans to rely on us to completely and accurately maintain such a database.

*Comment:* Several commenters stated that notification via U.S. mail occurs after the fact and suggests an alternative of beneficiary notification at the site of service.

*Response:* We continue to work with the industry to work on automated methods whereby beneficiaries are notified at point of sale that a drug dispensed is non-formulary. Until such time as these notifications are automated, plan sponsors must send written notice of transition fills through the U.S. mail.

*Comment:* One commenter requested CMS to define "other coverage" related to the requirement to provide a transition period for "newly eligible Medicare enrollees from other coverage" questioning whether this means that newly eligible Medicare enrollees who do not have "other coverage" should not qualify for a transition period. The commenter requests that we clarify that "newly eligible Medicare enrollee" would not include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65).

*Response:* We agree and clarify that "newly eligible Medicare enrollee" would include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65), including enrollees who do not have "other coverage" but who may be paying out of pocket for drugs they are currently taking.

*Comment:* One commenter supported the transition proposal but requests that CMS further revise § 423.120(b)(3) to standardize the amount of the temporary supplies that PDP sponsors are required to provide in the LTC setting. Some PDP sponsors have interpreted this element of CMS' transition policy that temporary supplies "may be for up to" 31 days to enable them to authorize fills of less than 31 days, even when physicians have prescribed a 31-day fill. The commenter recommends that we revise its proposed regulation to require PDP sponsors to provide transition supplies of at least 31 days unless a lesser amount is actually prescribed by the physician.

*Response:* We agree and are clarifying the existing language to state that the temporary supply of nonformulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 90 days in 31-day supply increments unless a lesser amount is actually prescribed by the physician. We believe this clarification is necessary to protect beneficiaries residing in LTC facilities from unnecessary delays in obtaining the full amount of a temporary fill or from uneven interpretation among plan sponsors.

*Comment:* Many commenters suggested that we articulate in regulation the extension of transition fills through the completion of any requested exception, even if that process takes longer than 30 days. Moreover, commenters suggested that we also require a transition fill whenever a member encounters formulary difficulties obtaining current prescriptions. A few commenters urged us to codify in regulation the requirement that Part D plans cover an emergency supply of nonformulary drugs outside of the initial 90-day transition period. One commenter suggested that the regulations should be strengthened to provide that without evidence of timely written notice to the affected enrollee, the enrollee should be entitled to continue to receive the relevant medication(s). Other commenters requested we codify current guidance encouraging Part D sponsors to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

*Response:* We note that current policy directs Part D sponsors to provide for a transition extension on a case-by-case basis when enrollees have not been successfully transitioned to the sponsor's formulary requirements. We do not believe that it is appropriate to codify this "case-by-case" directive into the existing rule. Our guidance already addresses that sponsors need to review an enrollee's request for an extension and the circumstances requiring such a request on an individual basis.

We also disagree with the comments that the regulation should be strengthened to provide that without evidence of timely written notice, the enrollee should be entitled to continue to receive the relevant medication(s). We believe that this situation would be more appropriately be handled through the complaint process given the level of scrunity that would be required to verify whether evidence exists that notice was provided to the enrollee by the plan sponsor.

We also disagree with the comment requesting that we codify into regulation at this time our current guidance encouraging transition supplies to be provided to current enrollees with level of care changes. As we have not encountered large number of complaints, we will continue to examine this issue. If we decide to mandate transition in this area, we will do so through future rulemaking.

Finally, we will consider codifying our emergency supply policy for LTC enrollees in future rulemaking.

*Comment:* Some commenters urged us to adopt the GAO recommendation to make the ANOC sent prior to each open season more individualized and thus more valuable to plan enrollees.

*Response:* We appreciate commenters recommending a more individualized ANOC being sent out prior to each open season. We believe that this is outside the scope of this proposal, which is to strengthen beneficiary protections during the transition process.

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464, § 423.466, and § 423.800)

In the October 22, 2009 proposed rule, under the authority of sections 1860D–23 and 1860D–24 of the Act, we proposed that sponsors make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. In making these proposed changes, we noted that some beneficiary changes (such as LIS status changes or midyear Part D enrollment changes), LTC pharmacy billing practices for dual-eligible beneficiaries, and the presence of secondary, tertiary, and even quartenary payers have contributed to a higher than expected volume of retroactive claims adjustments requiring Part D sponsor reimbursements and recoveries, as well as a greater than anticipated complexity of calculating these amounts. While we previously anticipated that beneficiaries would be owed reimbursements due to changes in LIS status, and that plan sponsors would be required to make such reimbursements under § 423.800(c), we did not believe our current regulations addressed the other entities that may sometimes need to be taken into account in reimbursement or recovery transactions. Moreover, we noted that no industry standard electronic process exists to explicitly handle underpayment recoveries or overpayment reimbursements created by these adjustments, and that the current Health Insurance Portability and Accountability Act (HIPAA) standard for coordination of benefits for pharmacy claims only partly supports these activities when the pharmacy initiates "reverse and rebill" transactions. As a result, Part D sponsors sometimes struggle with how to manage these retroactive adjustments and those sponsors that are refunding overpayments or seeking underpayment recovery are each doing it differently.

We also noted in the October 22, 2009 proposed rule that, since our current regulations do not address retroactive adjustments and the complexities associated with coordination of benefit activities that cannot be accomplished between the Part D sponsor and the pharmacy through reversal and rebilling, we have issued general guidance to direct sponsor coordination of benefit activities. As part of our implementation guidance on the automated process for the transfer of TrOOP-related data, we established a 45-day maximum time limit for the sponsor to take adjustment action, make a refund, and initiate recovery. We established this time limit after an informal survey and discussions with Part D sponsors and their processors.

We noted in the October 22, 2009 proposed rule (74 FR 54663) that many of the post-adjudication adjustments, such as those that are due to enrollment changes, are changes that affect beneficiary cost sharing, premiums and plan benefit phase. Establishing a reasonable time limit for all Part D adjustment, refund, and recovery activity is in the beneficiaries' best interests because it ensures that required changes are effectuated on a timely basis, thus correcting retroactive and prospective beneficiary premium and cost-sharing amounts. Moreover, it is in the best interest of others who have paid a claim on the beneficiary's behalf because it ensures that these amounts are resolved timely.

For these reasons, we proposed at § 423.464 and § 423.466 to codify our previous policy guidance by proposing that sponsors must make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. Further, we proposed adding a new timeliness standard at § 423.466 to require adjustment and issuance of refunds or recovery notices within 45 days of the sponsor's receipt of the information necessitating the adjustment.

As part of making these proposed changes, we noted that, to date, most Part D coordination of benefits activity has been performed at point-of-sale or soon after, so pharmacy reversal and rebilling of claims can be accomplished within the payers' timely filing windows. For Part D, this window must be a minimum of 90 days, but for other (non-Part D) providers of prescription drug coverage the filing window could be as short as 30 days. However, we acknowledged that with the volatility of LIS data and Part D enrollments creating a significant volume of retroactive adjustments, Part D sponsors are facing more claims adjustments than current pharmacy claim reversal and rebilling approaches can adequately address.

In addition, we acknowledged issues regarding proprietary pricing information and the chilling effect that disclosure of this information might have upon the ability of pharmacies to negotiate with payors. To ensure the confidentiality of pricing information, coordination of benefits on the initial claim is accomplished without reporting complete information on negotiated pricing. The amount then reported in the (Nx) transaction to the Part D plan is the amount of the beneficiary payment after the supplemental payment. As a result, a Part D sponsor attempting to determine refund or recovery amounts without having the pharmacy reverse and rebill the original claim can generally only impute the amount of any supplemental payment made by another payer by determining the difference between the Part D cost-sharing and the beneficiary amount paid after the supplemental payment. The only alternative is to ask the pharmacy to reverse and rebill the claim to all payers. However, such a procedure would be generally impractical after the industry standard 30-day window because many supplemental payers will not accept the late claim.

In the absence of legal authority to compel supplemental payer cooperation and to avoid pharmacy underpayment, imposing a requirement on sponsors to nonetheless calculate a precise reimbursement or recovery liability would require the creation of a new payer-to-payer transaction that would both enable reprocessing and address pharmacies' concerns about revealing their proprietary pricing. However, as we noted in the proposed rule (74 FR 54663), it is not clear that both goals can be achieved. Nor is it clear that even if this conflict could be resolved, that the cost of doing so would be justified by the benefits.

Therefore, while simple adjustments involving just the Part D sponsor and the pharmacy are relatively straightforward (and can and should be promptly transacted), those involving other payers are not. We solicited comments on alternative approaches to improving post-adjudication coordination of benefits necessitated by retroactive Medicare enrollment and low-income subsidy changes when multiple payers are involved, as well as our assessment that the costs of achieving precision in such transactions may outweigh the benefits.

Our specific proposals to modify § 423.464 included the following changes:

• Revising paragraph (a) to clarify that all Part D sponsors must comply with administrative processes and requirements established by CMS to ensure effective coordination between Part D plans and other providers of prescription drug coverage for retroactive claims adjustments, underpayment reimbursements and overpayment recoveries; and

• Adding a new paragraph (g)(7) to address the sponsors' responsibility to account for payments by SPAPs and other providers of prescription drug coverage in reconciling retroactive claims adjustments that create overpayments and underpayments, as well as to account for payments made, and for amounts being held for payment, by other individuals or entities. The new paragraph would also specify that Part D sponsors must have systems to track and report adjustment transactions and to demonstrate that—

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made,

(2) Reimbursements for excess cost-sharing and premiums for LIS eligible individuals have been processed in accordance with the requirements in § 423.800(c), and

(3) Recoveries of erroneous payments for enrollees have been sought as specified in § 423.464(f)(4).

Except as otherwise provided below, after considering the comments received in response to the proposed rule, this final rule adopts the proposed changes to the retroactive claims adjustment reimbursement and recovery provisions in § 423.464 and § 423.466.

*Comment:* Multiple commenters agreed that the costs of achieving precision in retroactive COB transactions outweigh the benefits of creating specialized electronic transactions for calculating payer-to-payer claims adjustments. A number of these commenters offered recommendations to CMS in response to our request for alternative approaches to improving post-adjudication coordination of benefits, including establishing a process to notify supplemental payers when an Nx transaction was not generated and the Part D sponsor is making a retroactive adjustment to the primary amount paid.

*Response:* We appreciate the commenters' concurrence with our assessment that the costs to create a specialized transaction for retroactive claims adjustments outweigh the benefits and their recommendations for improving post-point-of-sale adjudication coordination of benefits. Until such time as any cost effective alternative approaches are identified, we will not require the development of payer-to-payer coordination of benefit transactions for retroactive claims adjustments. Instead, we will work with the industry to develop work-around solutions, such as imputing amounts to be reimbursed based on best available information, and will take the commenters' recommended approaches into consideration during that effort.

In the interim, the existing coordination of benefit requirements require sponsors to coordinate not only with beneficiaries, but also with SPAPs, other plans or programs providing prescription drug coverage and beneficiaries and other individuals or entities that have made payment on the beneficiaries' behalf. These requirements include coordination of benefits at point-of-sale, as well as retroactive claims adjustments necessitated by not only beneficiary changes, such as retroactive LIS eligibility determinations, LIS status changes or mid-year Part D enrollment changes, but also other payer changes, beneficiary submission of paper claims, etc. In addition, as discussed elsewhere in this rule, sponsors must have systems to track and report adjustment transactions and to process adjustments and issue refunds or recovery notices within 45 days of the sponsor's receipt of information necessitating a retroactive claims adjustment.

As specified in subregulatory guidance in the Medicare Prescription Drug Benefit Manual chapters on Coordination of Benefits and Premium and Cost-Sharing Subsidies for Low-Income Individuals, Part D sponsors should also: work with other providers of prescription drug coverage to resolve payment issues; have a process in place to handle payment resolution that is not restricted by implementation of timely filing requirements; make retroactive adjustments and promptly refund monies owed to the correct party (including, but not limited to, the beneficiary); and generally limit requests for pharmacy reprocessing to those situations where the total payment to the pharmacy changes. Coordination of benefits guidance also includes the need to transfer TrOOP and gross covered drug cost balances to the new plan whenever a beneficiary transfers enrollment between Part D sponsors during the coverage year. As discussed elsewhere in this final rule, sponsors have a 45-day maximum time limit from receipt of changes in the reported transfer data to make an adjustment and issue a refund or initiate recovery.

*Comment:* One commenter suggested that CMS establish an exception that would permit a Part D sponsor to refund the beneficiary directly without accounting for other payers if the net claims adjustment is $10 or less and there is no N transaction reporting another payer amount paid on the claim.

*Response:* We disagree with this suggestion. Although individual claims adjustments may not exceed the suggested threshold, cumulative amounts due to other payers (such as SPAPs) could be substantial. Additionally, the other payers would be unaware that a claim had been retroactively adjusted and that a refund was issued to the beneficiary. As a result, the other payers would not know to seek recovery from the beneficiary. Therefore, we continue to believe that sponsors must comply with the coordination of benefits requirements without regard to the monetary amount of the adjustment.

Comment: One commenter asked that we clarify in § 423.464 that p*harmacies holding copayments are exempt from the coordination of benefits requirements since they do not meet the definition of a plan or program providing prescription drug coverage. The commenter noted that* this clarification will ensure that pharmacies recognize they are not a provider of prescription drug coverage, and are only entitled to reimbursement if the member should receive reimbursement and the pharmacy has attested that it is holding the member's cost-sharing amounts due and has not billed the member. Several other commenters requested that specific language be added to the regulations at either § 423.800(c), or § 423.464(g) and § 423.466(a), to clarify that the requirements, including the 45-day time period for issuing refunds or initiating recoveries due to retroactive adjustments, apply not only when a supplemental payer is involved, but also when a pharmacy is owed for cost-sharing initially withheld by the sponsor for LIS beneficiary claims.

*Response:* We agree that pharmacies are not providers of prescription drug coverage and, therefore, are not covered under § 423.464(g). However, it was our intention to apply the 45-day time limit to all retroactive adjustment regardless of whether a pharmacy alone, a pharmacy and the beneficiary, or a pharmacy, the beneficiary and another payer are involved. As a result, we are finalizing § 423.464(g) as proposed. In response to the concerns raised by the commenters regarding the application of the 45-day timeframe to pharmacies, in this final rule we are also amending § 423.800 to add a new paragraph (e) to make it clear that the 45-day timeframe

applies to adjustments involving pharmacies and beneficiaries, including LTC pharmacies holding cost-sharing amounts due. Generally, sponsors will reimburse the beneficiary for adjustments made to retail claims, but for full benefit dual-eligible individuals, in the absence of other information indicating the cost-sharing has been waived, the sponsor will reimburse the LTC pharmacy.

*Comment:* Several commenters argued that the 45-day time period for issuing reimbursement or initiating recovery should be changed to 90 days because of the various research and coordination issues that may need to be resolved with other stakeholders in the industry.

*Response:* We disagree with these commenters. We believe a 45-day period is more than sufficient to resolve any coordination of benefits issues and refund overpayments or institute recovery of underpayments resulting from the retroactive claims adjustments. As we stated in the proposed rule, we considered a 90-day time limit, but concluded that this longer timeframe was not in the best interests of beneficiaries because it would delay the payment of refunds and notification of the need for payment recovery. Moreover, we noted that as part of the automated transfer of TrOOP-related data, we established a 45-day maximum time limit for sponsors to take adjustment action, make a refund and initiate recovery. We further explained that we established this time limit after an informal survey and discussions with Part D sponsors and their processors. For these reasons, we continue to believe that a 45-day time limit represents a reasonable compromise. Therefore, we are finalizing the requirement as proposed.

13. Time Limits for Coordination of Benefits (§ 423.466)

In the October 22, 2009 proposed rule (74 FR 54664), we proposed to revise § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. In making this proposed change, we noted that currently, there is no statutory or regulatory time limit for Part D sponsor coordination of benefits with SPAPs, other providers of prescription drug coverage, or other payers. Current CMS guidance as set forth in the Coordination of Benefits (COB) chapter of the Medicare Prescription Drug Benefit Manual only directs Part D sponsors to establish at least a 90-day timely claims filing window and to make appropriate allowances for COB claims on a case-by-case basis. The COB chapter also directs sponsors, in retroactive enrollment situations, to coordinate benefits with other payers as required by the regulations at § 423.464(f), as well as to accept claims from the beneficiary without imposing time limits. This chapter further states that sponsors, even in those situations when retroactive enrollment is not an issue, are liable for claims received after the end of the coverage year as defined in § 423.308 and that, while contract provisions regarding timely claims filing may limit claims from network pharmacies, non-network pharmacies and beneficiaries must still have the opportunity to submit claims for reimbursement without the imposition of time limits by the Part D sponsor.

We also noted the benefits to be derived from this proposed change. In addition to limiting sponsors' financial liability, a specified time limit would strengthen the ability of SPAPs, other providers of prescription drug coverage and other payers, including beneficiaries, to obtain payment for covered Part D drugs within that time frame. Moreover, we would benefit from a COB time limit because it would enable us to conduct reopening efficiently and on a predictable schedule.

In considering whether to establish time limits on the submission of claims to Part D sponsors by beneficiaries and other payers of prescription drug coverage for proper coordination of benefits, we noted that the Medicare FFS time limit for filing claims, as specified in § 424.44, is 15 to 27 months depending on the date that the item or service was furnished and that under certain circumstances these time limits may be extended an additional 6 months. We also noted that the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1902(a)(25) of the Act, to provide for a 3-year time limit for States to seek recovery of Medicaid claims payments when the State is not the primary payer. Although this DRA provision does not address SPAPs and, therefore, does not impose a time limit on the requirement for Part D sponsors to coordinate benefits with SPAPs, it does establish the time limit for State Medicaid programs to recover from Part D plans.

Having considered these filing limit precedents, we proposed to establish a 3-year filing limit for Part D coordination of benefits with SPAPs, other entities providing prescription drug coverage, and all other payers, including beneficiaries or other individuals or (non-network) entities paying, or holding amounts for payment, on the beneficiaries' behalf. Specifically, we proposed to revise new § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. Part D sponsors would be required to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. Adding this provision to the regulation would clarify timely filing responsibilities and deadlines for all beneficiaries and payers, as well as place a limit on Part D sponsors' claims payment liabilities and coordination of benefits responsibilities.

As noted in our response to the comments below, after considering the comments received in response to this proposal, we continue to believe a 3-year time limit on Part D coordination of benefits is reasonable, and in this final rule, we are adopting the provision as proposed.

*Comment:* Two commenters expressed support for the establishment of a clear timeframe for coordination of benefits, and two others expressed agreement with the proposed 3-year time limit. A number of other commenters suggested alternative time limits of 2 years, 18 months or 1 year. The rationale cited by commenters for a shorter time period was that it would more closely align the COB time limit with the regulatory deadline for submission of Part D cost data, thereby reducing the number of payment reconciliation reopenings and curtailing the costs associated with maintaining open claims databases.

*Response:* We disagree that we should shorten the proposed coordination of benefits time limit. Other payers need time to seek reimbursement and sponsors need a clear limit in order to resolve claims for which they are responsible. We believe that a 3-year limit would permit CMS to address both needs. A timeframe that aligned with the regulatory deadline for submission of PDE data would allow only 6 months for submission of claims incurred late in the coverage year, a timeframe that we believe Part D experience to-date has demonstrated would not allow sufficient time for claim identification and subrogation. As we noted in the proposed rule, the 3-year limit is also aligned with the DRA timeframe, providing a uniform period for coordination of benefits for all payers, rather than creating different timeframes based on payer type (for example, SPAPs or other entities providing prescription drug coverage). This alignment will, in our view, ease administration for all parties.

Therefore, in the final rule, we adopt the requirement for Part D sponsors to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. By the effective date of this final rule, the timeframe for coordination will have ended for claims for prescriptions filled any time in 2006, as well as for prescriptions filled in the early months of 2007. For example, a Part D sponsor would be responsible for coordinating benefits on a claim for a covered Part D drug filled on March 3, 2008 until March 3, 2011.

It is important to note that this final rule establishes a time limit for Part D sponsor liability for coordination of benefits with other payers and does not affect the timeframes for Part D sponsors to pursue Medicare secondary payer (MSP) claims and to recover amounts paid by the sponsor as primary when an MSP payer is identified. Such timeframes are separately identified in 42 CFR part 411.

*Comment:* One commenter stated the application of the DRA's health claim reimbursement rules and standards to prescription drugs is inequitable, because Part D claims processing, unlike health claims processing, is predominantly real-time. As a result, a 3-year submission window is not necessary.

*Response:* We disagree. Although no interpretive guidance has been issued on this provision, the plain reading of section 1902(a)(25)(J) of the Act encompasses all Medicaid claims, including claims for prescription drugs. As a result, we believe the application of this standard for Part D is appropriate.

*Comment:* One commenter recommended that CMS impose time limits for the payment of COB claims once filed with the Part D sponsor.

*Response:* This suggestion is outside the scope of the proposed rule. We can consider whether such a time limit is warranted and address the issue as appropriate in future rulemaking. However, we note that once a COB claim has been submitted, we expect Part D sponsors will make good faith efforts to promptly coordinate benefits with the submitter of the claim, whether an SPAP, another entity providing prescription drug coverage, a beneficiary or someone acting on his or her behalf, or another payer. Any payer that does not believe a Part D sponsor is making good faith efforts to coordinate claims on a timely basis should report the complaint to CMS.

14. Use of Standardized Technology Under Part D (§ 423.120)

Under the authority of section 1860D–4(b)(2)(A) of the Act, we proposed to revise our regulations at § 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

As we noted in the October 22, 2009 proposed rule (74 FR 54665), the only way that an enrollee can be assured access to the negotiated price at the point of sale is through online adjudication of the prescription drug claim. Any other price available to the beneficiary at the point of sale cannot be deemed to be the negotiated price mandated under section 1860D–2(d) of the Act. Therefore, to ensure access to these negotiated prices, billing information on the NCPDP "Pharmacy ID Card Standard", which is the standard for identification cards for the Part D program, must be used by the pharmacies filling the beneficiaries' prescriptions to submit claims to the Part D sponsor (or its intermediary).

We noted that CMS guidance set forth in the Coordination of Benefits Chapter of the Prescription Drug Plan Manual (in section 50.4 entitled, "Processing Claims and Tracking TrOOP"), instructs plan sponsors to process all claims online real-time. The requirements of accurate TrOOP accumulations, Part D benefit administration of multiple coverage intervals, and coordination of benefits with other payers all necessitate online real-time adjudication of individual pharmacy claims. This guidance states further that we expect that Part D plan sponsors will establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and reduce opportunities for fraudulent duplicative claim reimbursements. We proposed to revise § 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

We proposed to codify this guidance in regulation because we have been made aware of an increasing number of instances in which network pharmacies are not submitting pharmacy claims to Part D Sponsors on behalf of Part D enrollees. Generally, we believe it is in the best interest of Part D enrollees to have their claims consistently processed through the Part D sponsor (or its intermediary). Not only does processing claims through the Part D sponsor ensure access to Part D negotiated prices, but it also ensures that proper concurrent drug utilization review (including safety checks) is performed. In addition, online, real-time processing facilitates accurate accounting for enrollees' true out-of-pocket (TrOOP) and total drug costs by the Part D sponsor so that each claim is processed in the appropriate phase of the benefit and accurate cost sharing assessed.

We also proposed to add a new paragraph (c)(2) to § 423.120 to codify our existing guidance that Part D sponsors utilize standard electronic transactions established by 45 CFR 162.1102 for processing Part D claims. We noted that we would issue guidance on the use of optional or conditional fields in the HIPAA standard transactions through the Call Letter and Prescription Drug Benefit Manual instructions. We noted further that we routinely work with NCPDP and industry representatives in arriving at recommendations for standardized use of such fields when necessary to improve administration of the Part D benefit.

Finally, noting that pharmacies cannot routinely distinguish Medicare Part D claims from other types of prescription drug coverage when the same routing information ("RxBIN and RxPCN") is used for all lines of business managed by a single processor, we also proposed to add a new paragraph (c)(4) in § 423.120 to require that sponsors and their intermediary processors establish and exclusively utilize unique RxBIN or "RxBIN/RxPCN combinations" to identify all Medicare Part D member claims, as well as to assign unique "RxID" identifiers to individual Part D beneficiaries. We solicited comments on the operational issues and timelines that would be involved in making these proposed technical changes to claims processing systems.

After reviewing the comments received in response to these proposals, we are adopting these provisions with some modification. Specifically, we revised § 423.120(c)(4) to specify that effective on January 1, 2012 sponsors assign and exclusively use unique Part D identifiers. Exclusive use of these

identifiers requires that claims will only be paid if these specific numbers are submitted in the claims transaction.

*Comment:* Many commenters concurred with our proposal that Part D sponsors mandate that pharmacies electronically submit all claims to the Part D sponsor or intermediary unless the beneficiary expressly requests otherwise. Several commenters offered recommendations related to implementation of this new requirement, including that CMS modify standard beneficiary communications (such as the EOB) to include language that helps the beneficiary understand that they should review their EOBs to confirm that all of their claims are being submitted and, permit either home infusion providers to attest to the plan, or the plan to validate on audit, the beneficiary's claims submission election, since it is impractical for small home infusion providers to bill electronically.

*Response:* We appreciate the support expressed for the proposed new provision and the commenters' recommendations. However, we believe the clarifications associated with the recommendations, since these are related to implementation, are better addressed in subregulatory guidance. As we develop our implementation guidance, we expect to consider the clarifications and to continue to seek input from the industry and NCPDP.

*Comment:* One commenter asked how the requirement that pharmacies electronically submit all claims to Part D unless the beneficiary expressly requests otherwise would be enforced if members do not show their ID card.

*Response:* The requirement applies to pharmacies and not the beneficiary. Therefore, we will undertake no enforcement action against the beneficiary if the claim is not submitted to the Part D sponsor. However, even if the member does not show his or her ID card, pharmacies will be able to identify Part D claims based on the unique RxBIN/PCN identifiers already in the pharmacy system or in the response to an eligibility query from the TrOOP Facilitator, and will generally be expected to submit claims whenever such data are on file.

*Comment:* One commenter urged us to allow 6 months for plan sponsors to implement the required network pharmacy contract change and noted that sponsor experience suggests that contract language alone will not ensure pharmacy compliance.

*Response:* We agree that this provision will require time for Part D sponsors to implement. Therefore, we will implement the requirement effective January 1, 2011. We likewise agree that contract language alone may not guarantee pharmacy compliance, but we expect other contract provisions will address the procedures the Part D sponsor will follow in the event a pharmacy fails to comply with this requirement.

*Comment:* One commenter requested that CMS clarify that notifying beneficiaries or discussing their options does not constitute "solicit[ation]" as mentioned in the preamble, that our lower cash price policy is still in place, and that any voluntary request to waive claim submission to the plan survives the entire life of the prescription and there would be no need to expect the beneficiary to make a request each time they refill that prescription.

*Response:* We agree with the commenter that discussing options per se does not constitute solicitation or steering. However, this must be a bona-fide discussion of options initiated by the beneficiary; that is, the discussion should not be initiated by the pharmacy with the intent to encourage the beneficiary to request his or her claims not be submitted to Part D in order for the pharmacy to avoid transactions fees. With regard to our lower cash price policy, we have not altered this policy. Finally, we intend to confirm in subregulatory guidance that any voluntary request to waive claim submission to the plan survives the entire life of the prescription and there would be no need to expect the beneficiary to make a request each time the prescription is refilled.

*Comment:* One commenter encouraged us to ensure that Part D sponsors' contracts with network pharmacies charge the beneficiary and the plan sponsor the lesser of the usual and customary price (U&C) or contracted rate without regard to special programs offered by the pharmacy.

*Response:* We believe that this comment is outside the scope of this proposal, which would only require that pharmacies submit all claims to Part D sponsors, unless the beneficiary requests otherwise. When a pharmacy's U&C prices are lower than the plan's negotiated price, we agree it is in the best interests of beneficiaries and taxpayers for the pharmacy to extend those U&C prices to Part D enrollees. However, because we do not directly regulate pharmacies, we have no authority to require them to do so.

*Comment:* Several commenters agreed with our proposed requirement related to unique payer/processor and enrollee identification, with several commenters suggesting that implementation be no sooner than January 1, 2011 or January 1, 2012 and not mid-plan year. One commenter stated that we should accommodate the continued use of unique identifiers already established by Part D sponsors, without regard to length or combination of characters. Other commenters were opposed to the requirement for Part D sponsors to create, and exclusively use, an RxBIN or an Rx BIN/PCN combination for Part D enrollees as well as to assign an Rx identifier to a Part D enrollee, because of the costs associated with implementation and potential disruption for pharmacies and beneficiaries. One commenter stated that CMS should emphasize that the RxBIN and RxPCN numbers should be assigned and differentiated at the sponsor level, and another commenter specifically requested clarification of the reference to "individual" Part D beneficiaries.

*Response:* We appreciate the general support for this provision and agree with the suggestions related to the timing of implementation, particularly in light of industry wide programming for HIPPA version D.0 conversion. Thus, the effective date for the requirement for a unique RxBIN or RxBIN/RxPCN combination and a unique Part D Rx identifier for each individual Part D member will be January 1, 2012. We believe this date will provide sufficient time for sponsors to implement necessary systems changes. Currently established unique identifiers may continue to be used. With regard to the level of assignment of the unique RxBIN or RX BIN/RxPCN combination, the appropriate level of assignment is at the Part D sponsor's parent organization rather than at the contract.

The assignment and exclusive use of these unique Part D Rx identifiers have a number of advantages for Part D. The primary advantage is the use of these identifiers enables pharmacies to recognize Part D beneficiaries, which is possible only with the level of identification supported by unique identifiers. Distinguishing Part D enrollees from the commercial insured permits the pharmacy to comply with any Part D-specific processing requirements, such as the requirement to submit claims electronically to the Part D sponsor or its intermediary, on behalf of the beneficiary unless the beneficiary makes an explicit request to do otherwise.

Other advantages to the use of unique Part D identifiers relate to the coordination of benefits. Currently, the TrOOP Facilitator and other switches that relay electronic pharmacy claims are unable to accurately determine whether an initial claim was paid by

Part D. As a result, the TrOOP facilitation process receives and processes coordination of benefits claims transactions even when the initial claims were not paid by Part D. This results in added processing costs for us and added workload for Part D sponsors receiving N transactions that cannot be matched to an initial claim because no Part D payment was made. Unique Part D Rx identifiers permit Part D claims to be processed independently and easily segregated for reporting and other purposes.

*Comment:* One commenter noted that the proposed requirements may have to be modified to conform to the new privacy provisions included in the Health Information Technology for Economic and Clinical Health (HITECH) Act that allow an individual to request that a covered entity restrict the disclosure of his or her protected health information.

*Response:* Our proposal would require Part D sponsors to require their network pharmacies to submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary "whenever feasible." Federal regulations implementing the privacy provisions of the HITECH Act have not yet been published. Upon publication of those regulations, we will review the provisions to determine if modifications of this requirement are necessary.

15. Absence from Service Area for More Than 12 Months Under Part D (§ 423.44)

We proposed to amend § 423.44 to allow a temporary absence from the PDP plan service area for up to 12 months before disenrollment would be mandatory, consistent with the time frame provided under the MA visitor/traveler policy, the nature of the Part D benefit and the strong likelihood that a PDP enrollee can access the full range of PDP benefits while temporarily out of the service area. In this final rule, we adopt this provision as proposed.

*Comment:* Most commenters supported our proposal. One commenter opposed the proposed change and preferred that we either make no change or revise the PDP rules to permit the offering of a visitor/traveler benefit, similar to the policy applicable to MA organizations.

*Response:* Although the permissibility of visitor/traveler benefits under the Part D program is not strictly within the scope of this proposed rule, we recognize that these types of policies serve an important function in the MA program. However, for the Part D program we believe that delivery of the drug benefit is much more easily accomplished through out-of-area access rather than a visitor/traveler benefit, given the national pharmacy networks that are generally involved in providing enrollees with their prescription drugs. Thus, we continue to believe, as did most commenters, that this population is better served by extending plans' flexibility to deliver services on an out-of-area basis, rather than by requiring the establishment and approval of formal visitor/traveler policies whenever an enrollee is out of the service area for more than 6 months.

*Comment:* One commenter wanted us to further codify that PDP enrollees temporarily absent from the plan service area and residing in a LTC facility be disenrolled after an absence of 6 months.

*Response:* We disagree with the commenter that an individual residing in a LTC facility while temporarily absent from the plan service area should be considered to have a permanent residence outside the plan service area and disenrolled on an involuntary basis due to his or her out-of-area status. Current subregulatory guidance (§ 50.2.1 of Chapter 2 of the Medicare Managed Care Manual and § 40.2.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual) instructs PDP sponsors to determine whether an enrollee's out-of-area status is temporary or permanent, such that involuntary disenrollment would occur prior to the expiration of the 6-month period only if it is confirmed that the enrollee has permanently relocated outside the plan service area. Under our proposed revision, PDP sponsors would effectuate an involuntary disenrollment upon confirmation of an enrollee's permanent residence outside the plan service area or expiration of a 12-month period, whichever occurs first. We believe this addresses the concern raised by the commenter with respect to ensuring a beneficiary's continued access to the Medicare prescription drug benefit while residing in an out-of-area long term care facility. Accordingly, we are adopting without change the revision as set forth in the proposed rule.

*Comment:* One commenter requested that we not extend the period of permissible temporary out-of-area residence for individuals enrolled in MA–PD plans.

*Response:* Since our proposed revision applies only to stand-alone PDP plans, we believe that this clarification is not necessary. The current 6-month rule for MA plans under § 422.74(d)(4)(B)(ii) will remain in effect.

16. Prohibition of Midyear Mass Enrollment Changes by SPAPS Under Part D (§ 423.464(e)

Consistent with the authority of sections 1860D–23(a)(1) and (b) of the Act, we proposed to add a requirement to § 423.464(e) to prohibit midyear mass enrollment changes by SPAPs. In making this proposed change we noted that most SPAPs perform mass enrollments on a calendar year basis for all its members who have not chosen a Part D plan. However, some SPAPs have chosen to perform these enrollments on a noncalendar year basis. In these situations, Part D sponsors have found that substantial disenrollment of large numbers of SPAP members from one plan, followed by mass enrollment into another during the calendar year significantly affects their financial operations. We also stated our belief that mass re-enrollment into a new plan midyear disrupts any continuity of care the beneficiary has established with his other current Part D plan, and introduces transition risks such as drugs not being covered by the member's new plan, or requiring the member to change his or her pharmacy that are not outweighed by any administrative convenience to the SPAP. In this final rule, we adopt these provisions as proposed.

*Comment:* A few commenters were concerned that SPAPs may need to change Part D enrollment midyear for their SPAP enrollees because the SPAP determines that its members are not being adequately served by the Part D plan (for example, the plan does not adequately cover the drugs needed by the individual SPAP member), or the Part D plan fails in its obligation to coordinate benefits with the SPAP. One commenter in particular suggested we change the regulation text to indicate that SPAPs not "routinely" engage in midyear plan or non-calendar year plan enrollment changes, but allow nonroutine mass re-enrollment when an SPAP has determined that such enrollment changes would better serve the needs of its members and has provided CMS with the appropriate prior notification.

*Response:* We disagree with the commenters that SPAPs should be allowed to mass re-enroll its members during the calendar year, even when it is nonroutine. There are currently two actions the SPAP can take when it finds that its members are not being adequately served by a Part D plan. First, if an individual SPAP member is not being adequately served by the Part D plan (for example, the SPAP member's drugs are not covered or

pharmacy access is impeded under the plan), the SPAP may, using its authorized representative status, re-enroll that individual into another Part D plan. This one-time special enrollment period for individual SPAP members is allowed and further discussed in our current enrollment guidance (Chapter 3 of the Medicare Prescription Drug Benefit Program Manual). If an SPAP finds that the Part D plan is not serving its members because the Part D sponsor is in violation of Federal statute or regulation, the SPAP should contact us to report the plan's violation(s). We will then take the appropriate action in accordance with its compliance rules. Actions by CMS may include developing a corrective action plan with the Part D sponsor, suspending enrollment into the Part D sponsor's plan, or, if necessary, termination of the Part D sponsor's contract. We believe that both of these actions will adequately address problematic plans and that an exception for nonroutine mass midyear enrollments will not be necessary.

17. Nonrenewal Beneficiary Notification Requirement Under Parts C and D (§ 422.506, and § 423.507)

In the October 22, 2009 proposed rule, under the authority of sections 1857(a) and (c) and 1860D–12(b)(1) and (b)(3)(B) of the Act, we proposed revisions to the nonrenewal beneficiary notification requirements at § 422.506(a)(2)(ii) and (b)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) and (b)(2)(ii) of the Part D regulations to change the beneficiary notice requirement from at least 60 days to at least 90 days.

We noted that the existing regulations required notification 60 days prior to the effective date of the nonrenewal for both enrollees and the general public. Changing the requirement for the personalized beneficiary specific CMS-approved notice to at least 90 days provides beneficiaries with an increased notice period giving beneficiaries more time to choose a new Medicare plan prior to the start of the new benefit year. We also noted that when we previously changed the required notice period to 60 days, we did so primarily to provide adequate time for the appeals process to conclude prior to the start of the next calendar year; however, our recent experience has indicated that the vast number of nonrenewals are voluntarily elected by the PDP sponsor or MA organization, so there is rarely a need to accommodate the appeals process. For this reason, we proposed at § 422.506(a)(2)(ii) and (b)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) and (b)(2)(ii) of the Part D regulations to change the beneficiary notice requirement from at least 60 days back to at least 90 days.

We also proposed removing the requirement for nonrenewing plans (in voluntary nonrenewal situations) and for us (in CMS-initiated nonrenewal situations) to provide notice of the nonrenewal to the general public by publishing a notice in one or more newspapers of general circulation. This change was motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation, weighed against the very limited benefit gained from notice to the general public who is minimally, if at all, affected by the nonrenewal. Also, nonrenewal information is now easily available to the general public through Internet Web sites maintained by us (for example, *http://www.Medicarsuch asov*), a resource not available to the public when the newspaper notice requirement was first adopted. We believe that this information, in conjunction with the requirement to provide personalized nonrenewal information to plan enrollees is sufficient to ensure adequate notice of the plan's nonrenewal. Therefore, we proposed deleting § 422.506(a)(2)(iii) and (b)(2)(iii) of the MA regulations and § 423.507(a)(2)(iii) and (b)(2)(iii) of the Part D regulations to remove the requirement that the general public be informed of the impending nonrenewal through the publication of newspaper notices.

*Comment:* One commenter stated that in order to improve the member experience and make the requirements consistent, the "90 day prior to the effective date of nonrenewal" notification deadline should only apply to enrollees whose coverage is being terminated, and not to enrollees that are being mapped to another plan (such as Consolidated Renewal or Renewal Plan with SAR/Modified ANOC scenarios) because they are not losing coverage.

*Response:* The change to the nonrenewal regulation only applies to beneficiaries who are losing coverage for the upcoming benefit year. It does not, as the commenter suggests, apply to beneficiaries who are involved in a plan consolidation, as their coverage will continue without interruption in the upcoming benefit year.

*Comment:* Many commenters support the change in the notice requirement from 60 to 90 days. Commenters agreed that beneficiaries should be given more time to choose a new Medicare plan prior to the start of the new benefit year.

*Response:* CMS appreciates these comments.

*Comment:* Many commenters agreed that the publication of a nonrenewal notice in newspapers is no longer an effective means of communication, and support removing this requirement for nonrenewing plans.

*Response:* CMS appreciates these comments.

*Comment:* Several commenters stressed the importance of CMS issuing its model nonrenewal notice in time for plans to meet the 90 day requirement.

*Response:* CMS agrees with these comments and plans to issue the model notice during the summer of each year, as it has in the past, to ensure that plans have enough time to fulfill this requirement.

*Comment:* One commenter asked if the 90-day period runs from the start of open enrollment.

*Response:* The regulation clearly indicates that the notice must be sent "at least 90 calendar days before the date on which the nonrenewal is effective."

*Comment:* One commenter suggested that the CMS approved nonrenewal letter which provides information about sources for help in comparing Medicare plans is a good means to provide information in the case of mutual terminations.

*Response:* We believe that the topic of notices for plans that are undergoing a mutual termination is outside of the scope of this proposed regulatory change. We note, however, that § 423.508 of the regulation requires that when a contract is terminated by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of the termination "within timeframes specified by CMS."

18. Notice of Alternative Medicare Plans Available To Replace Nonrenewing Plans Under Parts C and D (§ 422.506(a)(2)(ii) and § 423.507(a)(2)(ii))

To allow additional operational flexibility, in the October 22, 2009 proposed rule, we suggested changing the requirement for PDP sponsors and MA organizations to provide written notification of the alternative Medicare plans available to replace the nonrenewing plan. We proposed changing the existing requirement to permit the option of either providing a written list of alternatives available, or placing outbound calls to all affected enrollees to ensure beneficiaries know whom to contact to learn about their enrollment options. We believe this change is advantageous for beneficiaries because, depending on where the beneficiary resides, a listing of available plan options is often very long and may be too overwhelming for the beneficiary

to use appropriately. We noted that a much more useful approach would be to provide beneficiaries with contact information and resources for identifying the most appropriate option given their unique, individual circumstances. For this reason, we proposed revising § 422.506(a)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) of the Part D regulations, to provide the option of sending written notices of all available alternatives or placing outbound beneficiary calls to ensure beneficiaries know whom to contact to learn about their enrollment options. As discussed above, in either case, a personalized, CMS- approved beneficiary notice regarding the nonrenewal must still be sent to each beneficiary.

After reviewing the comments received in response to these proposals, we adopt the proposed changes into this final rule with some modification. Specifically, we revised the regulation at § 423.507 to require that both Part C and Part D organizations inform beneficiaries of all MA and PDP available options. We also revised the regulation at § 422.506(a)(2)(ii)(A) to require that Part C organizations inform beneficiaries of all MA, MA–PD, and PDP options.

*Comment:* One commenter suggested that instead of providing alternative plan information in the nonrenewal letter, organizations should have the voluntary option of calling beneficiaries. Additionally, the commenter believed that organizations should provide a letter that contains language that directs impacted members to the Medicare Web site for the most current Medicare plan information available in their service area.

*Response:* The requirement to list alternative plans is independent of the requirement to provide a personalized beneficiary notice. The required personalized beneficiary notice already contains information about using the Medicare Web site to obtain information about available plans. We disagree with the commenter's recommendation that organizations should not be required to provide alternative plan information and that the phone calls to notify beneficiaries be voluntary. Some beneficiaries may not be comfortable with, or do not have access to the Internet. Therefore, we believe it is in the best interest of the beneficiaries to be provided with either a written list of alternative plans or to receive a phone call informing them of whom to contact to learn about their enrollment options.

*Comment:* Several commenters supported the proposed change that provides nonrenewing plans with the option to choose to give advance information to enrollees about alternative Medicare plan options in writing or to make outbound calls to all affected enrollees to ensure beneficiaries know whom to contact to learn about their enrollment options. It was stated that this approach also provides plan sponsors with the flexibility to vary the outreach methods used in order to accommodate different segments of their membership on a timely basis.

*Response:* We appreciate the commenters support of our proposed changes.

*Comment:* One commenter suggested that in the event of a nonrenewing MA plan, CMS should require that the written notification include Original Medicare and stand-alone PDPs among the alternative options available to the affected beneficiary. (Under the proposed rule change, the MAO would only be required to "provide a CMS-approved written description of alternative MA plan options available for obtaining qualified Medicare services within the beneficiaries' region.") Should the information be communicated via telephone by the MAO, then the person responsible for informing the beneficiary of his or her enrollment options should similarly be required to tell the beneficiary about Original Medicare and stand-alone PDPs in addition to other relevant plan options.

*Response:* The list of available options is accompanied by the required personalized beneficiary nonrenewal notice that provides information about the beneficiary's various options including, when applicable, Original Medicare. We do agree with the commenter's suggestion to include additional alternative available Medicare plans; and therefore, have revised the regulation to require that both Part C and Part D organizations inform beneficiaries of both MA and PDP available options.

*Comment:* Several commenters requested that the notification requirements mandate different personalized notices with more specialized information for different populations, particularly dual eligible and SNP beneficiaries.

*Response:* We believe this comment is outside of the scope of the proposed regulatory changes because these changes did not address the information required within the personalized beneficiary notification. Rather, the proposed changes only discussed the list of alternative plans that must be provided with the personalized notice.

*Comment:* Multiple commenters raised strenuous objections to the change that allows plan sponsors and organizations to place outbound calls to enrollees in plans that they are terminating to tell them who to call to learn about enrollment options. Commenters believed that allowing telephone calls invites the possibility of marketing abuses. Specifically, the commenters stated that this change "creates a major marketing loophole, and allows plans to steer enrollees to other plans offered by the same sponsors and organizations, regardless of whether those plans are best for them." The commenters believed that beneficiaries need to be provided with all of the information about alternative plans, and all other options including returning to traditional Medicare. They stated that the information should be provided by CMS or by a neutral, trained counselor. In addition, they believed once plans have been told that their contracts will not be renewed, there is no incentive for the plans to act appropriately and according to Medicare marketing guidelines when interacting with beneficiaries. Commenters suggested that the proposed regulation authorizing calls to beneficiaries should be clarified to include strict plan communication restrictions that properly protect beneficiaries who are especially vulnerable as a result of plan terminations. Furthermore, CMS should make clear that any sponsor that markets plans when notifying beneficiaries of plan terminations will be considered to be violating Medicare marketing rules.

*Response:* We do ensure that beneficiaries are informed of all of their options by requiring all nonrenewing plans to provide a personalized beneficiary notice which is separate from the plan's requirement to provide a list of alternative plans or make outbound call to inform beneficiaries of whom to contact to learn about their enrollment options. The required personalized notice includes information about all of the beneficiaries' choices and provides contact information for CMS and SHIP offices so that beneficiaries can contact "neutral" parties to obtain additional information about enrollment options. CMS does not believe that plans should be prohibited from contacting beneficiaries by phone, especially in light of the fact that plans regularly speak to beneficiaries by phone as part of the normal course of administering Medicare benefits. Furthermore, we believe that phone calls can provide beneficial individualized beneficiary service. Additionally, CMS will issue

guidance that instructs plans to submit all nonrenewal related scripts for CMS approval so that plans are providing appropriate and accurate information about the beneficiary's plan choices.

*Comment:* One commenter stated that when plans map beneficiaries to an alternative plan offered by the sponsor rather than nonrenewing, the beneficiaries are not afforded nonrenewal rights that include a special election period and the personalized beneficiary nonrenewal notice. The commenter believed that the rights of members should be the same, and they should all default to Original Medicare with the option of enrolling in a PDP.

*Response:* This comment concerns Part C and D enrollment policy and is outside the scope of the proposed regulatory changes related to beneficiary notification included in the proposed rule. CMS will consider this comment when we prepare the annual nonrenewal guidance.

*Comment:* Several commenters proposed allowing plans to provide the alternative list of plans available via electronic format for beneficiaries who have chosen to "opt-in" to receiving communications by electronic means.

*Response:* We believe that for the purposes of ensuring consistency in the application of the notification requirements, the list of alternative plans should be provided only in hard copy at this time. Also, CMS believes that beneficiaries' access to and use of on-line resources is not yet widespread enough to justify the adoption of regulations that allow for notification exclusively (even on an opt-in basis) through electronic communication. Should Medicare beneficiaries' Internet use patterns change in the coming years, CMS may make appropriate revisions to this policy.

*Comment:* One commenter asked what number of attempts would be required of sponsors that elect the option to make calls to beneficiaries.

*Response:* We believe that it is appropriate to address this question through the issuance of nonrenewal or marketing sub-regulatory guidance which provides more flexibility for changes than the rulemaking process.

*Comment:* One commenter asked what to do if the list of alternative plans that is sent in the mail to the beneficiary is returned.

*Response:* We believe that the standard practices organizations have presently adopted for handling beneficiary mail that is returned should be applied by the nonrenewing sponsor in such instances.

*Comment:* One commenter stated that the rules for consolidation that map beneficiaries to another plan for the following benefit year results in disparate treatment of beneficiaries. For example, if one Plan Benefit Package (PBP) is entirely mapped into another PBP (so only one PBP continues in the upcoming year), all members in both original PBPs receive a standard Annual Notice of Change (ANOC). However, if some counties are mapped into another PBP but others remain (so both PBPs exist in both the current and upcoming years), members in the mapped counties receive a modified ANOC. The commenter stated that from the member standpoint, it doesn't matter which situation they are in, in either case they are mapped into a new plan. This disparate treatment of members in similar situations can lead to confusion among members and creates difficulties for customer service staff attempting to explain the contents of ANOC packets.

*Response:* This comment is outside of the scope of the proposed regulatory change.

*Comment:* One commenter stated that CMS must issue alternative plan information far enough in advance for plans to meet the requirement to include alternative plan information in the beneficiary specific letters that are due on October 1.

*Response:* We have an HPMS module that provides plan option information to nonrenewing sponsors. We acknowledge that we cannot hold sponsors accountable for meeting the October 1 deadline unless we provide timely plan option information through HPMS to the sponsors, and CMS intends to make every effort to ensure that sponsors receive this information in a timely manner.

*Comment:* One commenter proposed that if a plan chooses to call beneficiaries instead of sending a list, the plan should be obligated to document that the beneficiary was reached and that a message left on an answering machine in not sufficient.

*Response:* We believe that the issue of call documentation is better addressed through the issuance of nonrenewal guidance which provides more flexibility for changes than the rulemaking process.

19. Timeframes and Responsibility for Making Redeterminations Under Part D (§ 423.590)

In the October 22, 2009 proposed rule, we proposed to reconcile a discrepancy with respect to notice of completely favorable expedited redeterminations by adding new paragraph (d)(2) to § 423.590. The proposed change would allow Part D plan sponsors to make the initial notice of a completely favorable expedited redetermination orally, so long as a written confirmation of the fully favorable decision is mailed to the enrollee within three calendar days of the oral notice. As noted in the preamble to the proposed rule, the change is consistent with the requirements in § 422.590(d)(3) of the MA regulations.

We also proposed in § 423.590(d)(2) to allow Part D plan sponsors to make the initial notice of an adverse expedited redetermination orally, so long as a written confirmation of the decision is mailed to the enrollee within 3 calendar days of the oral notice. In addition, we proposed to revise paragraph (g) by adding cross references to paragraphs § 423.590(d)(1) and (d)(2) in order to apply the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. As noted in the preamble to the proposed rule, we believe adding these two notice requirements to the Part D expedited redetermination process is in the enrollee's best interests given the expedited status of these requests, and is consistent with our subregulatory guidance and the process for notifying enrollees of adverse expedited coverage determination decisions in § 423.572(b).

Similarly, we proposed adding § 423.590(h) to establish the form and content requirements for fully favorable redetermination decisions, and proposed making those notice requirements applicable to redeterminations issued under paragraph (a)(1). We also proposed to reference paragraphs (d)(1) and (d)(2) in paragraph (h), so that the form and notice requirements in paragraph (h) would also apply to fully favorable expedited redetermination decisions. As we noted in the proposed rule, incorporating these Part D standard redetermination notice requirements will provide an important beneficiary protection by ensuring continuity of care for Medicare beneficiaries who are obtaining refills of prescription drugs under Part D, and doing so does not conflict with the related MA provisions. After considering the comments received in response to these proposals, we adopt these provisions without modification in this final rule.

*Comment:* We received a number of comments supporting the proposal allowing Part D plan sponsors to make the initial notice of a fully favorable expedited redetermination orally, so long as a written confirmation of the fully favorable decision is mailed to the enrollee within three calendar days of the oral notice. However, one commenter suggested revising the 3

calendar day requirement to 3 business days.

*Response:* We appreciate the comments we received in support of this provision. With respect to the comment recommending that we revise the calendar day requirement to business days, we have consistently used the calendar-day timeframe for all Medicare appeals processes, and we do not believe there is a compelling reason to depart from that standard for written notice of favorable decisions. We note that plan sponsors are required to mail (not deliver) the notice within 3 calendar days.

*Comment:* We also received many comments favoring our proposal giving Part D plan sponsors the option of making the initial notice of an adverse expedited reconsideration orally and then following up with written confirmation of the decision. Commenters also supported applying the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. However, a number of commenters expressed concern about starting the 60-day timeframe for requesting an appeal on the date an enrollee receives oral notice of an adverse decision. The commenters noted that it may be very difficult for an enrollee to keep track of the deadline for filing an appeal if the 60-day timeframe begins on the date they receive oral notice of a plan's decision. The commenters suggested starting the 60-day timeframe on the date printed on the written denial notice.

*Response:* We agree and believe the 60-day timeframe for requesting an appeal of an adverse decision should begin on the date printed on the written denial notice. However, we believe the appropriate place to make this clarification is in our subregulatory guidance. Therefore, we will make this clarification in Chapter 18 of the Prescription Drug Benefit Manual.

*Comment:* A commenter requested that CMS develop a model letter for fully favorable redetermination decisions and written redetermination decisions that follow oral notice under § 423.590.

*Response:* We agree that it would be helpful to provide plan sponsors with either model language or standardized notices for use in issuing fully favorable redetermination decisions and written redetermination decisions that follow oral notice, and will explore the feasibility of implementing these options. Any notice(s) we develop will be published in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

*Comment:* Numerous commenters supported the proposal requiring plan sponsors to include specific information (such as, the conditions of approval) in favorable decision notices. However, one commenter opposed the proposed requirement and suggested instead that we allow plan sponsors to provide the approval conditions on request.

*Response:* Currently, plan sponsors must provide the conditions of approval to enrollees upon request. Thus, the commenter's suggestion would not address the issue we were trying to resolve in the proposed rule. As noted in the preamble to the proposed rule, we believe it is important to include the conditions of approval in favorable notices to help ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D. Prescription drugs are often provided to beneficiaries on a recurring basis. Therefore, it is important for an enrollee to know the conditions of the approval (such as, duration, limitations, and coverage rules for refills) before a refill is needed, so that, if necessary, the enrollee can work with his or her prescriber to secure prior approval for additional refills, obtain an exception, or switch to an appropriate alternative prescription.

20. Requirements for Requesting Organization Determinations Under Part C (§ 422.568)

We proposed specific language related to oral requests for organization determinations, except for payment-related requests. As we noted in the October 22, 2009 proposed rule, section 1852(g)(3) of the Act allows an enrollee to request an expedited organization determination either orally or in writing. However, the method for requesting a standard determination is not addressed in either the Act or the implementing regulations at § 422.568. Both beneficiary advocates and MA plans have voiced concern about the absence of express regulatory authority that would allow enrollees to request standard organization determinations both orally and in writing. Therefore, we added specific language in § 422.568 to allow oral requests for organization determinations, except where the request is for payment.

*Comment:* Although one commenter opposed allowing oral requests because of concerns about proving that a request was made, we received several comments in support of our proposed revision. Many of those who supported our proposal also suggested that we require plans to develop a confirmation and tracking system for oral requests.

*Response:* For several years, we have, without difficulty, allowed enrollees and physicians to orally request expedited organization determinations. Thus, we believe allowing enrollees to also request standard organization determinations orally will not pose any issues regarding tracking such requests. Currently, Chapter 13 of the Medicare Managed Care Manual (section 50.2) instructs plans to maintain a process for tracking expedited organization determinations, and we agree with the commenters' recommendation to place a similar requirement on plans regarding oral requests for standard organization determinations. Accordingly, we are revising § 422.568 as proposed without change. We will also add this requirement to Chapter 13 of the Medicare Managed Care Manual to ensure compliance.

21. Organization Determinations Under Part C (§§ 422.566 and 422.568)

We proposed to remove the language from § 422.566(b)(4) and § 422.568(c) that an enrollee must disagree with the plan's discontinuation or reduction of a service for the plan's decision to be considered an organization determination. Section 1852(g)(1)(A) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive health services or payment under the program. In accordance with section 1852(g)(1)(A) of the Act, § 422.566 and § 422.568 establish the requirements related to organization determinations and notices. Existing § 422.566(b)(4) specifies that an organization determination includes a decision resulting in "[d]iscontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary" (emphasis added). Similarly, under § 422.568(c), a plan must give an enrollee a written notice of the determination "if an enrollee disagrees with the MA organization's decision to discontinue or reduce an ongoing course of treatment"(emphasis added). We indicated that we no longer believe that it is necessary to require an enrollee's "belief" that the services in question are medically necessary in order to consider these reductions or discontinuations to be organization determinations, nor did we believe that it is appropriate to condition the delivery of a notice on an enrollee's "disagreement" with the discontinuation or reduction of an ongoing course of treatment. Therefore, we proposed to change this language by removing the phrases "if the enrollee believes that continuation of the

services is medically necessary" and "if an enrollee disagrees with an MA organization's decision." We noted that § 422.620 through § 422.626 already provide enrollees who are receiving care in an inpatient hospital, skilled nursing facility, home health, or comprehensive outpatient rehabilitation facility (CORF) setting with the right to receive a notice and expedited review of service terminations for ongoing courses of treatment in these settings. Thus, our intention was to ensure that enrollees who are receiving previously authorized ongoing courses of treatment outside the settings covered by § 422.620 through § 422.626 would automatically receive notice and appeal rights if such services were terminated, and enrollees in all settings would automatically receive notice and appeal rights if the level of care or amount of such services was reduced.

*Comment:* Most commenters supported our proposed revisions. However, a few commenters requested further clarification about whether and how this revision altered plan or provider notice requirements. One of these commenters also requested clarification that the changes proposed would not create a new requirement for plans to notify enrollees each time a participating provider discontinues treatment under § 422.566 and 422.568. This commenter noted that the clauses proposed for deletion were originally added as part of the notice and comment process when the requirements for an enrollee's expression of dissatisfaction were first adopted.

*Response:* As we note previously, § 422.620 through § 422.626 automatically trigger the requirement for plans and providers to give a notice with appeal rights whenever enrollees experience service terminations while they are receiving care in the inpatient hospital, skilled nursing facility, home health, or CORF settings. Conversely, § 422.566 and § 422.568 currently require an enrollee to express dissatisfaction about a termination or reduction of services in order to receive notice and appeal rights. Therefore, our goal in no longer requiring an enrollee's disagreement was to ensure that plans would be required to provide notices whenever they discontinued or reduced a previously authorized ongoing course of treatment, regardless of the setting. However, as we considered these comments, we recognized that some additional restructuring of the provision would be needed to ensure a clear and consistent understanding of the policy.

Enrollees who are receiving care in settings governed by § 422.620 through § 422.626 receive notices with appeal rights only when services are being terminated. However, enrollees do not automatically receive notices when previously authorized ongoing courses of treatment are reduced in these settings. Consistent with our proposal, we are establishing the policy to require notice and appeal rights, in all settings, for previously authorized ongoing courses of treatment that either end or are reduced prematurely. We note that the phrase "previously authorized ongoing course of treatment" means a series of services or treatments that have been approved in writing (such as through a plan of care). Accordingly, a reduction in the level of care of a previously authorized ongoing course of treatment may include a change in the mix or range of services/sessions, a decrease in the intensity of the care, or a reduction in the amount of services/sessions provided relative to the original authorization.

Unlike the provider settings under § 422.620 through § 422.626, when a course of treatment ends in other settings under § 422.568(c), it will not result in automatic notice and appeal rights if the enrollee received all of the services as planned in the original authorization. In these cases, if an enrollee believes that those services should continue, he or she must request a new organization determination from the health plan. Accordingly, we are finalizing § 422.566(b)(4) and § 422.568(c) to include the revisions noted previously.

22. Representatives (§ 422.561, § 422.566, § 422.574, and § 422.624)

We proposed to amend § 422.561 to clarify that a representative may act on an enrollee's behalf with respect to the grievance process. As we explained in the preamble to the October 22, 2009 proposed rule, for various reasons, enrollees may choose or need to have someone represent them in order to protect their interests. Presently, under sections 1852(f) and (g) of the Act, a representative may act on behalf of an enrollee or other party when filing a grievance. However, unlike the corresponding Part D regulation, existing § 422.561 does not explicitly permit representatives to file grievances on behalf of an enrollee. In order to rectify this and be consistent with the Part D definition of representative at § 423.560, we proposed to amend the definition of representative under § 422.561. Similarly, we proposed to remove the term "authorized" before "representative" in § 422.574 and § 422.624, so that the definition is consistent throughout subpart M.

*Comment:* Several commenters supported removing the word "authorized" before "representative" in order to be consistent with the definition of the term "representative" and less limiting in the application of the term. However, a perceptive commenter noted that we overlooked making this revision in two places under § 422.566(c).

*Response:* We intended to make this change throughout all of subpart M, and as such, will finalize § 422.566(c) in the final rule to include these additional revisions.

*Comment:* A few commenters requested that we restructure all of subpart M of part 422 so that the general provisions section (§ 422.562) includes provisions about enrollee rights and MA provider notice responsibilities for services rendered by skilled nursing facilities (SNFs), home health agencies, (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs) and services provided in the inpatient hospital setting. These commenters also recommended creating new sections to describe provider notice requirements for all settings and the notice requirements and appeal rights specifically related to Part B services. This restructuring, the commenters suggested, would provide a more thorough overview of beneficiary rights under subpart M, and place the notice and appeal language in a more appropriate place in the regulatory scheme.

*Response:* This comment is beyond the scope of the proposed rule. However, we note that subpart M, like subpart I of part 405 and subpart M of Part 423, describes the various levels of the MA appeals process, including the associated beneficiary rights and provider notice requirements, in the order in which they occur. We believe this structuring of the appeals provisions makes it easier to follow the process. We do not agree with the suggestion that the current order of the regulatory provisions prevents enrollees from appealing adverse decisions about Part B (or any other Medicare) services and believe that restructuring subpart M as recommended, would not result in additional notice or appeal rights for enrollees. Finally, to make certain that beneficiaries understand the MA appeals process and their rights under this process, we ensure that beneficiary materials and notices, such as the Evidence of Coverage and Notice of Medicare Noncoverage are comprehensive, clear, and easy for enrollees to understand.

23. Disclosure Requirements Under Parts C and D (§ 422.111(g) and § 423.128(f))

In the October 2009 proposed rule, we proposed adding new provisions (§ 422.111(g) and § 423.128(f)) to the existing regulations that govern the information that must be disclosed to enrollees and potential enrollees. Specifically, we proposed to add that CMS may require a sponsoring organization to disclose to its enrollees and potential enrollees information concerning the sponsoring organization's performance and contract compliance deficiencies in a manner specified by CMS. While a number of commenters opposed this proposal, an equal number of commenters supported it. The latter noted that they support the goals of this proposal to provide beneficiaries with the information they need to assess the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. We also solicited comments on whether these disclosure requirements should be imposed only in those circumstances where a beneficiary would be afforded the opportunity to act on them (for example, requiring disclosure during the particular times of the year when beneficiaries would ordinarily be able to make change or elections, except in those situations where the compliance deficiency is so significant that a beneficiary may be afforded a special enrollment opportunity).

We are finalizing the proposed changes to § 422.111(g) and § 423.128(f)) with a modification to § 422.111(g) discussed in detail below.

*Comment:* A number of commenters were concerned that we have not provided enough detail about the proposal, including what compliance and performance deficiencies would rise to a level to trigger the disclosure requirement, as well as the types, format and timing of these disclosures. These commenters were concerned that the proposed regulations allow CMS too much discretion, could be inconsistently applied and may lead to unnecessary confusion and alarm for beneficiaries. Also, commenters stated that the existing performance ratings, through the Medicare Web site, currently provide adequate disclosure to beneficiaries.

*Response:* As we clarified in the proposal, our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. One example of a situation where enrollees should be notified of performance or compliance deficiencies would be when a sponsoring organization fails to provide beneficiaries with the proper premium notices to collect premium amounts in arrears. Another example would be if a sponsoring organization failed to provide access to services and we instructed the sponsor to contact enrollees regarding this issue and assist them with obtaining needed services or medications. In each of these situations we would require a sponsoring organization to disclose the deficiency to its enrollees and take affirmative steps to alleviate any problems for enrollees, such as providing enrollees with options to fix the issue.

The performance ratings routinely available to beneficiaries, while equally important for the promotion of transparency and informed choice, generally will not include information about the type of performance deficiencies that will be the subject of these disclosure requirements. Also, we intend to use the normal account management oversight processes to review and approve any disclosures before they are made to beneficiaries to ensure that information disclosed is clear, and unambiguous and to lessen the potential for confusion, alarm or other potential negative impacts on beneficiaries.

*Comment:* Several commenters raised concerns that this requirement would be administratively and financially burdensome on some sponsoring organizations either because these disclosures could lead to a significant increase in grievances and expenditures responding to beneficiary concerns over the disclosures or could unnecessarily alarm beneficiaries and lead to requests for disenrollment. These commenters also were concerned about the utility of these kinds of disclosures based on their experience that Medicare beneficiaries rarely request information about compliance and performance and have demonstrated no interest in information about sanctions taken by CMS.

*Response:* As we stated in our October 22, 2009 proposed rule, the primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. We intend to exercise our authority judiciously in those situations where we believe that the information being required to be disclosed will have a positive effect on transparency and informed choice. Similarly, we intend to use our normal account management oversight processes of review and approval of materials disclosed to beneficiaries to lessen the prospect for beneficiary confusion or concern which could lead to unnecessary grievances and requests for disenrollment. Finally, we believe that beneficiaries would be interested in receiving information about serious or significant compliance or performance deficiencies which potentially could affect them.

*Comment:* Several commenters provided suggestions concerning how we should make this information available to enrollees. One commenter stated that we should require that sponsoring organizations make information available upon request or on the Medicare Web site and another commenter requested that we consider alternative means of supplementing existing performance information available to beneficiaries through the CMS Web site.

*Response:* We do not agree with the suggestion that sponsoring organizations should only make such information available upon request or on the Medicare Web site. We intend to require that enrollees receive this information from sponsoring organizations in those circumstances where we believe beneficiaries must be affirmatively made aware of these deficiencies. Providing information upon request or merely posting on a Web site which enrollees may or may not access does not promote the degree of transparency and accountability by sponsoring organizations, for their deficiencies, that was contemplated by our proposal. Also, not all beneficiaries have access to the Medicare Web site and we believe beneficiaries may not be aware that they can request this information.

*Comment:* One other commenter suggested that sponsoring organizations should not be required to disclose deficiencies that occurred in the past because those issues may have been corrected and are not relevant to the current status of the plan.

*Response:* We intend to conduct our oversight responsibilities in a manner such that the kinds of compliance and performance deficiencies contemplated by these disclosures come to our attention as quickly as possible and are similarly disclosed to enrollees in a timely manner. However, it is not always possible for us to be aware of situations contemporaneous with their occurrence. We intend to take into account whether the deficiencies have been corrected and the utility of making

such disclosures to beneficiaries in these instances when making a decision as to whether disclosure will be required.

*Comment:* A number of commenters expressed concern with the timing of these required disclosures and the related issue of whether beneficiaries may elect other options once they receive one of these disclosures. Several commenters requested that disclosure be imposed only in those circumstances where a beneficiary would be afforded the opportunity to elect another plan option, some requested that disclosure of performance deficiencies be immediate so that beneficiaries would have more time to plan their health care decisions and several commenters believe that disclosures throughout the plan year would decrease the likelihood that information would get lost during the annual coordinated election period (AEP) or open enrollment period (OEP).

*Response:* We agree with the commenters who recommended that disclosure of these compliance and performance deficiencies be made as expeditiously as possible to beneficiaries and therefore we also agree that these disclosures may be required throughout the plan year. Also, with respect to the comments relating to allowing beneficiaries to elect other options, based on the nature and extent of the deficiencies that necessitated the disclosure, we intend to exercise our authority to grant a special election period for beneficiaries affected by the plan's compliance or performance deficiencies as permitted in § 422.64 and § 423.38. Our intention is to provide actionable information to beneficiaries. In some cases, the appropriate action may be to afford beneficiaries an opportunity to elect another plan option. In other cases, it may be sufficient to require plans to disclose the deficiency to its enrollees and provide enrollees with options to fix the issue.

*Comment:* We received one comment that questioned CMS' authority to require a sponsoring organization to disclose to its beneficiaries its compliance or performance deficiencies. The commenter provided no specifics for the assertion and merely stated that they have expressed to us on numerous occasions the "well-founded legal and policy objections" to self-disclosure.

*Response:* We currently have both statutory authority pursuant to sections 1851(d) and 1860D–1(c) of the Act and existing regulatory authority under § 422.111(f)(8)(v) and § 423.128(c)(1)(vii) to require sponsoring organizations to disclose information to its enrollees to help them make informed choices about their healthcare. We note that the commenter did not provide a further description or citation to the "well founded legal and policy objectives" that they stated had been previously submitted to us. To the extent that the commenter is referring to a prior proposal related to the mandatory self-disclosure of fraud, waste, and abuse issues, the disclosures that are the subject of these proposals are entirely distinguishable and this proposal is completely unrelated to any past proposals involving the mandatory self-disclosure of fraud, waste, and abuse issues. The current provision, for which there is explicit statutory authority, involves disclosures of compliance and performance deficiencies that we are already aware of and has determined involve an issue that enrollees should be notified of expeditiously. However, we are modifying the language in § 422.111(g) to replace the term "self-disclosure" with "disclosure" to avoid any confusion.

*Comment:* One commenter questioned how CMS intends for sponsoring organizations to disclose to their enrollees that they have resolved the disclosed compliance/performance issues after the required disclosure is made.

*Response:* We recognize that sponsoring organizations will want to correct any underlying compliance or performance deficiencies that led to these kinds of disclosures quickly. Our proposal was specifically intended to utilize transparency to incentivize and promote sponsoring organizations' compliance with CMS requirements. As with the required disclosure notice, we intend to use the normal account management oversight processes to review and approve any notices that sponsoring organizations wish to provide to enrollees concerning a correction of the underlying compliance or performance deficiencies that led to the disclosure.

*Comment:* One commenter requested that we issue a written warning to sponsoring organizations before sending the actual notice requiring disclosure.

*Response:* We do not believe issuing a written warning to sponsoring organizations prior to requiring disclosure furthers any particular compliance or oversight objectives and additionally may not always be feasible, especially if the deficiency has just occurred and beneficiaries need to be notified immediately. We retain the discretion to issue a compliance action (including a written warning), separate and apart from the requirement to have sponsoring organization's disclose deficiencies to enrollees, based on the underlying associated compliance or performance deficiency. Therefore we are not incorporating this commenter's suggestion.

*Comment:* One commenter expressed concern that sponsoring organizations do not have the opportunity to challenge or appeal the application of this requirement.

*Response:* These disclosure provisions merely require sponsoring organizations to provide beneficiaries with access to information. There is no statutory or regulatory right to challenge or appeal a CMS requirement to disclose information to enrollees. However, to the extent we take a contract or enforcement action (for example, an intermediate sanction or a civil money penalty) against the sponsoring organization for an associated underlying compliance or performance deficiency, the sponsoring organization would be afforded any appeal rights associated with the action taken.

*Comment:* One commenter was concerned that sponsoring organizations would not comply with the requirement.

*Response:* We have established mechanisms for ensuring compliance and fully intend to enforce these requirements and to take appropriate corrective and enforcement action should sponsoring organizations fail to comply with this requirement.

*Comment:* One commenter recommended that defined timeframes be issued in which CMS should respond to a beneficiary's inquiry related to the disclosure of a plan's performance or compliance deficiencies.

*Response:* We have established mechanisms for ensuring we respond to all beneficiary inquiries and these established mechanisms would apply equally to any inquiries received from beneficiaries concerning these kinds of disclosures.

*Comment:* One commenter suggested that we make public the information on its Web site in a manner that is more detailed and easier to find.

*Response:* Our proposal was not intended to solicit comments about the information on our Web site and therefore we are not specifically addressing this comment.

*Comment:* One commenter requested that we modify the plan ratings for special needs plans (SNPs) because they do not accurately measure plan performance.

*Response:* Our proposal was not intended to address the methodology for plan ratings and therefore we are not specifically addressing this comment.

24. Definition of MA Plan Service Area (§ 422.2)

We proposed to amend the definition of an MA plan "service area" at § 422.2 to exclude facilities in which individuals are incarcerated, consistent with the definition of service area for a Part D plan and in light of the fact that incarcerated beneficiaries are unlikely to have access to MA plan services, as required under § 422.112. We received several comments on this provision, all of which supported our proposal. We appreciate the support for the changes and are finalizing the proposed revision to the definition of MA plan "service area" without modification.

*C. Changes To Provide Plan Offerings With Meaningful Differences*

This section addresses proposals in our October 22, 2009 proposed rule that were designed to promote plan offerings with meaningful differences, and ensure plan viability. We discuss below proposed revisions that would help ensure that plans offered by the same organization in the same area have meaningful differences from each other, provide for a transition to the applicability of such rules when an existing organization is acquired by or merged with another organization, and provide that plans that have failed to attract enrollees over a period of time without justification may be non-renewed. We believe that these revisions will help us accomplish the balance we wish to strike between encouraging robust competition and providing health plan and PDP choices to beneficiaries that do not create confusion for beneficiaries because there are meaningful differences in benefit packages among the plans offered. We discuss these provisions in connection with comments we received in response to the proposals outlined in Table 3.

TABLE 3—PROVISIONS TO ENSURE MEANINGFUL DIFFERENCES IN PLAN OFFERINGS

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Bid Submissions: Ensuring Significant Differences. | Subpart F | § 422.254 | Subpart F | § 423.265 |
| Bid Review Process | Subpart F | § 422.256 | Subpart F | § 423.272 |
| Transition Process in Cases of Acquisitions and Mergers). | Subpart F | § 422.256 | Subpart F | § 423.272 |
| Non-renewing Low-enrollment Plans | Subpart K | § 422.506(b)(1)(iv) | Subpart K | § 423.507(b)(1)(iii) |

1. Meaningful Differences in Bid Submissions and Bid Review (§ 422.254, § 423.265; § 422.256, and § 423.272)

Under our authority in section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds "necessary and appropriate" and with respect to Part D, our authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing "reasonable minimum standards" for Part D sponsors, our October 22, 2009 proposed rule proposed changes to our regulations to ensure that plan offerings by MA organizations and Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Specifically, we proposed to revise § 422.256(b)(4)(i) and § 423.272(b)(3)(i) to specify that we would only approve a bid submitted by an MA organization or Part D sponsor if its plan benefit package or plan cost structures were substantially different from those of other plans offered by the organization or sponsor in the area with respect to key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. We also proposed to make related changes to § 422.254(a)(5) and § 423.265(b)(3)(i) to require that MA organizations and Part D sponsors must ensure that multiple bids submitted for plans in the same area are submitted only if the plans meet the foregoing test of being substantially different from each other.

After reviewing the comments we are finalizing our proposals with the technical changes to § 422.254(a)(4), § 423.265(b)(2), § 422.256(b)(4)(i) and § 423.272(b)(3)(i), explained below.

*Comment:* Most commenters supported our proposal to require meaningful differences in bids but asked for greater specificity about how the new rules would apply. Several commenters requested that CMS identify the specific thresholds and criteria to be used in determining that meaningful differences between plans exist, and several others requested that CMS annually publish the standards early in the year preceding the contract year to which the thresholds and criteria apply. A few commenters requested that criteria for meaningful differences be published annually and be subject to public comment. One commenter requested that CMS include public notice of areas with limited plans.

*Response:* We agree with the commenters that it is important to provide more information and greater specificity concerning standards that we will use in assessing meaningful differences, and agree that MA organizations and Part D sponsors should have this information early in the year preceding the contract year to which the standards would apply in order to assist them in developing their plan offerings for the contract year. However, we also believe it is important to retain flexibility when considering meaningful differences. Therefore, as specified in our October 2009 proposed rule, our final regulations at § 422.256(b)(4) and § 423.272(b)(3) continue to include the general substantive standard we will use when assessing plan bids, with the expectation that greater specificity in how this standard will be applied will be provided, with an opportunity for comment on our more detailed criteria, through guidance such as our annual call letter. We do not agree that it is necessary to provide a separate public notice of areas with limited plan choices, as the number of choices available in an area is already provided to beneficiaries in that area in the Medicare & You Handbook, and on the Medicare Web site.

*Comment:* One commenter opposed the proposed changes and recommended that CMS reevaluate its policy on differences that are meaningful to beneficiaries, which the commenter believed was based purely on actuarial policies. The commenter argued that CMS' policy could be considered discriminatory because geography would be a factor in whether multiple plans had to be different from each other.

*Response:* We believe our proposed policies would require differences in criteria that beneficiaries, not actuaries, would find meaningful, while still providing MA organizations and Part D sponsors with flexibility in offering different plan options. We disagree with the commenter who believes that considering the geographical region of a plan could be considered discriminatory, since the beneficiary confusion issue we are addressing in this rule only applies when duplicative plans are offered by the same organization in the same area. Moreover, we believe that greater scrutiny of differences between an organization's plan offerings in an area where more plans are offered is justified in that the higher the total number of plans offered in an area, the greater is the potential for beneficiaries to be confused and overwhelmed.

*Comment:* Several commenters had specific questions, concerns, or suggestions about how to best assess meaningful differences. Several commenters wrote that CMS should not place so much focus on Part D formularies as a means of determining meaningful differences. In connection with this issue, several commenters believed that focus on the plan formulary could lead to sponsors offering at least one plan with a "bare bones" formulary. Such "baseline" or "benchmark" plans could harm LIS enrollees, as such enrollees would likely be disproportionately enrolled in such plans and are least able to navigate barriers such as utilization management restrictions. Concerning other specific issues, a commenter wrote that MA–PD plans offered by the same organization should be assessed for meaningful differences based on the health care benefits offered by each plan and not the Part D benefits of each, as standardization of the Part D benefit is generally helpful for beneficiaries.

*Response:* With respect to focusing on plan formularies as a criterion for assessing meaningful differences in Part D plans, we note that while we believe differences in formularies to be a fundamental area for assessing plan differences, this was not the only element of Part D plan offerings we proposed to assess. Indeed, we proposed to look at premiums and cost-sharing, as well. With respect to the concerns that focusing on the formulary could lead to "bare bones" plans in which LIS beneficiaries could be disproportionately enrolled, the Part D program requirements clearly specify the minimum requirements for basic prescription drug coverage, and plans' formularies are reviewed and approved only if they are determined to provide adequate access consistent with those requirements. As explained in 30.2.7 of Chapter 6 of the Medicare Prescription Drug Manual (*see http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage*), we review submitted drug lists to ensure that they are consistent with best practice formularies currently in widespread use today. Our goal is to ensure that all Part D formularies are sufficiently broad in scope so as to contain the drugs most commonly used to treat the conditions faced by Medicare beneficiaries. Nothing in our proposed regulations would permit a sponsor to offer anything less than the current standard for the basic Part D benefit.

*Comment:* A commenter asked if five SNP plans offered by the same MA organization would be considered meaningfully different, even if the formulary offered by each resulted in similar out-of-pocket costs, simply because the plans offered were SNPs. Another commenter cautioned that coverage in the gap may be little different than no coverage in the gap if such coverage consists solely of generic drugs. The commenter suggested that a plan's initial coverage limit is a better indicator of meaningful differences between plans. A commenter noted that that his studies indicate that enhanced Part D benefits are increasingly meaningless, and that genuine coverage in the gap is the primary indicator between enhanced and standard plans, given that cost-sharing and premiums are often no different between enhanced and basic prescription drug coverage. According to this commenter, his studies show that gap coverage is also often not meaningfully different because such coverage is: (1) Almost always accomplished through generic drugs; (2) many generic drugs are not normally covered by plans claiming to offer such coverage; and (3) copayment amounts in the gap are higher than copayments before reaching the initial coverage limit. The commenter suggested that a plan should be required to cover all formulary drugs in the gap if the plan wants to offer gap coverage and, if this is not feasible, plans offering gap coverage for generics should be required to offer the same coverage in the gap for generics that they offer in the initial coverage period. Another commenter wrote that its experience was that utilization of generic drugs is one of the best ways that a member can delay onset of the coverage gap.

*Response:* With respect to the comment on multiple SNPs offered by the same organization, we would not consider five SNPs offered by the same organization to be meaningfully different simply because the plans offered are SNPs. As is also the case in our provision to non-renew low enrollment plans, we believe that SNPs may warrant special attention when assessing meaningful differences because of such factors as the enrollee population served and differences in benefits (Medicare and Medicaid in the case of dual-eligible SNPs). However, we do not believe that such plans should receive exemptions from either the requirements concerning low enrollment or meaningfully different plans simply because they are SNPs.

Half of all Medicare beneficiaries have over 40 MA plan choices (this figure does not include special needs plans or employer group health plans which have additional criteria for enrollment), and many states offer 50 or more stand alone Part D plans, a number that can double when one includes Medicare Advantage plans with a Part D benefit. Several studies suggest that the MA and Part D program offerings are so numerous that they can be confusing. In a report by Marsha Gold of Mathematica Policy Research, Inc., for example, Gold writes of the MA program that "Existing research suggests that simplification may have advantages for beneficiaries," and that one such advantage is preventing competitors from taking advantage of the system "through product design." [1] Gold continues by identifying the sheer array of plan types with their different characteristics, such as access to services or cost structures, as confusing to beneficiaries to the point that they may not choose the plan that is best for them in terms of costs or benefits. In his study, "How Much Choice is too Much? The Case of the Medicare Prescription Drug Benefit, T. Rice argues, based on Part D beneficiary studies that he and others in the field have conducted, that "The results show that decision quality [of seniors' ability to choose plans with the lowest annual total cost] deteriorated as the number of plans increases." [2] In another study of Part D plan offerings, published in a 2009 paper by Jason T. Abaluck and Jonathan Gruber, the authors determine that "elders place much more weight on plan premiums than they do on the expected out of pocket costs that they will incur under the plan" and that

[1] Gold, Marsha. Strategies for Simplifying the Medicare Advantage Market. Publication prepared for the Kaiser Family Foundation. July, 2009.

[2] Rice, T. Reducing the Number of Drug Plans for Seniors: A Proposal and Analysis of three Case Studies. Presentation at Academy Health Annual Research Meeting: Washington, DC. June 9, 2008.

"they substantially under-value variance reducing aspects of alternative plans," confirming that the array of Part D plan offerings can often lead to inconsistent choices among seniors with respect to determining costs, and plan features most beneficial to them.[3]

We agree with the commenter who wrote that coverage in the gap may not always be meaningfully different if such coverage consists solely of a subset of formulary generic drugs but we disagree that an enhanced alternative plan should be required to cover all formulary drugs in the gap if the plan wishes to claim to offer gap coverage. Rather, we believe that a meaningful difference with respect to an enhanced plan must be represented by a significant increase in benefits over basic coverage. Similarly, if two enhanced plans are offered by the same sponsor in a service area, a meaningful difference among those two plan offerings must be represented by a significant difference in benefits offered.

*Comment:* One commenter recommended that we permit an MA organization to offer three plans of each plan type in a service area, while another wrote that CMS should not arbitrarily limit the number of plans offered by an MA organization in a service area.

*Response:* Although permitting an MA organization to offer three plans of each plan type may be reasonable in some circumstances, we do not agree with the commenter that this should necessarily be the case. To the extent that the three plans have meaningful differences from each other that avoid beneficiary confusion, we believe that three plans of the same type (for example, coordinated care plan) would be permissible. Because the number of plans of the same type that would be permitted under this rule would depend on the plan design, and on ensuring that beneficiaries are not confused, we disagree with the commenter that we are imposing an "arbitrary" limit on plan offerings.

*Comment:* A commenter suggested that CMS require all health care plans to have at least one basic, standardized plan that would be transparent and understandable to beneficiaries no matter where or by which organization the plan was offered.

*Response:* We do not agree with the commenter that all MAOs offer at least one standardized plan no matter where or by which organization the plan is offered. While it is important to ensure that plan options are meaningfully different, we also believe MAOs should have the flexibility to craft distinct plan options for beneficiaries.

*Comment:* One commenter implied that CMS was not aware that plan benefit designs with low or no premiums and higher cost-sharing may be attractive to some beneficiaries, and plans with no deductibles and higher premium attractive to others and, as a result, both structures should remain a viable choice in the marketplace. A commenter urged CMS to look at an organization or sponsor's plans "holistically" when assessing meaningful differences. Another commenter cautioned that while establishing meaningful differences among plans offered by an MAO or sponsor is important, CMS must watch for complexities in plans' cost-sharing structures, as these various structures make it far more difficult for beneficiaries to evaluate differences between or among benefit packages.

*Response:* Contrary to the commenter's suggestion, we are well aware that some beneficiaries prefer plan benefit designs with low or no premiums and higher cost-sharing while others may prefer high deductible/high premium plans, and we have no intention of prohibiting these as "a viable choice" for beneficiaries. To the contrary, our requirement that plans have meaningful differences from one another is designed to promote such differences in plan design. CMS' concern is with MAOs and Part D sponsors that offer several plans in the same service area that have few distinctions, not with plans with benefit or cost structures which are clearly quite different.

*Comment:* A commenter requested that we consider premiums, the provision of health and wellness programs, and dental or vision coverage in our assessment of meaningful differences between MA plans. Another commenter took exception to our example in the proposed rule that an HMO with a point of service (POS) option and local PPO can sometimes be similar, that is, may not be meaningfully different, and wrote that local PPOs are, in fact, different by virtue of offering out-of-network coverage. Another commenter agreed that HMOs with a POS option are largely indistinguishable from local PPO plans.

*Response:* The focus of our review for meaningful differences is primarily on cost differentials between plans for Parts A and B services, the presence of a Part D benefit, the ways beneficiaries access services (that is, through a network, as in an HMO or in a non-network context such as a PPO) and overall plan costs. The addition of individual supplemental benefits may not trigger the annual thresholds we have used to establish significant differences in overall plan costs among an MA organization's plan offerings in a service area. That said, our recent experience in reviewing plan benefit packages suggests that the addition of some supplemental benefits can result in significant differences in out-of-pocket costs. Therefore, it is possible that an individual supplemental benefit or group of supplemental benefits could result in plans being meaningfully different from one another. With respect to the comments concerning our example that PPOs and HMOs with a POS option could be considered similar if offered by the same MAO even though they technically are different plan types, we cited this example to illustrate that even though these are different plan types it is possible that such plans, if offered by the same MAO, could be considered similar under some circumstances. For example, if access to care in-network, and coverage of services out-of-network is essentially the same in both plans, and there are no other significant differences between the two in benefits or costs, there would not be "meaningful" differences between the two plans.

*Comment:* A commenter cautioned that CMS should be aware that an MA organization offering several dual SNP plans might have several similar benefit packages for Medicare benefits, but the same plans could have quite different Medicaid benefits. Another commenter supported our intention, as expressed in the proposed rule, to permit multiple plan filings by the same MA organization in certain circumstances and wrote that CMS should formally recognize the "Medicaid agency's purchasing strategy" ' in any assessment of meaningful differences among dual eligible SNP plans.

*Response:* We do not consider differences in Medicaid benefits among dual eligible SNPs offered by the same MA organization as significant differences for purpose of our review, since we are reviewing differences in MA plan offerings, not Medicaid benefits. We would consider Medicare premiums (as part of a plan's cost structure) as part of its review of bids. In short, as an earlier commenter urged, CMS intends to look "holistically" at an organization or plan sponsor's offering in a service area when determining whether or not an organization's or

[3] Abaluck, Jason T, and Jonathan Gruber. Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program. NBER Working Paper Series. Working paper 14759. February, 2009. *http://www.nber.org/papers/w14759.*

sponsor's offerings are meaningfully different.

*Comment:* A commenter wrote that CMS should ensure that CMS' policies do not inadvertently remove meaningful choices in areas where choices may be comparatively limited (*Barrow County, Alaska* v. *Dade County, Florida,* for example). Another commenter wrote that CMS should consider limiting an organization's or sponsor's plan offerings in a geographic area similar to the Federal Employee Health Benefits Program or plans offered by some other employers.

*Response:* We do not intend to prevent plan choice in rural areas through implementation of the requirement for meaningfully different plans. The intent of the provisions is to ensure genuine choices for beneficiaries as well as transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. For this reason, we do not agree with the commenter who suggests that we limit an organization/sponsor's plan offerings in a geographical area to an arbitrary number of plans, since this could actually limit additional meaningful choices.

*Comment:* Two commenters cited discrepancies in the preamble and regulations text for Parts C and D concerning bid submissions (§ 422.254(a)(4) and § 423.265(b)(2)) and asked that we ensure the final regulations text reflects the language of the preamble by specifying that meaningful differences include differences in "cost-sharing or benefits offered, (MA regulations)" and "premiums, cost-sharing, formulary structure, or benefits offered" (Part D regulations) instead of the proposed regulations text for these sections, which was more general "benefit packages and plan costs" (MA regulations), "beneficiary out-of-pocket costs, and formulary structures" (Part D regulations). In addition the commenters asked that the list of meaningfully different elements cited in the bid submission and review sections be connected with the coordinating conjunction "or" instead of "and." One of the commenters recommended that the bid review sections for both the Part C and D regulations at § 422.256(b)(4)(i) and § 423.272(b)(3)(i) cross reference the criteria for meaningful differences in the bid submission sections for both programs (§ 422.254(a)(4) and § 423.265(b)(2)).

*Response:* We agree with the comments suggesting that the regulations text for the bid submission and review sections specifying the criteria we will use in assessing if an MA organization's or Part D sponsor's bids are meaningfully different should be connected with "or" instead of the coordinating conjunction "and." As a result, we are revising our regulations at § 422.254(a)(4), § 422.256(b)(4)(i), § 423.265(b)(2), and § 423.272(b)(3) to state that an [MA or Part D] organization's bids must reflect differences in "benefit packages or plan costs." We also are making conforming changes to § 422.256(b)(4)(ii) and § 423.272(b)(3)(ii) which concern acquisitions and mergers, as these sections use similar language. However, we disagree with the commenter who urged that the preamble language referencing "plan characteristics such as premiums or cost-sharing" (MA program) or "premiums, cost-sharing, formulary structure," (Part D program) should be reflected in the regulations text. Although these are certainly elements that may result in meaningfully different plans, we believe the current language captures these elements while providing the necessary flexibility to view plans "holistically."

In addition, the commenter correctly points out that in order to make the Part C and D regulations consistent, § 422.256(b)(4)(i), which concerns MA bid reviews, should cross reference § 422.254(b)(4), which concerns submission of MA bids.

With the exception of the revisions noted previously, we are finalizing the provisions as proposed.

2. Transition Period in Cases of Mergers and Acquisitions (§ 422.256, § 423.272)

In connection with our proposal to ensure that plan offerings represent meaningful differences, we proposed to add § 422.256(b)(4)(i) and § 423.272(b)(3)(ii) to provide MA organizations and Part D sponsors involved in mergers or acquisitions a 2-year transition period from the merger or acquisition to ensure that plans offered by the MA organization or Part D sponsor are significantly different from each other. After a transition period of 2 years, we would only approve a bid submitted by an MA organization or Part D sponsor, or a parent organization to that entity, if the benefits or plan cost structure represented by that bid were substantially different from any other bid submitted by the same MA organization or Part D sponsor (or parent organization of that entity). We requested comments regarding the adequacy of our proposed transition period length of 2 years in both the MA and Part D contexts, particularly since we had previously, as articulated in the 2008 Call Letter for Medicare health plans and PDPs, that PDP sponsors affected by mergers or acquisitions would be afforded a 3-year transition period. After reviewing the comments received in response to this proposal, we are finalizing the proposed provisions without modification.

*Comment:* Several commenters agreed with our proposal to require organizations and sponsors acquiring or merging with existing entities to offer plans with meaningful differences within two years of the merger or acquisition. One of the commenters wrote that 2 years was "more than adequate" for affected organizations and sponsors to offer meaningfully different plans. Another wrote that while 2 years was sufficient, CMS should consider notifying beneficiaries 1 year in advance of a plan's non-renewal so that they have clear notice of any changes.

Several commenters disagreed with the proposal to permit 2 years for transition, recommending, instead, that CMS maintain the current 3-year requirement articulated in the 2008 Call Letter. A few commenters believed that the language in the proposed rule could be interpreted to permit as little as one bidding cycle/bidding year between an acquisition or merger and the offering of meaningfully different plans. One commenter said that a 2-year transition period would be disruptive to beneficiaries and would not permit plans to develop adequate benefit packages. This commenter requested that CMS permit a 3-year transition period. Another commenter contended that organizations/sponsors need 3 years after a merger or acquisition in order to adapt their benefit packages to comply with the meaningful differences rule, and to implement a robust communications plan for implementing required changes.

Another commenter argued that CMS should not state that the transition period will be "as determined by CMS," but rather specify how the transition period will be measured. The same commenter wrote that if CMS does finalize the proposed requirement, we should not apply it to any acquisition prior to issuance of the rule, as the organization would have already taken action based on transition-related guidance in the 2008 and 2009 call letters.

*Response:* As stated in the preamble to the proposed rule, based on our experience, we believe that our proposed timeline for transitions provides ample time for organizations and sponsors to ensure that benefit packages are sufficiently different and to notify enrollees of any changes. Because the transition period actually applies for

the two contract years following the year of the acquisition or merger, that is, if a merger takes place in 2010, the MAO or sponsor would have until 2013 to offer meaningfully different plans, we believe this period is disruptive neither to plans nor to beneficiaries, and thus disagree with the commenter who asserted that a 3-year transition was needed to allow MA organizations and Part D plan sponsors to adapt their benefit structures and communicate to beneficiaries about the changes being made.

We clarify that only organizations or sponsors that merge or are acquired after the effective date of this final rule will be subject to the requirement at § 422.256(b)(4)(ii) and § 423.272(b)(3)(ii) that their offerings are meaningfully different after a 2-year transition period. In the case of plans offered by organizations or sponsors that merge or acquire other plans prior to the effective date of this regulation, the previously articulated 3-year transition period would apply.

3. Non-Renewing Low-Enrollment Plans (§ 422.506(b)(1)(iv), § 423.507(b)(1)(iii))

As part of our process to streamline and simplify the plan selection process for beneficiaries, and ensure that beneficiaries are only offered plans with long-term viability, we proposed in § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to include, as a specific ground for non-renewal of a contract, a finding that a Part C or Part D plan has failed to attract a significant number of enrollees over a sustained period of time. We justified this requirement on the grounds that, as a general matter, continuing such a low enrollment plan was not consistent with effective and efficient administration of the Medicare program for purposes of section 1857(c)(2)(B) of the Act (incorporated for Part D under section 1860D–12(b)(3)(B) of the Act), which provides authority to terminate a contract under such circumstances. In the preamble to the proposed rule, we acknowledged that there may be instances in which low enrollment over a sustained period of time is a function of the type of beneficiaries served, geographic location, or other circumstances, and that we would consider continuing to renew a low enrollment plan in such situations including, but not limited to, chronic care SNPs offering health care services especially tailored to this category of beneficiaries and not available elsewhere or employer group health plans offering benefits augmenting those of an MA plan to employees of a small business. We further stated that, if a case could be made that low enrollment is justified, and the absence of such a plan would significantly limit beneficiary health care options in a service area, consistent with effective and efficient administration of the Part C or Part D benefit, we would not non-renew that plan. Similarly, we also stated that the threshold for low enrollment could fluctuate, although we noted that we used a threshold of 100 enrollees for purposes of reducing the number of low enrollment plans for contract year 2010. Therefore, we did not propose to revise our regulations to specify a specific threshold. We solicited comments on this approach and whether we had provided sufficient clarity on how we would determine whether a low-enrollment plan would be non-renewed.

*Comment:* Several commenters supported the proposal to non-renew low enrollment plans, but recommended that the threshold and guidelines we would use to apply this requirement (including such factors as the number of plans in a market, plan enrollment, and the number of years of operation with low enrollment numbers) be clear and transparent, and that they be made available publicly early in the year preceding the contract year to which they will apply. One commenter wrote that CMS should convene a working group prior to enacting our proposed policy to non-renew low enrollment plans. Another commenter wrote that CMS should consider low enrollment to be in the 250 to 500 enrollee range rather than 100 enrollees (the number used in our efforts to reduce low-enrollment plans for contract year 2010, as detailed in the preamble to our proposed rule). Another recommended a low enrollment threshold of 1000 enrollees because it believes that plans serving fewer than 1000 people in a service area would be unable to offer negotiated savings, quality managed care, or popular plan features. A commenter asked CMS to clarify what is meant by "a small number of enrollees over a period of time."

*Response:* We agree that guidelines concerning minimum enrollment thresholds and criteria should be published annually and as early as possible in the year preceding the contract year to which they will apply. While we disagree that we should specify thresholds in regulations, we intend to provide opportunities for the public to review and comment on our proposed thresholds and criteria for assessing low enrollment for the following contract year (for example, through our annual call letter). We recognize that we must be flexible in assessing minimum enrollment to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering (such as, a chronic care SNP), or recent establishment of the plan, may continue to operate and that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to provide for public input annually on our implementation guidance and will consider the suggestions for specific threshold amounts submitted by the commenters in that context, we do not believe the suggested "workgroup" to be necessary. With respect to the question of what constitutes "a small number of enrollees" over a period of time, the process described above may also be used to determine the number of enrollees that would trigger application of this regulation, as well as the period of time for which the small number would have to be sustained.

*Comment:* Another commenter recommended that CMS make clear that the length of time a plan has had low enrollment will be a primary factor in determining whether a plan is non-renewed, and that we should modify our regulations language to explicitly provide for "waivers" of the proposed requirement at § 422.506(b)(1)(iv) (§ 423.507(b)(1)(iii) for Part D plans) when special circumstances such as the type of beneficiaries served, geographic location, and absence of the plan would significantly limit beneficiary health care options in a service area.

*Response:* The length of time in which a plan has had low enrollment is only one of the factors that we will consider in determining whether it is consistent with effective and efficient administration of the Part C or Part D benefit. We will also consider the type of benefits being offered under the plan and the nature of the enrollment in the plan. As stated above, we recognize that we must be flexible in applying any minimum enrollment requirement to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering or recent establishment of the plan, may continue to operate. This flexibility will ensure that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to apply this requirement in a flexible manner that considers the particular circumstances of each low enrollment plan, we do not

believe it is necessary to modify the proposed regulations at § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to provide explicitly for "waivers" of this requirement.

*Comment:* A commenter recommended that non-renewed plans be permitted to passively enroll affected enrollees into another plan offered by the MA organization or Part D sponsor.

*Response:* With respect to the recommendation to provide for passive enrollment of beneficiaries in a non-renewed plan into another plan offered by that organization, we believe this is appropriate only in limited circumstances when a compelling case can be made that such passive enrollment is in beneficiaries' best interests. In making such determinations, we take into consideration criteria such as benefits, cost sharing, the provider network, and premiums to ensure a comparable plan offering. In all other cases, we believe it is most appropriate to leave enrollment decisions to beneficiaries, who will have an opportunity during the annual coordinated election period to select another MA plan or Part D plan offered by the MA organization or Part D sponsor offering the plan being terminated. If a plan is terminated or nonrenewed, the affected organization or sponsor must follow all beneficiary and CMS advance notification requirements as specified in §§ 422.506, 422.508, 422.510, and 422.512 (MA program regulations), §§ 423.507, 423.508, 423.509, and 423.510 (Part D program regulations) and related guidance for both programs. In addition, passive enrollment initiated by an organization or sponsor in the absence of CMS approval is not among the transactions permitted by us in our annual renewal/non-renewal guidance. Because of these requirements and policies, an MA organization or Part D sponsor wishing to enroll members from the terminating or non-renewing plan into another of their plans could not do this without prior CMS review and consent. If we were to determine that such a transaction was in beneficiaries' best interests, we would, as is our practice, facilitate and closely monitor the process. We note as well that beneficiaries in terminated or non-renewed plans have guaranteed issue Medigap rights, access to information about other available health care options, and other information that will assist them in finding plans most suited to their needs.

*Comment:* Several commenters supported our proposal but asked that we make exceptions for SNPs. One commenter requesting the SNP exception wrote that "status as a SNP should be prima facie evidence that low enrollment is justified." A few of these commenters specifically requested that such exceptions be codified in the final regulations text. One commenter requested an exception be made for employer group plans. One commenter requested an exception for MA-only plans, stating that enrollees who get their prescription drugs through some means other an MA–PD should still have the option of remaining in an MA-only plan, and another commenter requested that "national" plans be exempted from these requirements.

*Response:* While we will consider exceptions on a case-by-case basis to any low-enrollment thresholds we establish, we do not believe it is necessary to exempt any specific plan type a priority. As we stated in the preamble to the proposed rule, there may be reasons for exceptions based on plan type, geography, or special health conditions of enrollees served that warrant a waiver of the requirements. However, a specific plan type, for example, a SNP or employer group plan, will not automatically be exempt from the minimum enrollment standard for renewal due to plan type alone. While sustained low enrollment may well be justified in the case of certain SNPs serving individuals with a relatively rare condition, a SNP serving an individual with a more common disease such as diabetes, or serving dual eligibles, should be able to attract enrollees. Similarly, we do not believe there is justification for exempting MA-only plans or "national" plans from the requirements unless there are other reasons to exempt them (for example, lack of other health care plan options, the specialized nature of the plan, or the recent establishment of the plan).

4. Medicare Options Compare and Medicare Prescription Drug Plan Finder

In the proposed rule we asked for comments on ways to improve the web tools, Medicare Options Compare (MOC), and the Medicare Prescription Drug Plan Finder (MDPF). We summarize and respond to these comments below.

*Comment:* One commenter requested that CMS add a function to limit the information that can be seen in the MOC so that users of the tool can focus on information they need most.

*Response:* The 2011 contract year update will include functions that expand and collapse which will help users of the MOC better focus on specific information.

*Comment:* Another commenter asked that the MOC contain direct links to the plan(s) discussed, not just the organization's Web site as is now often the case.

*Response:* We are not making the suggested change at this time as we believe that MOC already includes sufficient information to contact plans.

*Comment:* Another commenter requested that the tool clearly indicate what is meant by an "enhanced plan," even if this is just a general description in the tool of the typical features of an enhanced plan.

*Response:* We do not believe that revisions are necessary as information on enhanced plans is currently available in the glossary and at *http://www.medicare.gov/medicarereform/howtoread.asp*.

*Comment:* A commenter requested that CMS add back the search function in MPDPF notifying the user of the number of drugs covered by a particular plan. The same commenter requested that information be included about when a plan last updated its drug pricing information and that the tool includes information about coverage of drugs traditionally covered under Part B, for example, infused and injectable drugs for MA–PD plans.

*Response:* Currently the drugs an individual beneficiary takes may be entered and displayed to determine coverage, but the MPDPF does not permit display a list of all the drugs a plan covers as this would take a very long time for the tool to display. CMS reviews drug pricing on a regular basis and the data is updated monthly to reflect any changes. We believe the compare function best permits users to tailor their searches for the specific drugs in the specific forms that they need.

*Comment:* Another commenter wrote that the MOC is relatively thorough but inconsistent in that some plans in the tool do not include information about health care costs and that saved searches often yield different results when retrieved later. The commenter recommended that the tool be refined to allow the user to move easily back and forth between information for MA and Part D plans, that the conditions required for enrollment in a chronic care SNP be specified, and that the function concerning costs for tiers of drugs is "incredibly unfriendly and confusing."

*Response:* We are considering how best to streamline and make the use of these comparative functions easier.

*D. Changes To Improve Payment Rules and Processes*

This section addresses three payment issues under Part C. These provisions are outlined in Table 4.

TABLE 4—IMPROVING PAYMENT RULES AND PROCESSES

| Provision | Part 417/422 | Part 417/422 | Part 423 | Part 423 |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Risk Adjustment Data Validation | Subpart F | § 422.2 | N/A | N/A. |
| Dispute and Appeals Process | Subpart G | § 422.311 | | |
| Payments to Medicare Advantage Organizations-Actuarial Valuation | Subpart F | § 422.254 | N/A | N/A. |
| Determination of Acceptable Administrative Costs by HMO/CMP Cost Contract and Health Care Prepayment Plans (HCPPs). | Subpart O | § 417.564 | N/A | N/A. |
| Calculation of the Minimum Percentage Increase under Part C | Subpart G | § 422.306 | N/A | N/A. |

1. Definitions Related to Risk Adjustment Data Validation Appeals (§ 422.2) and Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures (§ 422.311)

In the October 22, 2009 proposed rule, we proposed regulations establishing an appeals process to be used by MA organizations to appeal the error calculation resulting from Risk Adjustment Data Validation (RADV) audits. As explained in the preamble of that proposed rule, under RADV audits and medical records are reviewed to determine whether they support diagnosis codes (known as Hierarchical Condition Codes, or HCCs) submitted to us under the MA risk adjustment methodology. Under this methodology, certain diagnosis codes are considered to signify higher costs for the enrollee, and therefore, we pay a higher amount to the MA organization for an enrollee to reflect these higher costs. If, in fact, a diagnosis code was not justified by the enrollee's medical condition, the higher payment amount associated with that diagnosis code would have been an overpayment. Under the RADV audit process we plan to recover the overpayments identified during the RADV audit. The appeals process we proposed in the October 22, 2009 proposed rule was intended to provide a mechanism for MA organizations to appeal the error calculation associated with the overpayments identified under RADV audits. We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process, but on the RADV audit process and underlying MA payment policy producing the overpayment findings and our definitions proposed at § 422.2. Since neither the statute nor existing MA program regulations currently specify a process for appealing overpayments resulting from RADV audits, the appeals process we proposed was based on our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act. Specifically, we proposed adding a new § 422.311 to part 422, subpart G, to specify RADV dispute and appeal rights for MA organizations. We proposed regulatory provisions allowing MA organizations that undergo RADV audit(s) to—(1) submit physician and other practitioner signed attestations relating to physician and other outpatient medical records that had a missing signature, or credentials that resulted in a payment error finding; (2) dispute certain other types of medical record review-related findings through the use of a documentation dispute process; and (3) appeal our RADV payment error calculation. By availing themselves of these RADV dispute and appeal processes, we noted that MA organizations would be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we proposed the following provisions under part 422:

- To revise § 422.2 to add definitions of six terms that pertain to RADV activities, and thus to our proposals for implementing a RADV dispute and appeal processes.
- A new § 422.311 describing procedures that we would implement to afford MA organizations facing a potential overpayment determination resulting from RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations, and to have other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarized the RADV audit procedures. Beginning with § 422.311(c), we proposed implementing a three-pronged RADV dispute and appeal procedure that MA organizations could employ to reduce their RADV payment error rate, including—
- Physician/practitioner attestation(s);
- Documentation dispute; and
- RADV payment error calculation appeal.

We noted that analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing signatures or credentials on medical records. Medicare program rules dictate the necessity of physician signatures on medical records, and MA risk adjustment requirements dictate that risk adjustment diagnosis data be accepted only for health services that were provided by certain physician specialties. Therefore, RADV audit procedures require that, in addition to finding diagnosis information that would support the HCCs submitted by the MA organization for risk adjustment purposes, physician signatures, and appropriate credentials must be present on medical records. Medical records with missing signatures or credentials are scored as errors under RADV audit procedures. We estimated that if given the opportunity to do so, many physicians and other practitioners that provided the diagnosis information on RADV-reviewed medical records would in fact attest that they documented the information in these medical records, even though signatures and credentials were missing from those records. Moreover, the presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors

that would otherwise originate from medical record signature, or credential-related discrepancies.

Therefore, in proposed § 422.311(c)(1), we proposed to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for providing and documenting the health services in the physician and outpatient medical record(s) that were submitted for RADV audit. We specified at proposed § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature or credential-related discrepancies found on inpatient medical records. The proposed use of an attestation would not in any way supplant the medical record, nor would it permit attesting physicians/practitioners to alter the existing medical record. Attestations would not be acceptable to address any issues outside of the RADV-audit process.

At proposed § 422.311(c)(1)(C)(iv), we indicated that we would prospectively notify MA organizations that if the "one best" medical record used to validate an audited HCC were missing a physician/practitioner signature or credential, the MA organization would be permitted to submit a CMS–RADV attestation along with the medical record, to fulfill the requirement that medical records contain physician/practitioner signatures and credentials.

We described the proposed process that we would jointly undertake to review attestations submitted for our review at proposed § 422.311(c)(1)(iv) and (v), noting the following:

- Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) would be eligible for consideration. Failure to meet these requirements would result in us not reviewing or accepting submitted attestations.
- CMS attestations that have been altered or amended (for example, striking out prepopulated words and replacing them with hand-written replacement words) without instruction or written concurrence from us would not be accepted.
- Attestations would need to accompany the medical record at the same time that the medical record was submitted to us for RADV audit. MA organizations would not be permitted to submit attestations before or after submission of their RADV medical records.
- Attestations would need to originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We would not accept attestations or medical records from any party other than the MA organization.
- Organizations would not be permitted to submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2) and § 422.311(c)(3).

At proposed § 422.311(c)(1)(iv), we described the process that we would undertake to review attestations and notify appellant MA organizations of the results of these attestation reviews. Our attestation review determinations would be final and binding upon both parties and would not be eligible for further appeal.

We further proposed affording MA organizations the option of disputing other nonsignature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we described in new paragraph § 422.311(c)(2). Under our proposal, in order to be eligible for documentation dispute, MA organizations would need to submit their "one best" medical record in accordance with RADV medical record submission deadlines established by us during the RADV medical record request process.

At proposed § 422.311(c)(2)(a), we specified the types of RADV-related errors that would be eligible for the proposed documentation dispute process. The documentation dispute process would apply only to the errors that arise out of operational processing of medical records selected for RADV audits and submitted to us by established deadlines. In this context, errors that arise from operational processing mean errors that arise from the collection and processing of medical records for a RADV audit.

At § 422.311(c)(2)(ii), we proposed limitations that we would impose upon the documentation dispute process; namely that MA organizations would not be permitted to dispute any medical record coding discrepancies, nor would MA organizations be permitted to submit altogether new medical records in place of previously submitted medical records. Payment errors that resulted from missing medical records would not be eligible for documentation dispute. At proposed § 422.311(c)(2)(iii) and (iv), we indicated that we would prospectively notify MA organizations of RADV payment errors that would be eligible for documentation dispute, describe the documentation dispute process that we would undertake, along with the process that we would undertake to notify MA organizations of the results of documentation dispute reviews. As described at proposed § 422.311(c)(2)(v), our documentation dispute review determination would be final and binding upon both parties and would not otherwise be eligible for further administrative appeal.

Proposed § 422.311(c)(3) would establish an appeals process under which RADV payment error calculations would be subject to appeal. Unlike our proposed attestation process described at § 422.311(c)(1), and proposed documentation dispute process describe at § 422.311(c)(2), which would afford MA organizations the opportunity to dispute aspects of our medical record review process, the proposed RADV payment error calculation appeal process was specifically designed to afford MA organizations the opportunity to appeal our contract-level RADV payment error calculation. Under the proposed RADV payment error calculation appeal process, we proposed establishing a three-level appeal process whereby MA organizations may—

- Seek reconsideration;
- Appeal the reconsideration decision to an independent CMS Hearing Officer; and
- Appeal the decision of the independent CMS Hearing Officer to the CMS Administrator.

Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we stated our belief that it was prudent to afford appellant MA organizations multiple-layers of RADV-related payment error appeal.

At proposed § 422.311(c)(3)(ii), we also specified that MA organizations would not, under the proposed RADV payment error calculation appeal process, be permitted to appeal medical record review errors, nor would MA organizations be permitted to seek formal appeal of physician or practitioner signature or credential-related review errors. We believed that medical record review-related issues would be addressed as a result of the rigorous medical record review process, and the attestation and documentation dispute processes described earlier in the proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process would only apply to errors identified in the RADV payment error calculation. MA organizations would not be permitted to

utilize the payment error calculation appeal process as a method for submitting any medical records for consideration in the calculation of the payment error. In order to be eligible for RADV payment error calculation appeal, MA organizations would need to adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, we noted that MA organizations would not be permitted to appeal our RADV payment error calculation methodology. Our justification for excluding methodological appeals was two-fold. First, we said the methodology that we planned to employ to calculate RADV payment errors was methodologically sound and academically defensible. We stated that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing annual notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. MA organizations that object to CMS' RADV payment error calculation methodology would be given an opportunity to provide comment to us under ours annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we stated that we would provide an expanded explanation of methodology as part of each RDV audit report that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology would be RADV payment error calculation factors unique to each audited MA organization that would enable the MA organization to independently calculate its own RADV payment error.

At proposed § 422.311(c)(3)(iii) and (v), we specified that MA organizations would be notified of their RADV payment error calculation appeal rights at the time we issue a RADV audit report to that organization. MA organizations would have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration would need to specify the issues with which the MA organization disagrees, the reasons for the disagreements and explain why the organization believes the issues are eligible for reconsideration. The request for reconsideration would need to include additional documentary evidence that the MA organization considers material to the reconsideration, though MA organizations would be prohibited from submitting medical record-related evidence such as new or previously submitted medical records or physician or practitioner attestations and from appealing any issues pertaining to the methodology applied in any part of the RADV audit. At proposed § 422.311(c)(3)(iv), we further specified that the MA organization would bear the burden of proof to demonstrate that our RADV payment error calculation was clearly incorrect.

We described our proposal regarding the conduct of a RADV payment error calculation reconsideration, the decision of the reconsideration official and the effect of the CMS reconsideration decision official at proposed § 422.311(c)(3)(e) and (f).

At proposed § 422.311(c)(3)(v) and (vi), we described the first level of RADV payment error calculation appeal, the request for reconsideration of our RADV payment error calculation. Under this process a CMS official or our contractor not otherwise involved in error-rate calculation activity would review our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculate the payment error utilizing our RADV payment error calculation methodology (as specified in our standard operating procedures), and render a determination whether the RADV payment error calculation was accurate. This CMS official or CMS contractor not otherwise involved in RADV error-rate calculation activity would recalculate and arrive at an independent RADV payment error. Whether the official or contractor agreed with our payment error calculation, or overturned the calculation and established a new RADV payment error, this party's RADV payment error calculation determination would be issued to a CMS reconsideration official. The CMS reconsideration official would review their analysis and make a determination whether to accept or reject the findings of the CMS official or CMS contractor that recalculated the RADV payment error. In instances when the CMS official or contractor recommended overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agreed with the newly calculated RADV payment error, we would issue a reconsideration decision which informed the appealing MA organization in writing of its reconsideration decision, in effect, notifying the MA organization of its new RADV payment error. If the reconsideration official upheld the decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly would notify the appellant MA organization of its determination. In either instance, the decision of the reconsideration official would be final and binding, unless a request for hearing was filed by CMS or the appellant MA organization.

At proposed § 422.311(c)(4), we clarified that if CMS or an MA organization were dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3), CMS or the MA organization would be permitted to request a second-level RADV payment error calculation appeal, which is a hearing on the RADV payment error calculation determination. CMS or MA organization choosing to pursue a hearing would be required to file a request for hearing within 30 calendar days of the date the MA organization received the written RADV payment error calculation reconsideration decision, as described at proposed § 422.311(c)(3)(vi).

We noted that CMS or MA organizations requesting a hearing would need to do so in writing, including a copy of the CMS reconsideration official's decision to either uphold or overturn the initial RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagreed with and why they disagreed with them. The hearing would be conducted by the CMS Office of Hearings and presided over by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration of the RADV payment error calculation. The hearing would be held on the record, unless the parties requested, subject to the Hearing Officer's discretion, a live or telephonic hearing. The Hearing Officer would also be permitted to schedule a live or telephonic hearing upon their own motion. The CMS Hearing Officer would be limited to a review of the record that was used for the initial RADV payment error calculation and the reconsidered RADV payment error calculation.

Additionally, we noted that the Hearing Officer would have full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers would include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

At proposed § 422.311(c)(4)(iv), we also indicated that the CMS Hearing Officer would review and decide

whether the reconsideration official's decision was correct and to notify CMS and the MA organization in writing of his/her decision, explaining the basis for the decision, which would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.311(c)(5).

We explained that the third level of RADV payment error calculation appeal that MA organizations can request would be discretionary review by the CMS Administrator. We described this proposed process at § 422.311(c)(5). At this level of appeal, CMS or the MA organization would be permitted to appeal the decision of the CMS Hearing Officer by requesting that the CMS Administrator review the CMS Hearing Officer's determination. Parties requesting CMS Administrator review would have to request the review within 30 calendar days of receipt of the CMS Hearing Officer's determination. If the Administrator agreed to review the case, the Administrator would review the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and would determine whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination would be final and binding.

We also noted that, based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it would be necessary for us to establish a "compliance date" to use as a reference point in issuing a ruling regarding RADV audit findings. Therefore, we proposed at § 422.311(b)(2), to require that the compliance date for meeting Federal regulations requiring MA organizations to submit medical records for the validation of risk adjustment data (§ 422.310(e)) also be the due date when MA organizations (or their contractor(s)) selected for RADV audit would need to submit medical records to us. We stated we would inform an MA organization in writing regarding selection for RADV audit, including the due date for submission of medical records.

We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process described in proposed § 422.311—but also the RADV audit process and underlying Medicare Advantage payment policy. These comments have resulted in changes to our above-described proposals as discussed below.

While many comments that we received relate to the underlying RADV audit process and risk adjustment methodology and may not directly address the RADV appeals process specifically, we are responding to these comments, because they appear to be relevant to the RADV appeals process that we had proposed in our Notice of Proposed Rulemaking. Certain comments were outside the scope of our proposed rule and we have not included responses to those comments.

*Comment:* A comment alleged that it was premature for CMS to propose rules related to the RADV appeals process because the commenter stated that the Administrative Procedure Act (APA) required that the underlying RADV audit process giving rise to the overpayments that would be appealed under our proposed regulations be subjected to notice and comment rulemaking.

*Response:* We disagree and believe that the RADV audit process does not establish any substantive rules within the meaning of the APA or section 1871 of the Act, but rather is a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute, and in regulations that have been subjected to notice and comment procedures. Regulations specifying that payment amounts are subject to audit (for example, § 422.504(d)(1)(i) have been subjected to notice and comment procedures, and provide ample notice of the fact that we have the right (and, indeed, the duty) to ensure that MA payment amounts are accurate. See also, § 422.310(e), which states that MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS, and that there may be penalties for submission of inaccurate data.

Indeed, we would point out that throughout the Medicare program, and government programs generally, audit policies and procedures intended to ensure or verify payment accuracy assist in the enforcement of rules, and are not themselves substantive rules subject to APA notice and comment procedures. Therefore, to the extent we are providing a RADV appeals process, we are providing an opportunity that does not currently exist for MA organizations to appeal audit findings that they would otherwise not have been permitted to question.

*Comment:* Some commenters stated that CMS did not follow proper procedures and stated that procedures set forth in our proposed regulations, such as our "one best medical record" and other documentation requirements, established a substantive legal standard governing the payment to MA organizations, and therefore, they had to be included in the annual notice of changes to payment methods required under section 1853(b)(2) of the Act, which requires that MA organizations be afforded an opportunity to comment on changes in the methodology for determining MA payments.

*Response:* We disagree. The requirement in section 1853(b)(2) of the Act to provide an advance notice of methodological changes to MA organizations of proposed changes to the methodology and assumptions used to compute annual MA capitation rates pertains to the methodology for determining the proper amount of payment. All substantive changes to the risk adjustment methodology at issue in the RADV audit process have been described in the annual advance notice. The RADV audit process and appeals procedures proposed in the October 22, 2009 proposed rule do not make any substantive changes in the methodology for determining MA payment amounts. Rather, they are designed to ensure that this payment methodology has been applied correctly, and the MA organization has received the amount to which it was entitled under this methodology. The risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition. The RADV audits and appeals process are designed to ensure that the enrollee in fact has that condition, and that the MA organization is thus entitled to the amount that has been paid for that condition. The fact that audits might determine that an MA organization was not, in fact, paid correctly, is not a change in methodology or assumptions related to how the payment amount is to be determined and therefore is not subject to the advance notice requirements under section 1853(b)(2) of the Act. Nonetheless, in our October 22, 2009 proposed rule, we proposed to provide notice of RADV audit methodology to the public, as well as a summary of RADV methodology issues for each audited MA organization at the time we issue our audit finding pursuant to an actual RADV audit. We offered to provide details of our RADV audit methodology in an attempt to provide additional transparency related to the process. We anticipate providing additional notice of RADV audit methodology to the public by publishing the methodology in some

type of Medicare program document—most likely in a Medicare manual later this year (2010).

*Comment:* A commenter stated that CMS was not complying with requirements in section 1871(a)(2) of the Act, which states that "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, * * * shall take effect unless it is promulgated by the Secretary by regulation* * *"

*Response:* As discussed previously, the RADV audit process, and the appeals procedures addressed in this rulemaking, do not "establish" or "change" any "substantive legal standard governing * * * payment." To the contrary, they are designed to ensure that the substantive legal standards for payment set forth in the statute and regulations are correctly applied. The substantive rules governing the amount of payment to which the MA organization is entitled are unchanged as governed by statute and implementing regulations.

*Comment:* A commenter urged that CMS suspend RADV audits until such time as CMS subjects the rules to notice and comment rulemaking.

*Response:* As discussed previously, we do not believe subjecting the RADV audit process to rulemaking is required or appropriate, there would be no basis for suspending the audit process.

*Comment:* One commenter noted that when the risk adjustment system was initially established, the Secretary was required to submit a report to Congress in accordance with section 1853(a)(3)(A) of the Act that documented the proposed method of risk adjustment of MA payment rates, and that included an evaluation of the method by an outside, independent actuary of the actuarial soundness of the proposal. The commenter believed that such an evaluation was required in the case of the RADV audit process.

*Response:* We disagree that RADV audits impact the risk adjustment system in any manner. As indicated earlier, RADV audits are solely to verify that the risk adjustment methodology is being correctly applied.

We also received a large number of comments from MA organizations, managed care trade associations and a law firm regarding RADV methodological-related issues. While some comments were not relevant to the rules that CMS proposed regarding the RADV appeals process, there were a number of comments that we believe should be addressed, and as such, we do so as follows.

*Comment:* Many commenters recommended that CMS independently test and validate its RADV methodology before CMS implements it. The commenters indicated that CMS failed to provide any record of submitting its methodologies to an academic review and that if CMS has done so, we should have included such studies with the proposed rule so that interested parties could review and comment on any of these academic studies. The commenters recommended that CMS provide a process that permits thorough review and comment by plans of RADV audit methodology issues before undertaking further RADV audits. Several commenters further recommended that all methodological issues pertaining to RADV audits be appealable.

*Response:* Previously in this preamble we indicate that the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years. Over the course of this timeframe, we have been advised on the RADV process by statisticians, senior analysts, expert medical record coders, physicians, managed care professionals, and other health care providers. From a medical record coding perspective, we have secured expert direction from Peer Review Organizations (PROs) (in the past) and Quality Improvement Organizations (QIOs) (currently) by incorporating them into the RADV team. From an analytic design and implementation perspective, we have in the past and continue to employ senior level expert analysts from different academic fields as independent contributors to the RADV operations team to review and validate the accuracy of the findings across the RADV process, including peer review of statistical sampling and payment error calculation methodologies. The independent expert analysis and review is similar to that conducted in an academic setting in that the participating parties are credentialed in a specific field of study, such as statistics, and possess substantial years of expertise conducting similar processes and analyses. The independent methodology review processes also involve the use of internal controls, and tests for consistency and accuracy. RADV procedures are subject to the evaluation requirements of the CMS Annual Financial Audit.

In addition, the RADV methodology that we employ in the process of reporting a component of the national Part C payment error is similar to the methodological approach that we employ in conducting contract-specific RADV audits and error calculations. This methodology has been reviewed and approved by officials at the HHS.

This notwithstanding, in considering the commenters' questions, where necessary, we will incorporate additional independent third party review for purposes of validating RADV error-calculation methodology. As indicated in our proposed rule and cited elsewhere in the preamble to this final rule, we intend to publish its RADV methodology in some type of public document–most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary. Finally, to ensure that audited organizations understand how their RADV error rate was calculated, as indicated in our proposed rule, we further intend to describe our RADV methodology in each audited organization's RADV audit report.

Given these efforts to ensure that the RADV process is transparent to audited MA organizations and the public, and that the methodology used under that process is reasonable, consistent, and accurate, we do not believe any further action is required.

*Comment:* Several commenters argued that CMS should include Medicare plan enrollees for whom no diagnosis code was submitted under the risk adjustment methodology as part of its RADV error testing samples. These commenters also recommended that CMS include "under-coding" findings in the audit error estimates in order to more accurately account for members' health status.

*Response:* Our RADV audit policy does account for both underpayments and overpayments. The RADV process addresses under-coding through the application of rules for crediting a sampled enrollee with additional HCCs that are identified incidentally, during medical record review. We emphasize that these "additional" diagnoses were not originally submitted for payment for enrollees selected in the sample, and yet we provide audited organizations credit through our RADV medical record review process.

However, we have not and do not expect to sample enrollees for whom no HCCs were submitted. This is because the RADV is an audit process that is intended to validate the HCCs that were submitted by MA organizations in order to determine whether the additional payment amounts associated with these

diagnosis codes were properly made. Under our separate Risk Adjustment Data Submission Process, the data submission period for any given payment year is lengthy and extends beyond the actual payment year, providing a substantial amount of time for organizations to submit and/or correct enrollee HCC risk adjustment data for any given payment year—to reflect of enrollee health status. This is sufficient time for plans to submit data on all their enrollees, including those with no HCCs. The RADV audit process is not intended to serve as a de facto mechanism for extending the HCC data submission deadlines under which MA organizations operate.

We received a number of comments from MA organizations and a law firm regarding the financial impact of RADV audits. While these comments did not pertain directly to our proposed RADV appeals procedures, some comments nevertheless indirectly impact the RADV appeals rules. Therefore, we respond to several of these comments here.

*Comment:* Several commenters suggested that CMS's proposed methodology to calculate and apply error rates and payment adjustments across contract years after payments were made undermines the actuarially-based risk assumptions inherent in Plans' bid submissions.

*Response:* Regarding the assertion that RADV audits undermine the Part C bidding process, beginning with the introduction of the HCC risk adjustment model for CY 2004, we have published clear guidelines to be followed by MA organizations in the collection and support of diagnosis codes underlying risk scores for plan enrollees. In their preparation of a MA bid, certifying actuaries are expected to ensure that the underlying data are reasonable and appropriate for the circumstance, including the base year risk scores. If the ultimate risk scores for a plan's population are lower than initially forecast by the certifying actuary, then the plan is likely to experience lower than expected margin. Conversely, if the ultimate risk scores for a plan's population are higher than initially forecast by the certifying actuary, then the plan is likely to experience greater than expected margin. These results illustrate the nature of health plan capitation and the risk borne by MA organizations.

*Comment:* Commenters stated that the establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could not have considered in developing bids for affected prior years. Commenters suggested that CMS' sampling methodology undercuts the mandate in section 1854(b)(6)(B)(iv) of the Act that MA organizations' rates reflect the revenue needs of the organization. The commenters assert that MA organizations did not develop bid submissions for calendar years 2006 through 2009 with an expectation that CMS would implement contract-wide payment adjustments based on provider documentation issues outside of the MA organizations' control. As a result, if payments effectively are reduced retroactively as the result of RADV audits, the bid submissions (and resulting payments) arguably would not adequately reflect Plans' risks, and MA organizations may be forced to dip into their reserves to repay dollars that were not anticipated to be at risk.

*Response:* We disagree. If plan bids are developed based on faulty data, such as inappropriate claim costs or risk score data, there is a greater likelihood of error in the bid projection. There are many factors that influence the accuracy of bid projection, and data quality is just one such factor. There is no legal authority to change a bid amount after it has been accepted regardless if additional information suggests that the bid is too high or too low.

In general, it is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve— with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnoses leading to such costs being incurred have a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C actually further actuarial equivalence, rather than conflicting with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

*Comment:* Several commenters questioned whether CMS's RADV medical record review coders have the qualifications and experience necessary to code RADV-related medical records. Commenters specifically questioned whether RADV coders were equipped to code accurately in situations in which clinical training may be required in order to recognize all extractable ICD–9 codes. They inquired into the certification and coding experience qualifications for the RADV coders.

*Response:* The coders that CMS uses to review RADV medical records are fully qualified to code RADV-related medical records. All coders are professionally certified for example, Certified Professional Coder (CPC), Certified Coding Specialist (CCS), Registered Health Information Administrator, (RHIA) and Registered Health Information Technician (RHIT), and must have prior experience coding medical records. Coders have access to physician consultation as needed. Coders also have access to our Independent Coding Consultant—a coding expert with more than 10 years of professional coding experience, which we require to be RHIA, coding certified and to have at least 5 years of experience in RADV-specific coding.

*Comment:* Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices who must produce medical records necessary to conduct audits. These commenters recommended that CMS take into account the potential impacts of more aggressive program integrity efforts on the medical practices that provide care to MA plan enrollees. Outside of the proposed rule, we have also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by Medicare health plans that mimics the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that Medicare health plans were misrepresenting their internal audit activity as official CMS RADV audits.

*Response:* Section 422.310(e) requires that providers who voluntarily enter into contracts with MA organizations submit data to CMS contractors/IVCs for RADV audits. In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage health plans to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices, it is our belief that the impact of RADV audits on providers can be minimized.

We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA plan's own audit or in accordance with an official Medicare program RADV audit which is subject to legislative requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV, and providers may request this authorizing letter before responding to requests by the MA plan.

We received a large number of comments from MA organizations, managed care trade associations and a law firm regarding the "one best medical record" policy that CMS proposed to apply to the RADV program. By way of explanation, the "one best medical record" policy specifies that for any one sampled beneficiary—with any one HCC—the MA organization is allowed to select and submit supporting medical record documentation of a face-to-face encounter for a physician or outpatient visit (one date of service) or an inpatient stay (range of dates from admit to discharge). The face-to-face encounter would have needed to occur at some point during the data collection year (from January 1st to December 31st).

*Comment:* Commenters contended that the one best medical record policy forces plans to omit relevant data that could be supported through documentation that CMS does not permit—such as prescription drug data and lab results.

*Response:* The RADV risk adjustment model is based upon FFS claims data from specific risk adjustment provider types, and not alternative data sources, such as, prescription drug data or lab results. Therefore, the RADV audit process is based upon supporting medical record documentation from provider data sources that are used to calibrate the model. As for the one best medical record policy, while MA organizations that voluntarily submit HCCs for Medicare payment are prospectively paid based on these unaudited and unvalidated HCCs submissions, we, upon the recommendation of MA organizations, agreed to allow any one medical record from across an entire data collection period to validate an HCC incorporated into the payment to the MA organization.

*Comment:* Some commenters contend that if CMS is going to rely on the one best medical record policy to the exclusion of other sources of information that might confirm an HCC, the RADV appeals process should allow for HCC medical record review findings to be appealed.

*Response:* To address these comments as described in § 422.311(c)(2) of this final rule, we have revised the process so that MA organizations may appeal medical record review determinations in accordance with the procedures specified in § 422.311(c)(2).

*Comment:* A number of commenters argued that the one best medical record policy is flawed in that it provides an insufficient basis for confirming an HCC for members with chronic diseases when a collection of several records, perhaps from various providers, considered in the aggregate might better verify a patient's condition.

*Response:* We disagree. In the case of a chronic disease such as congestive heart failure, all that is required is medical record documentation from one visit to a physician or a hospital, over the course of the data collection year, to validate the audited HCC.

*Comment:* We received several comments comparing the RADV audit and appeals process to varying program attributes of the Medicare FFS program. For example, some commenters argued that CMS' one best medical record rule conflicts with Medicare FFS standards since there is no one best medical record rule applied to Medicare payment error-rate testing for FFS providers.

*Response:* Payment error-testing under original Medicare is different than payment error testing under Medicare Part C. Under original Medicare, much of what comprises the error testing regimen is aimed at validating that a particular level of service was provided and therefore justifies a given level of Medicare payment. Under RADV, the payment error testing focuses on validating HCCs by examining medical records to determine whether they contain supporting diagnostic codes. This error testing is aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid for, and not whether a particular level of service (for example, level 1 office visit vs. level 2 office visits) was provided. Moreover, there is no evidence to support the notion that the Congress, in establishing the Part C payment process, ever intended the Part C payment process to mimic payment processes under Original Medicare. Indeed, they are fundamentally different.

Moreover, we believe that the one best medical record policy and the operational process associated with it are far less restrictive than Medicare FFS. MA organizations are not limited to the specified date(s) of service they reported to us with regard to selecting a medical record as supporting documentation for a specific HCC. We continue to believe that the one best medical record policy is appropriate for the Medicare Part C risk adjusted payment system which is distinct from a FFS payment system where payment is determined on a claim-by-claim basis. Under Part C, we only require that plans send one HCC for payment for an entire year; it therefore logically follows that we would only require one medical record to validate this HCC.

*Comment:* Some commenters stated that the one best medical record rule was inconsistent with the mandate that MA payment adjustments be actuarially equivalent to the FFS sector.

*Response:* It is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve—with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnosis leading to such costs being incurred has a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employs to ensure accuracy under Medicare Part C we believe furthers actuarial equivalence, rather than conflicts with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

*Comment:* A commenter noted that in Medicare Part A and B appeal contexts, supplemental information and testimony are considered, and given such weight as the fact finder determines is appropriate.

*Response:* Under our proposed appeals procedures that affords MA organizations the ability to appeal the Part C error calculation specifiedat § 422.311(c)(3), the CMS Hearing Officer

has the discretion to conduct the hearing in alternative ways beyond conducting the hearing on the record. For example, the Hearing Officer can choose to conduct the hearing by way of teleconference or in person. The CMS Hearing Officer also has the discretion to request supplemental information or to accept testimony, as he or she deems necessary. Also, under the medical record review appeal processes that we specify at § 422.311(c)(2), we afford MA organizations the ability to submit supplemental information—the attestation reviewed by the IVC— to validate the same HCC that the Initial Validation Contractor (IVC) initially determined to be in error.

*Comment:* Several commenters, focusing on the relationship between MA organizations and their providers, noted that errors in documentation are ultimately attributable to providers, not MA organizations. These commenters argued that, due to the nature of the MA program, while CMS makes a capitated payment to organizations that have relationships with providers, these providers may not have an incentive to document the HCCs which affect payment to the MA organization. The commenters also stated that contract-level payment adjustments penalize MA organizations, while it is providers who are responsible for maintaining adequate records. A commenter also suggested that we accept "other data" to supplement, or substitute, a medical record.

*Response:* Section 422.504(i)(1) clarifies for MA organizations that they are ultimately responsible for the risk adjustment information submitted to CMS. This section of the regulations states, "Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS." MA organizations are further directed in § 422.504(i)(2) that all their "first tier, downstream, and related entities are required to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect * * * medical records." Therefore, while we acknowledge the comments, we maintain that it is the responsibility of MA organizations to ensure that they submit accurate risk adjustment information, and that the providers with whom they contract are aware that we have authority to audit medical records to verify this information.

We do not require MA organizations to submit HCCs for beneficiaries; MA organizations choose whether or not to do so. For risk adjustment diagnoses that are submitted, it is the responsibility of the MA organization to obtain appropriate documentation. If MA organizations are not confident in the information they obtain from their providers, they may wish to initiate education efforts, or include provisions in their contracts that ensure providers appropriately document diagnoses and provide medical record documentation to the plan upon request.

In regards to supplemental information, we have determined, and MA plans have been informed multiple times, that the appropriate format for obtaining risk adjustment information is a medical record. For validation purposes, plans are asked to submit the one best medical record documenting the HCC. We carefully determined the one best medical record policy, after consultation and input from the industry supporting this policy. We do not believe that supplemental information would be sufficient, or add value to a record that does not support an HCC for which the plan had been paid.

*Comment:* Many commenters from the MA industry recommended that before CMS audit MA organizations under RADV, the agency first account for any error rates inherent in Medicare FFS data that affect MA error rates. These commenters stated that through the proposed RADV audit appeal process, CMS is imposing a set of rules regarding physician recordkeeping that were not anticipated in the ICD–9CM coding guidelines, is not consistent with standard practices and is not enforced on original Medicare claims. The result, they allege, is *de facto* MA payment adjustments based on recordkeeping discrepancies without an adjustment to original FFS Medicare risk scores for the same recordkeeping discrepancies.

*Response:* We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue.

*Comment:* A number of commenters stated that the CMS-defined attestation process was overly narrow and should be expanded to provide for more widespread use of attestations in the RADV audit process. Commenters contended that attestations should be expanded to provide MA organizations with a greater ability to correct medical record coding-related errors or deficiencies in submitted medical records. Commenters requested that CMS permit MA organizations to submit attestations that attest to the presence of medical conditions not fully supported in the medical record submitted to CMS. The commenters further argued that CMS should permit attestations to be used to validate not only the physician signature and credentials that are missing from a medical record, but also for patient name, identifier, date of service, and other documentation inadequacies that can result in a RADV medical record coding error.

*Response:* Taken in the aggregate, commenters' recommendations regarding an expanded use of attestations in the RADV audit process reflect a misunderstanding of what attestations are intended to accomplish. Many of the comments submitted suggest that we adopt a policy that in effect, allows attestations to stand in the place of the medical records that are required to validate the HCCs that have resulted in higher payments already made to MA organizations. For example, permitting physicians to use attestations to "correct' medical record coding-related deficiencies determined pursuant to medical record review; or allowing attestations to be an acceptable vehicle for the submission of new HCCs that were not otherwise already submitted to CMS for payment.

We believe that we must validate the HCCs that result in additional payment through the existence of clear, unambiguous diagnostic information in a beneficiary's medical record. A medical record provides the written support for the diagnosis that was made and must meet certain well recognized documentation requirements. Consistent with the Medicare FFS program, medical record documentation, rather than other alternative documentation, such as attestations, is required to validate information provided to us for the purpose of making provider payments. The existence of an accompanying attestation simply provides a mechanism for the physician to validate that the medical record that is missing a signature or credential is in fact his or her patient's medical record. That is, attestations are intended to complement medical records, not stand in the place of them.

We continue to believe that the Medicare program is best served by limiting the applicability of attestations to instances in which the original diagnosing physician submits a signed and dated attestation to validate that the medical record in question is theirs. We see no justifiable reason for CMS to expand the applicability of attestations beyond this intended purpose and therefore, we are not accepting these comments.

*Comment:* Several commenters objected to CMS' prohibition on using attestations for inpatient medical-record-related RADV coding errors, and noted that CMS did not provide sufficient explanation why CMS would not permit them. The commenters recommended that CMS permit attestations to be submitted with respect to inpatient records.

*Response:* We do not believe that permitting attestations for inpatient medical records is justifiable. The decision to permit attestations for RADV was in response to industry concerns about the lack of signatures in medical records that are generated out of physician-office settings and not hospital settings. Upon preliminary evaluation of RADV findings, our data corroborates industry concerns in that it clearly shows that the majority of RADV-identified payment errors associated with lack of provider signatures were derived from medical records submitted and reviewed under the guidelines for physician/outpatients settings. Indeed, the data further corroborates that payment errors related to the lack of signature in inpatient medical records is minuscule.

Note that, with respect to the ongoing use of attestations within the RADV audit context, we reserve the right to continue to evaluate payment error related to physician/practitioner signatures, and the impact that attestations have upon these types of errors. We further reserve the right to amend the regulations in the future regarding the use of attestations should experience under the program justify this change.

*Comment:* Several commenters recommended that CMS implement an administrative appeals process for reviewing attestation determinations made by CMS.

*Response:* We understand the commenters' concerns, but do not believe this additional appeals process is necessary. As noted in section § 422.311(c), in light of the changes we are making in this final rule to the proposed RADV appeal procedures that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, MA organizations will be permitted to appeal medical record review-related determinations whose outcome was determined by the existence or absence of an attestation.

*Comment:* Some commenters recommended that CMS allow attestations to be used as acceptable vehicles for introducing new HCCs to the Medicare Part C payment process. Several commenters suggested that MA organizations be allowed to submit a letter from a provider group or other responsible party, along with an attestation in instances where the diagnosing physician is no longer able to sign and date an attestation—for example, in instances in which the diagnosing physician has died, moved or is no longer working for the medical practice.

*Response:* As stated previously in our response to earlier commenters' recommendations that we expand the applicability of attestations, we do not agree that attestations are acceptable vehicles for submitting new risk adjustment data and enrollee HCCs for payment to CMS. The data submission period for any given payment year opens 12 to 18 months before the start of payment year, and closes 3 months after the actual payment year ends, providing in total, at least 27 months for MA organizations to submit or correct enrollee HCC data for any given payment year. This provides ample time for MA organizations to voluntarily submit HCCs to CMS for Medicare payment.

Furthermore, a fundamental tenet of RADV is validating the existence of diagnoses information in a medical record. Consistent with Medicare FFS, medical record documentation rather than other documentation, such as attestations, is required to validate information provided to us for the purpose of making Medicare payments. Therefore, we see no justifiable reason to abandon this principle by allowing the submission of unsubstantiated HCCs via attestations, and therefore, reject the commenters' recommendations.

Under our RADV audit policy, to the extent we discover acceptable diagnoses codes contained in the one best medical record that plans submit for purposes of HCC validation that were not earlier submitted to CMS for payment via the Risk Adjustment Payment System (RAPS) system (what are known as "additional HCCs") —we credit these diagnoses codes to the submitting MA organization. Our reason for giving health plans credit for these additional diagnoses is precisely because they existed in beneficiaries' medical record(s)—and not in other types of documentation that would not be acceptable in any Medicare venue for justifying Medicare payment.

*Comment:* Several commenters stated that the 12-week timeframe for submitting attestations was unreasonably short. These commenters recommended that CMS afford plans additional time to gather and submit attestations.

*Response:* We do not agree. We proposed that the submission timeframe for attestations line-up with the deadline for submitting medical records in order to simplify the medical record and attestation submission process for plans. Under the proposed process the medical record and associated attestation are submitted together. We strongly believe that 3 months is sufficient time for MA organizations to obtain and submit to us the medical records and attestations necessary to validate audited HCCs. To provide additional time beyond the 12 weeks afforded to MA organizations to submit the requested medical records would split-up and unnecessarily complicate the medical record and attestation submission process. Since the attestation is intended to in effect—make the medical record "whole" by way of the signature and/or credential attestation—we believe it is unreasonable to set up a submission system that separates the attestation from the submission of the medical record. Therefore, we are not accepting this recommendation and instead are finalizing the requirement that attestations be submitted to us by the medical record submission deadline.

*Comment:* Several commenters recommended that CMS permit health plan officials to amend the CMS attestation form through hand-written annotations or to submit MA organization or provider-developed (that is, attestation forms that were not generated by CMS) attestation forms to CMS. A more limited number of commenters recommended that CMS allow physicians not involved in the diagnostic face-to-face encounter to attest to medical records in instances where the diagnosing physician is either dead or no longer at the medical practice or facility from which the medical record originated. These commenters reasoned that in extenuating circumstances such as the death of a provider or a provider having relocated, another provider within the medical practice could be permitted to sign the attestation on behalf of the treating provider. Under this scenario, the signing provider would annotate the CMS attestation form explaining the situation—for example, "Due to the expiration of Dr. Smith on June 1, 20xx, I am signing this attestation on his behalf."

*Response:* We believe opening the door to allowing modifications to a CMS payment-related document raises serious program integrity-related concerns and could result in fraud to the Medicare program. The extent to which one provider can reliably and

validly attest to a medical record prepared by another provider is questionable. We consulted with other Medicare program components within CMS that are or will be utilizing attestations or similar-like documents (for example, certificates of medical necessity, attestations used in conjunction with Comprehensive Error Rate Testing (CERT)) that have some bearing on Medicare payment and confirmed that there are very limited circumstances under which we permit external modification to any payment-related documents. Given these program integrity-related concerns, we are rejecting these recommendations.

We received a large number of comments regarding our proposed RADV documentation dispute procedures.

*Comment:* A commenter noted that the proposed definition of "Documentation Dispute Process" in § 422.2 indicates that MA organizations can "dispute medical record discrepancies that pertain to incorrect ICD–9–CM coding * * *'' and appeared to conflict with language in proposed § 422.311(c)(2)(ii)(A) stating that medical record coding discrepancies are ineligible for the documentation dispute process. Another commenter contended that the term "operational processing" as described in the regulation, was vague and needed to be further defined. One commenter recommended that CMS allow MA organizations 60 days to request documentation dispute instead of the proposed 30 days. Several commenters recommended that MA organizations be permitted to appeal documentation dispute review determinations.

Many other commenters asserted that the proposed documentation dispute process was too limited in scope, and effectively amounted to nothing more than a mechanism for rectifying clerical errors that provided no meaningful way to contest the accuracy of the auditors' interpretation of the medical records submitted, or to supplement the record being audited.

*Response:* As noted in § 422.311(c) of this final rule, in light of the changes to the proposed RADV appeal procedures that we are making in this final rule that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, we are withdrawing the proposed documentation dispute procedures described in the proposed rule. By way of this final rule, MA organizations that wish to dispute RADV medical record review determinations that arise out of operational processing of medical records selected for RADV audit (that is, determinations that arise from the collection and processing of medical records by CMS' RADV IVC) will now be permitted to do so via the medical record appeals process described in this final rule at § 422.311(c).

We received many comments from MA organizations and a managed care industry trade association regarding the proposed RADV appeals process at § 422.311(c)(3).

*Comment:* Many commenters stated that the proposed RADV appeals process was too narrow, and failed to allow for all relevant evidence to be considered as part of the appeal process. Of particular interest to many commenters was the fact that MA organizations were prohibited from appealing the substance of medical record coding determinations, as described in our proposed regulation at § 422.411(c)(3). With regard to the RADV appeals process, these commenters specifically recommended that CMS:

- Expand the scope of issues that may be raised in the appeals process to include, at minimum, challenges to medical record coding decisions and challenges to methodology—audit methodology, sampling methodology, and error-calculation methodology.
- Permit MA organizations to appeal HCC findings from the medical record review process.
- Permit MA organizations to submit coding corrections along with the additional medical records necessary to validate audited HCCs that CMS determines are in error.
- Incorporate diagnoses identified in medical records, but not previously submitted nor assigned to a member (so called "additional") in its RADV-related payment adjustment calculations.

*Response:* At proposed § 422.311(c)(3)(ii) we specified that MA organizations would not be permitted to appeal medical record review because medical record review-related issues would be resolved as a result of the medical record review process and the attestation and documentation dispute processes described earlier in the proposed regulation. However, based on the public comments we received, we have reconsidered this proposed restriction, and are for purposes of this final rule, changing our policy to now allow MA organizations to appeal medical record review that occurs at the IVC level.

Therefore, under a new final § 422.311(c)(2), we are implementing a process that would allow MA organizations to appeal medical record review that occurs at the IVC level of medical record review.

In order to be eligible for RADV medical record review appeal, MA organizations must adhere to established RADV audit and RADV appeals requirements, including the submission of medical records and documents in the manner and by the deadlines specified by CMS. Failure to do so will render the MA organization ineligible for RADV medical record review appeal. At § 422.311(c)(2)(i)(1) of this final rule, we specify that in order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow our rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization's request for appeal invalid.

At § 422.311(c)(2)(i)(2) of this final rule, we provide that the medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV IVC.

MA organizations must submit the original, IVC-audited medical record and any attestation reviewed by the IVC to CMS for consideration under the appeals process. MA organizations' request for appeal may include the attestation reviewed by the IVC in accordance with § 422.311(c)(1) but may not include any additional documentary evidence.

At § 422.311(c)(2)(ii), we specify that MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS. We also specify that any other documentation submitted to us beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by us under the medical record review determination appeal process. MA organizations' written requests for medical record review determination appeal must specify the audited HCC(s) that we identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal. A request for medical record review determination appeal must specify the issues with which the MA organization disagrees and the reasons for the request for appeal.

We describe the manner and timing of a request for medical record appeal at

§ 422.311(c)(2)(iii). We will issue each audited MA organization an IVC-level RADV audit report that provides details on the results of the medical record review findings. This RADV audit report will clearly specify the HCC determinations that are eligible for appeal. MA organizations will have 30 calendar days from the date of the issuance of the RADV audit report to submit a written request for medical record review determination appeal. A request for RADV medical record review appeal must specify the HCCs that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal. The request for appeal must also include the IVC-audited one best medical record and may include an attestation form in accordance with the rules at § 422.311(c)(1), but may not include additional documentary evidence. Please note that MA organizations are not obligated to appeal HCCs that we have identified as being eligible for medical record review determination appeal.

At § 422.311(c)(2)(iv), we describe the process that we will undertake to conduct the medical record review appeal. We designate a Hearing Officer to conduct the medical record review determination appeal. The Hearing Officer need not be an ALJ. We also describe procedures for disqualifying a Hearing Officer in the event either party objects to the designation of a Hearing Officer. We provide written notice of the time and place of the hearing at least 30 calendar days before the schedule date. The hearing is conducted by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS Hearing Officer is limited to the review of the record that was before the IVC.

The CMS Hearing Officer reviews the IVC-audited one best medical record and any attestation submitted by MA organizations to determine whether it supports overturning medical record determination errors listed in the MA organization's IVC RADV audit report. As soon as practical after the hearing, the Hearing Officer issues a decision which provides written notice of the Hearing Officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS. Pursuant to the Hearing Officer's decision, we recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization.

As described at § 422.311(c)(2)(v), the decision of the CMS Hearing Officer regarding RADV medical record review appeal will be final and binding upon the MA organization unless the MA organization requests review by the CMS Administrator. At § 422.311(c)(2)(vi), we indicate that the MA organization has 30 calendar days to request a review of the CMS Hearing Officer's determinations and that the CMS Administrator has discretionary authority whether to review the determination of the Hearing Officer. After receiving a request for review, the Administrator has the discretion to elect to review the Hearing Officer's decision or to decline to review the hearing decision. If the Administrator elects to review the hearing decision, the Administrator must review the CMS Hearing Officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified. The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the CMS Hearing Officer is final. It is important to note that notwithstanding our implementing procedures that permit MA organizations to appeal HCC determinations at the IVC level of medical record review that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal, the ability of MA organizations to appeal these IVC-level medical record review determinations does not otherwise alter MA organizations' ability to appeal RADV payment error calculations described at § 422.311(c)(3). However, MA organizations cannot appeal RADV payment error calculations until all RADV medical record review-related appeals are finalized.

*Comment:* Several commenters suggested that CMS afford MA organizations a reasonable amount of time after the medical record submission deadline to submit additional documentation that corroborates an already-submitted medical record.

*Response:* We do not agree that the amount of time provided to MA organizations to submit medical records under existing RADV audit policy is unreasonable. We provide MA organizations 3 months to obtain and submit to CMS the medical records necessary to validate the HCCs that MA organizations voluntarily submitted to CMS for Medicare payment. Moreover, a policy that supports submitting corroborating evidence to accompany an already-submitted medical record violates CMS' one best medical record policy. Therefore we are not accepting the commenters' suggestion.

*Comment:* Several commenters recommended that CMS afford MA organizations 60 days, rather than 30 days, to submit a written request for reconsideration of its RADV payment error calculation to provide sufficient time to prepare for the request.

*Response:* We do not agree. We continue to believe that 30 calendar days is sufficient time for any MA organization considering appealing its RADV payment error calculation to prepare and submit such a request. We are therefore, rejecting this recommendation.

*Comment:* Several commenters objected to the fact that all RADV-related appeals tasks are conducted by either CMS employees or agents employed by CMS. The commenters suggest that to ensure impartiality and an independent review of plan appeals, the appeals process should allow for independent reviewers outside of CMS. Plans should be allowed to choose and pay for a third party review of the error-rate calculation under reconsideration—rather than use the CMS contractor.

*Response:* As described in our proposed rule at § 422.311(c)(3)(v) and (vi), the CMS officials and/or contractors that will adjudicate individual appeal cases will be fully independent of the initial RADV error determinations. One important attribute in constructing an independent appeal structure for the RADV program is ensuring that the review officials or contractors called upon to perform these tasks have the necessary expertise to serve in the capacity of an independent appeal official. It would be altogether unreasonable for us to assume that plans would select appeal officials that meet our standards, not would we be able to validate this process in a timely manner. We cannot be put in the position of having to review the qualifications of plan-selected appeal officials and still be able to effectively administer the appeals process in a timely manner. As such, we are rejecting the suggestion that plans be allowed to choose and pay for their own independent review officials.

*Comment:* A commenter stated that the CMS' RADV appeal rules should provide for a meaningful way to appeal payment determinations.

*Response:* We believe that the commenter means that our ability to

adjust payments once RADV audit results are finalized should likewise be subject to appeal. We agree and for this reason, as explained in the proposed regulation, we are providing multiple avenues for MA organizations to appeal the RADV findings, including the ability to appeal mistakes in the contract specific payment error estimate as determined by our payment error estimate calculation methodology. These opportunities to appeal provide ample recourse to MA organizations to have RADV findings fairly readdressed. As part of this process, at § 422.311(c)(3)(vi)(B) and (D), we specified that we would hire an independent RADV payment error appeals contractor to replicate and validate the payment determinations that result in our error-calculation. Therefore, MA organizations that seek to appeal their error rate calculation can rest assured that the payment determinations that result in our error calculation are reviewed by an independent contractor.

*Comment:* Several commenters noted that, although the proposed rule provides for the review of the RADV calculation by a neutral third party, the proposed rule did not specify the criteria that the independent third party will utilize in determining whether the error rate calculations are correct. These commenters recommend that CMS be required to accept the third-party's findings or that CMS otherwise ensure that the decision on the findings is not made by an official who has a role in the RADV payment error calculation that is under review.

*Response:* The independent third party will utilize the same error-calculation criteria that will be employed by us in calculating its initial error calculation. This methodology will be known to audited MA organizations. In the preamble to our proposed rule and as stated previously in this preamble, we state that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. We anticipate publishing the RADV error calculation methodology in some type of CMS document—most likely some type of Medicare manual—and annually providing notice of any changes that will be made to this manual. In addition to providing an annual notice of RADV audit methodology, we indicated we would provide an expanded explanation of methodology as part of each RADV audit report that we send to MA organizations that undergo RADV audit.

At proposed § 422.311(c)(3)(v) and (vi), we specified that a CMS official or contractor not otherwise involved in error-rate calculation activity would review the written request for reconsideration, the RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation. We are finalizing that proposal in this rule.

*Comment:* A commenter believed that the level of detail proposed for the RADV appeals process was too specific. This commenter indicated that because MA organizations' and CMS' experience with data validation is relatively new, CMS should avoid putting a high level of detail into the regulation and should instead, maintain the flexibility necessary to do what makes sense in the context of the data validation.

*Response:* We do not agree that our experience with data validation is relatively new, since we have been performing RADV audits for over 10 years. The expertise and experience brought to the development of this function in that timeframe has enabled us to present a balanced level of detail with regard to the proposed regulation.

While we certainly appreciate the commenters' concerns regarding the level of specificity proposed—and now finalized—in the regulation, we contend that this level of detail is necessary in order for the public to fully understand how the RADV appeals process will operate. We concur with the recommendation that we remain flexible as we take further steps to implement these rules.

*Comment:* One commenter stated that the compliance date proposed by CMS is unduly restrictive. This commenter recommended that CMS consider additional evidence and testimony after the compliance date has passed.

*Response:* We disagree. Based on our experience with appeals of MA and Medicare Part D program contract determinations, it is absolutely essential for us to establish a compliance date to use as a reference point in issuing a ruling regarding RADV audit findings. In proposed § 422.311(b)(2), we specified that the compliance date be the date that MA organizations are required to submit medical records for the validation of risk adjustment data (§ 422.310(e)). By way of this final rule, we are extending the compliance date to include the date that MA organizations that choose to appeal IVC medical record review in accordance with § 422.311(c)(2) must submit medical records for review by the date we determine for the appeal process.

Without a specific date as a reference point for evaluating compliance, MA organizations could choose to assert that while they were unable to meet RADV audit requirements on the date we specified as the due date for medical record submission, they were later able to do so. Under this scenario, organizations would be free to assert the right to submit medical records in place of, or in addition to, records that were or were not, as the case may be, submitted to us by the RADV audit due date. The medical record review process could continue ad-infinitum, preventing us from closing out RADV audits and collecting any identified overpayments. The notion of considering additional evidence and testimony after the compliance date has passed negates the intended purpose of establishing a compliance date in the first place, and is therefore rejected.

2. Payments to Medicare Advantage Organizations—Actuarial Valuation (§ 422.254)

We proposed amendments to § 422.254 to expressly require an actuarial certification for Part C bids. As we noted in the preamble to the proposed rule, operationally we require an actuarial certification to accompany every bid, for both Parts C and D. A qualified actuary who is a Member of the American Academy of Actuaries (MAAA) must complete the certification. The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections. This requirement is already set forth in the Part D regulations at § 423.265(c)(3). We noted that our change in the Part C regulation text will bring the Part C regulation at § 422.254(b)(5) in line with current operational requirements and Part D. We are adopting § 422.254(b)(5) as proposed into this final rule.

*Comment:* We received three comments supporting the addition of this operational requirement to regulatory text. We also received one comment asking us if this requirement would apply to 2011 Part C bids.

*Response:* The 2011 Part C bids are due on June 7, 2010, the first Monday of June. Regardless of whether this regulation is final by that date, we will expect MA organizations to submit Part C bids in accordance with current operational guidance, which guidance is consistent with the regulatory language we are finalizing in this rule.

3. Determination of Acceptable Administrative Costs by HMO/CMP Cost Contractors and Health Care Prepayment Plans (HCPPs) (§ 417.564)

We proposed revising the regulations governing payments to health care prepayment plans (HCPPs) authorized under section 1833(a)(1)(A) of the Act and cost HMOs/CMPs authorized under section 1876 of the Act to clarify how we believe the reasonable cost principles in section 1861(v) should apply to HCPPs and HMOs/CMPs by specifying the methodologies that must be used in determining the different allowable administrative costs for both such entities.

Specifically, we proposed revising § 417.564(b)(2) to clarify how HCPP and cost contractors authorized under section 1876 of the Act must determine "reasonable" administrative costs. At § 417.564(b)(2)(iii), we proposed that personnel costs claimed for administrative costs in both HCPP and cost contracts authorized under section 1876 of the Act must be linked to the specific administrative function performed by persons, at a specific rate of pay, for a specified period of time. We also clarified in the proposed rule that this level of information must be available to us upon request or in the course of a review. Additionally, we proposed revising § 417.564 by adding a new paragraph (c) that specifies that, in order for costs to be considered "reasonable costs" within the meaning of section 1861(v) of the Act, which expressly excludes "incurred cost found to be unnecessary in the efficient delivery of needed health services," the following costs must be excluded when computing reimbursable administrative costs:

- Donations.
- Fines and penalties.
- Political and lobbying activities.
- Charity and courtesy allowances.
- Spousal education.
- Entertainment.
- Return on equity.

In the proposed rule we specifically asked for comments on our clarification of reimbursable administrative costs. As indicated below, after considering the comments we received, we are adopting our proposed § 417.564(b)(2)(iii) and § 417.564(c) without further modification in this final rule.

*Comment:* We received two comments that supported the list of costs that we proposed must be excluded by HCPPs and HMO/CMP cost contractors when computing reimbursable administrative costs. The commenters agreed that these costs should not be included in cost reports and that the new provision codifies what they understood to be CMS' existing policy regarding the exclusion of these costs.

*Response:* We agree with the commenters supporting our proposal to exclude the costs described in § 417.564(c) when reimbursable administrative costs are computed by HCPPs and HMO/CMP cost contractors. Accordingly, we are adopting § 417.564(c) without further modification in this final rule.

*Comment:* Two commenters agreed with our proposals to clarify how HCPPs and HMO/CMP cost contractors must determine reasonable administrative costs, and the requirement that this information be available to CMS upon request. However, these commenters wanted CMS to consider the following recommendations with respect to the proposed requirements—(1) providing guidance that would further clarify CMS' expectations about how cost contractors will document this information, including examples of how time should be tracked and how to evaluate the match between skill level and tasks performed; (2) ensuring that the documentation requirements will be reasonable and structured in a manner that is not unduly burdensome to cost contractors; (3) providing cost contractors an opportunity to comment on this guidance before it is finalized to ensure that operational issues can be fully considered; and (4) applying the requirements to cost years following the year in which the regulation is effective.

One of the commenters also recommended that CMS consider modifying this proposal to clarify the meaning of the term "task," and limit the tracking of time for the performance of separate tasks performed by a single individual to circumstances when it is necessary to achieve the objectives of the rule (for example, when the tasks, consistent with CMS rules and policy, have different apportionment statistics). The commenter also suggested that CMS clarify in the final rule that when personnel perform some administrative functions that are included in the administrative and general specified cost areas while performing some administrative functions that are viewed as plan administration, only the time spent on the administrative and general functions should be tracked and documented.

*Response:* We believe that it is important for HCPPs and HMO/CMP cost contractors to have the flexibility to establish their own methodology for determining reasonable administrative costs in order to meet the requirement described in § 417.564(b)(2)(iii); therefore, we are not providing the specific guidance that was requested by these commenters at this time. We intend to provide further sub-regulatory guidance to HCPPs and HMO/CMP cost contractors on issues that would generally impact all HCPPs and cost contractors. We will also provide assistance to individual HCPPs and cost contractors on a case-by-case basis.

4. Calculation of the Minimum Percentage Increase Under Part C (§ 422.306)

In the October 22, 2009, proposed rule, we proposed to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD. As we noted in the preamble to the proposed rule, section 5301 of the DRA added section 1853(k) of the Act to create a single rate book for calculating MA payments and applicable adjustments. Section 5301 of DRA also modified the methodology for updating the MA payment rates by adding section 1853(k)(1)(B) of the Act. Beginning in 2007, the statute requires, for purposes of calculating the minimum percentage increase rate, that the previous year's benchmarks be updated annually using only the national per capita MA growth percentage for the year—as described in section 1853(c)(6) of the Act. Prior to 2007 the minimum percentage increase rate was the greater of 102 percent of the MA capitation rate for the preceding year, or the MA capitation rate for the preceding year increased by the national per capita MA growth percentage for the year.

We noted that since the statute, as revised by the DRA, no longer provides for the 2 percent minimum update, we can no longer apply it to the MA rates. The 2 percent minimum update still applies to the end stage renal disease MA update because the statute at section 1853(a)(1)(H) of the Act provides that ESRD rates are to be calculated in a manner consistent with the way those rates were calculated "under the provisions of [section 1853 of the Act] as in effect before the date of enactment of the MMA." The pre-2003 version of section 1853 of the Act included the 2 percent minimum update. Therefore, we proposed to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD. We are adopting § 422.306(a) as proposed into this final rule.

*Comment:* A few commenters supported CMS's proposed requirement. A commenter believed CMS' interpretation of section 1853(k) of the Act was incorrect and suggested that

CMS retain the 2 percent minimum update requirement and recalculate (and pay) any retroactive payment from prior years (where the 2 percent minimum update would have caused payments to be higher than they would have been in its absence). The commenter contended that section 1853(k)(1)(B) of the Act only removes the minimum percentage increase for years prior to 2004.

*Response:* We disagree with the commenter. Section 1853(k)(1)(B) of the Act is clear in saying that it applies to years subsequent to 2007, in other words, to payment years beginning with calendar year 2008. Section 1853(k)(1)(B)(i) of the Act applies to all payment years other than years in which rebasing is done in accordance with section 1853(c)(1)(D)(ii) of the Act. In rebasing years, the calculation of MA payment rates is determined by section 1853(k)(1)(B)(ii) of the Act where the amount payable is the greater of: Either the amount calculated under section 1853(k)(1)(B)(i) of the Act, the MA payment amount for the previous year increased by the national per capita MA growth percentage; or the amount calculated under section 1853(c)(1)(D) of the Act, which is 100 percent of fee-for-service costs. Further, in section 1853(k)(1)(B)(i) of the Act, we are also required to ignore any adjustment under section 1853(c)(6)(C) of the Act for any year before 2004 when calculating the national per capita MA growth percentage. This adjustment, called the "adjustment for over or under projection of national per capita MA growth percentage," also did not include such an adjustment for years before 2004 when the minimum percentage increase was calculated per section 1853(c)(1)(C)(v) of the Act for years between 2004 and 2006. Finally, the calculation of MA payment increases based on the national per capita MA growth percentage beginning with payment year 2007 were never less than 2 percent. However we note that even if it were, there would be no additional payment due MA organizations on this basis because the 2 percent minimum increase was eliminated beginning with 2007.

*E. Changes To Improve Data Collection for Oversight and Quality Assessment*

This section discusses and finalizes four proposals in our October 22, 2009 proposed rule intended to improve Part C and D data collection and use for oversight and quality assessment. The first proposal would address quality improvement programs and data on quality and outcomes measures under Part C. As part of this proposal, we proposed to address data collected by Quality Improvement Organizations for MA quality improvement and performance assessment purposes.

The second and third proposals would address payment for beneficiary surveys and independent yearly audits of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by us. The last proposal would amend our rules on the collection and use of prescription drug event data for nonpayment-related purposes.

TABLE 5—IMPROVE DATA COLLECTION FOR OVERSIGHT AND QUALITY ASSESSMENT

| Provision | Part 422 | | Part 423 | | Part 480 |
|---|---|---|---|---|---|
| | Subpart | Section | Subpart | Section | |
| Requirements for Quality Improvement Programs under Part C. | Subpart D | § 422.152<br>§ 422.153 | N/A | N/A | § 480.140 |
| Require that Sponsors pay for the Consumer Assessment Health Plan Survey (CAHPS). | Subpart D | § 422.152(b)(5) | Subpart D | § 423.156 | N/A |
| Require validation of reporting requirements. | Subpart D | § 422.516<br>§ 423.514 | Subpart D | § 423.514 | N/A |
| Allow collection of all PDE data elements to be collected for non-payment purposes. | N/A | N/A | Subpart D | § 423.505 | N/A |

1. Requirements for Quality Improvement Programs Under Part C (§ 422.152, § 422.153, and § 480.140)

In our October 22, 2009 proposed rule, under the authority in sections 1851(d)(4)(D), 1852(e)(1) and 1852(e)(3)(A) of the Act, we proposed several new requirements related to quality improvement programs and data on quality and outcomes measures under Part C.

Section 1851(d)(4)(D) of the Act requires us to make available to MA eligible individuals information comparing MA plan options, including information on plan quality and performance indicators to the extent this information is available. Separately, section 1852(e)(1) of the Act requires that each MA organization have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by the MA organization. Section 1852(e)(3)(A) of the Act requires that, as part of this quality improvement program, MA organizations collect, analyze, and report data that permits the measurement of health outcomes and other indices of quality as part of their quality improvement program for their coordinated care plans. To the extent that local PPO, regional PPO, PFFS, and MSA plans have a network of contracted providers, these plan types must meet the same quality improvement requirements as other coordinated care plans. Section 1852(e)(3)(B)(i) of the Act generally limits the collection of data on quality, outcomes, and beneficiary satisfaction under section 1852(e)(3)(A) to facilitate consumer choice and program administration to "the types of data" that were collected as of November 1, 2003.

a. Quality Improvement Programs

In our October 22, 2009 proposed rule, we noted that under our current regulations at § 422.152(c) and § 422.152(d), MA organizations have flexibility to develop criteria for chronic care improvement programs (CCIPs) and initiate any quality improvement projects that focus on clinical and non-clinical areas based on the needs of their enrolled population. However, based on our experience with MA organizations employing inconsistent methods in developing criteria for their CCIPs and quality improvement projects, we expressed concerns in the proposed rule that giving MA organizations complete discretion to establish their own CCIPs and quality improvement projects does

not allow beneficiaries to effectively compare plans and organizations to manage and report projects. More importantly, we expressed concerns that these projects are not addressing quality improvement areas that we believe best reflects beneficiary needs. For example, some projects may be designed to improve processes only, without linking the processes to clinical outcomes. We are interested in MA organizations focusing on individual as well as population-specific health risk needs, such as MA organizations' use of internal data sources to identify clinical outcomes that not only fail to meet national averages, but also may jeopardize the overall health and quality of life of the beneficiary.

As a result of our concerns, we proposed to revise § 422.152(a)(1) and § 422.152(a)(2) to require that MA organizations conduct CCIPs in patient populations, and conduct their required quality improvement projects, in areas identified by CMS based on our review of data collected from MA organizations. Specifically, we proposed to determine what areas would most benefit from quality improvement, and to provide guidance on specific quality improvement projects for MA organizations to implement, either based on those organizations' specific quality improvement needs, or quality improvement needs for MA plans generally. We also proposed suggesting methods and processes by which to manage a quality improvement project as appropriate.

We proposed in the preamble to our October 22, 2009 proposed rule to annually inform MA organizations individually and/or generally which patient populations and areas we have determined would benefit most from a CCIP and quality improvement project, respectively. We would convey generally applicable information via the Medicare Managed Care Manual and the Health Plan Management System (HPMS), and convey information that is plan specific directly to the organizations offering the MA plans in question. We are adopting § 422.152(a)(1) and § 422.152(a)(2) without further modification in this final rule and are clarifying, in our responses to comments below, that MA organizations will continue to have the flexibility to develop criteria for CCIPs and quality improvement projects based on the needs of their enrolled population.

*Comment:* We received many comments that supported our proposals to require that MA organizations conduct CCIPs in patient populations, and quality improvement projects in areas, identified by CMS. Some of these commenters wanted CMS to consider additional recommendations with respect to our proposed requirements, including: (1) Providing an opportunity for public comments as CMS develops priority areas for MA organizations and on the process that CMS will use to identify specific areas for quality improvement with respect to particular MA organizations; and (2) establishing a fixed time period after CMS establishes its CCIP goals during which CMS could not establish new CCIP goals.

*Response:* As we develop our requirements, we will offer opportunities for the industry and other interested parties to offer recommendations. While our goal is to keep any such requirements stable, we note that it may be important for us to modify our requirements in keeping with our goal of ensuring that CCIPs and quality improvement projects address those quality improvement areas we believe reflect beneficiary needs.

*Comment:* Many commenters opposed our proposals to require that MA organizations conduct CCIPs in patient populations, and quality improvement projects in areas, identified by CMS. Some of the concerns commenters raised were: (1) CMS' requirements may not be aligned with MA organizations' identified priorities for benefiting their enrollees; (2) systemic inequities would develop among competing MA plans that would undermine the competitive structure of the MA program; and (3) organizations would lose the flexibility to pursue projects of special clinical and operational value to their enrollees.

*Response:* We agree that CCIPs and quality improvement projects should be based on the needs of the plan's enrolled population, and in line with the organizations' identified priorities for benefiting their enrollees. We will continue to provide MA organizations generally with the flexibility to identify topics for the development of CCIPs and quality improvement projects based on the particular needs of their members. However, we are finalizing the revisions to § 422.152(a)(1) and § 422.152(a)(2) to require that, under certain circumstances, some MA organizations conduct CCIPs in patient populations and quality improvement projects in areas identified by CMS based on our review of data collected from MA organizations and the populations served by the plans.

To date, we have communicated with MA organizations about specific operational areas and member populations for which we believe, based on data collected through HEDIS, audit findings, member complaints, and other survey data, there is a need for CCIP or quality improvement projects development due to performance and/or clinical outcomes. We have offered MA organizations identified through this targeted methodology assistance during our initial communication regarding the need for CCIP or quality improvement project development. Technical assistance for the development of CCIPs and quality improvement projects is also available to all MA organizations on an as needed basis.

Using the HPMS, the Medicare Managed Care Manual, and other means of communication that we determine to be appropriate, we will annually inform MA organizations individually and/or generally of the process by which CCIPs and quality improvement projects must be conducted, which tools to use to report activities, and the time frame for submitting data and reports. We will also use these communication methods to identify the patient populations and areas we have determined would benefit most from CCIPs and quality improvement projects. However, as noted previously, this does not preclude MA organizations from developing CCIPs and quality improvement projects that they independently determine to be needed for their population.

*Comment:* Many commenters suggested alternatives for CMS to consider to its proposed requirements for CCIPs and quality improvement projects. These recommendations generally fell into three groups—(1) CMS should not adopt the proposed policies and should allow MA organizations to develop their own CCIPs and quality improvement projects; (2) CMS should provide general guidance to MA plans on CCIPs and quality improvement projects and develop a process for approving a plan's CCIPs and quality improvement projects prior to the plan implementing them; and (3) CMS should consult industry before making changes to CCIP and quality improvement project requirements.

Some commenters specifically recommended that CMS impose CCIP or quality improvement project obligations on all MA organizations operating within a given geographic area rather than on an MA plan-specific basis and that CMS provide a list of programs and projects for MA plans to choose from and allow plans to select the programs, projects, and populations to which they should apply in order to maximize the benefit to beneficiaries. One commenter suggested that, to address CMS' concern that some plans focus on process, rather than outcomes, CMS focus on those plans, and work with them to identify

more appropriate programs and projects. Another commenter believed that CMS could provide more generalized guidance on the types of measures that are acceptable (for example, the commenter suggested that CMS consider requiring that CCIPs and quality improvement projects link processes to clinical outcomes). Several commenters suggested that CMS consult with experts in the industry to before imposing specific CCIP and quality improvement project requirements on MA plans. One commenter recommended that CMS hold MA organizations accountable for choosing a CCIP based on their own population and data, and prior approve quality improvement project topics and methodologies based on specific quality improvement needs identified by MA organizations. This commenter further indicated that a prior approval process would allow CMS to assist MA organizations in focusing on quality improvement areas that reflect beneficiary needs and include sound methodologies that address clinical as well as process outcomes.

*Response:* As discussed previously, MA organizations will continue to have the flexibility to choose CCIP and quality improvement project topics that meet the needs of their population and operational processes, and we will offer opportunities for the industry to offer recommendations for fine-tuning our CCIP and quality improvement project requirements. We will take into consideration the specific recommendations offered by commenters as we develop future guidance related to CCIPs and quality improvement projects.

*Comment:* Several commenters were concerned that the proposed requirements could impinge on the efforts of MA organizations to satisfy accreditation standards for National Committee for Quality Assurance (NCQA) or other accrediting bodies.

*Response:* MA organizations that participate in the quality improvement deeming program will be subject to the standards of their accreditation organization. We will continue to ensure that standards applied by deeming organizations are at least as stringent as those applied by us.

*Comment:* Several commenters were concerned about special needs plans (SNPs) meeting the proposed requirements. Commenters recommended allowing MA organizations to customize overall quality improvement programs for their specialized populations in chronic care special needs plans (C–SNPs), deeming all the individual model of care and quality improvement initiatives required of C–SNPs to fulfill this requirement, and allowing dual-eligible SNPs (D–SNPs) to implement specific projects for the dual-eligible population. Several commenters were concerned that the CCIP and quality improvement project models that CMS develops may not be appropriate for special needs plans (SNPs) and that some SNPs will face significant challenges meeting State as well as MA requirements in the event that CMS requirements for specific quality improvement topics that differ from State requirements.

*Response:* As discussed previously, MA organizations will continue to have the flexibility to choose CCIP and quality improvement project topics that meet the needs of their population and operational processes. When MA organizations are required to conduct CCIPs in patient populations and quality improvement projects in areas that we identify which are appropriate for SNPs, SNPs will follow the same quality improvement project and CCIP processes identified for other types of MA plans. We will not expect SNPs to employ quality improvement project or CCIP programs that are not appropriate for their population. We note that CMS may use data collected from SNPs to determine if there are population-specific topics that require targeted monitoring in the future.

*Comment:* A few commenters were concerned about the challenges MA organizations would face in allocating additional resources to meet the proposed requirements as well as the potential for increased administrative costs.

*Response:* With respect to commenters' concerns about the additional cost of implementing these requirements, we do not believe that MA organizations will experience significant additional financial burdens as a result of these requirements.

b. New Quality Measures

In our October 22, 2009 proposed rule, we stated that as we strengthen our oversight of quality improvement programs implemented by MA organizations, we believe it is necessary to collect additional data on quality and outcomes measures in order to better track plan performance. We currently collect from MA organizations data on quality, outcomes, and beneficiary satisfaction under the Healthcare Effectiveness Data and Information Set (HEDIS®), the Health Outcome Survey (HOS), and the Consumer Assessment Health Providers Survey (CAHPS). We stated in the proposed rule that we anticipated additional collection and reporting of the same types of data on health outcomes and quality measures that we currently collect as part of these processes.

We also noted that we believed the collection of these data to be consistent with our authority under section 1852(e)(3)(A) of the Act, and that we do not believe that the limitation described under section 1852(e)(3)(B) of the Act limits this proposed additional data collection because the data collected would be of the same "type" of data that we currently collect as part of the HEDIS®, HOS, and CAHPS® processes. In the preamble to the proposed rule, we noted post-surgical infections or patient falls as examples of additional areas on which we planned to collect data. Therefore, we proposed to modify § 422.152(b)(3) and § 422.152(e)(2) to require MA plans to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that plans are currently required to collect and report to CMS. We also proposed that, consistent with the Paperwork Reduction Act (PRA), we would provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements.

We are finalizing our proposal to require MA plans to collect, analyze, and report quality performance data identified by CMS as described in the proposed rule and adopting § 422.152(b)(3) and § 422.152(e)(2) without further modification in this final rule.

*Comment:* A number of commenters supported CMS' proposal to require MA plans to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that plans are currently required to collect and report to CMS. Commenters also supported CMS' proposal to provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements, consistent with the PRA.

*Response:* We agree with the commenters supporting our proposal to require MA plans to collect, analyze, and report quality performance data of the same type of data that plans are currently required to collect and report, that we identify. Accordingly, we have finalized our proposed § 422.152(b)(3) and § 422.152(e)(2) in this final rule.

*Comment:* A few commenters did not support our proposal to require MA plans to collect data on additional quality performance measures. Commenters were concerned about the administrative burden and costs associated with additional data collection and recommended that CMS

use existing quality measures rather than require new measures. One commenter questioned whether additional quality measures beyond the HEDIS, HOS, and CAHPS would be useful since these measures are accepted industry standards. One commenter questioned CMS' efforts to use quality measures to "score" plans, indicating that plans with lower enrollment and more direct control over patient care, for example a closed model HMO, could achieve better measures through more intensive interventions.

*Response:* As the MA program has evolved, attracting an increased number of beneficiaries that present with specialized health concerns, it has become increasingly important for us to focus on developing measures that meet the MA population's needs. We believe that collection of additional data on quality outcomes measures is necessary to better track plan performance in this area. As noted previously, we disagree with commenters that MA plans will experience significant additional financial burden as a result of these requirements.

*Comment:* Commenters provided suggestions on how to identify the measures for which additional collection of quality performance data will be required. Several commenters recommended that we use existing nationally endorsed, clearly specified measures for any new reporting requirements we place on MA organizations, and that the measures be those of national standard setting organizations. One commenter indicated that it would like to work with CMS to see if any of the new measures should be incorporated into HEDIS. Two commenters requested that the new quality measures be measurable through administrative data instead of chart reviews. One commenter supported the examples we provided of new quality reporting requirements we indicated in our proposed rule, specifically, post-surgical infections or patient falls and recommended that the reporting be expanded to all health care acquired conditions (the Medicare "never events") and all infections. Another commenter indicated that additional broad based measures, such as readmission rates, also could provide critical insights on performance. Additionally, one commenter suggested that CMS consult with the Medicare Payment Advisory Commission, which recently finalized recommendations related to quality in the MA program and the measures that could be adopted to compare MA plans to one another as well as to Original Medicare. Some commenters suggested that CMS involve the industry in the development of the new measures for which additional collection of quality performance data will be required.

*Response:* We will identify measures and standards using internal CMS methods as well as nationally recognized methodologies. These measures and standards will be based on the information that is currently collected, as well as any additional data we find to be necessary to collect for this purpose. We have begun a year-long project to research and analyze population specific health outcomes and plan operations data. As an important part of this project, industry leaders, researchers, and individuals with expert knowledge of the Medicare population will be involved in the discussions as we identify appropriate quality measures and standards for the MA program. We plan to use this information to further develop and analyze the effectiveness of the current and future measures associated with health outcomes, operational procedures and processes, and member experience. As indicated in the proposed rule, we will provide the public at least two opportunities for public comment through the PRA process before imposing additional quality-related collection and reporting requirements.

*Comment:* One commenter encouraged us to explore ways to release timely, plan-specific data to third parties to allow them to experiment with different ways to analyze claims data, and underlying plan performance data, to assist consumers with the identification, selection, and use of their MA plans or PDPs based on plan performance or quality attributes.

*Response:* We do not collect claims data from MA and Part D plans. However, we do collect Part D prescription drug event (PDE) data, which is based on claims data submitted by pharmacies to Part D sponsors. These data are available for research purposes, consistent with § 423.505. We are working to provide additional public use files based on PDE data in the future. More information on PDE data for research purposes may be found at *http://www.resdac.umn.edu/Available_CMS_Data.asp.* For the quality and performance data for Part C and Part D plans, we release a database with all of the contract-level individual measures that make up the Part C and Part D plan ratings. These data are available on the CMS Web site at *http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp.*

c. Use of Quality Improvement Organization Review Information

In our October 2009 proposed rule, we asserted that data collected by Quality Improvement Organizations (QIOs) to accomplish their mission represent an important data resource for CMS in our efforts to improve quality under the MA program. QIOs collect survey, administrative, and medical records data in order to monitor and assess provider performance. These data are frequently required by scope of work contracts administered by CMS to assess whether or not QIOs are meeting performance goals.

We discussed several proposed uses of the data collected by the QIOs. For example, certain QIO data could be used to develop a standardized core set of clinical and non-clinical quality and performance measures that could be applied to all MA plans in order to allow beneficiaries to make better comparisons across all MA plan types and make an informed decision when selecting a plan. These measures could also be used to rate plans according to their performance.

We also outlined our plan to develop minimum performance levels and requirements that address clinical and nonclinical areas from the data collected by QIOs, as part of our efforts to provide meaningful information to beneficiaries when selecting an MA plan. In addition to tracking plan performance, these data could also be used to monitor plan compliance with MA contract requirements and support compliance or enforcement actions against plans that are poor performers on certain quality and performance measures. These data would also be appropriate for use in a competitive value-based purchasing program based on quality of care.

Finally, we explained our intent to use one particular type of information already collected by QIOs, that is, quality review study (QRS) information (defined in 42 CFR 480.101(b)) and retool the data elements to make them specific to beneficiaries enrolled in MA plans. A QRS is "an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up." By QRS information, we mean all documentation related to the QRS process. We proposed to obtain from the QIO only the data that relate to MA plan beneficiaries, providers, practitioners, and services and to then aggregate the data applicable to each MA plan based on beneficiary enrollment.

Accordingly, we proposed adding a new § 422.153 to indicate that we would obtain and use quality review study information that is generated, collected, or acquired by QIOs under 42 CFR part 480. We stated our intent to use these data for the following functions:

- Enabling beneficiaries to compare health coverage options and select among them, measuring performance under the plan.
- Ensuring compliance with plan requirements under Part 422.
- Other purposes related specifically to MA plans, as specified by CMS.

We also clarified that we did not plan to disclose any beneficiary identifiable information.

In addition, we proposed amending § 480.140 to add a new paragraph (g), authorizing our use of quality review study information solely for the purposes specified in § 422.153. As described below, we are modifying § 422.153 and § 480.140(g) in this final rule.

*Comment:* A number of commenters were concerned about the use of data collected from QIOs to measure plan performance and recommended that CMS reconsider its proposal. One commenter recommended that CMS discuss current MA experience with QIO studies and the potential future uses of QRS information with plans. Some of the concerns cited by commenters are that—

- There may be inconsistencies among QIOs on their assessments and findings, which may disadvantage some plans. Individual QIOs may offer consistent and reliable data sources, but aggregating data from multiple State-specific entities may dilute the consistency and reliability that would be required to accomplish CMS' proposed uses;
- Some MA organizations have experienced delays in the receipt of QIO study findings; therefore, the organizations do not have timely notice of any deficiencies and are not able to use the findings in their quality improvement activities. The delay in dissemination of findings may not be sufficiently timely for CMS' intended purpose;
- Depending on the QIO, there is often a substantial lag in the availability of QIO data. Current MA performance assessment should not be assessed based on data that are 2 or 3 years old; and
- There may be additional burden placed on deemed plans that do not submit to the QIOs so that the data could be all inclusive from the QIOs.

Commenters recommended that CMS clarify whether plans that are already deemed by NCQA would also be required to send additional information to their QIO to comply with the proposed regulation. One commenter indicated that the use of QIO review information would be administratively burdensome and duplicative of current reporting measures such as HEDIS.

*Response:* We share the concerns raised by commenters about the inconsistency and timeliness of the data collected by QIOs. These concerns relate to QIO review of beneficiary quality of care concerns, medical necessity reviews, appeals, and other case reviews.

After reviewing these comments, we have discovered that the data that will be needed to meet the functions described in § 422.153 is not collected from QIO case reviews. Instead, hospitals report this information to us as part of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, which is authorized under section 1886(b)(3)(B)(viii) of the Act. Much of this data is self-reported by hospitals on a quarterly basis, and some is validated for accuracy. Further, the data does not possess any of the timeliness and reliability issues cited by the commenters. Hospitals self-report patient-level quality measure data for patients covered by MA plans, Original Medicare, and other payors to CMS for the RHQDAPU program.

In response to the comments we received, we are narrowing the scope of our proposed § 480.140(g) to provide that QIOs must disclose to us QRS information collected as part of the RHQDAPU program following hospital review of the data (with identifiers of MA plan beneficiaries, hospitals, practitioners, and services) when we request this information for the sole purpose of conducting activities related to MA organizations as described in § 422.153. We believe that restricting our access to include only RHQDAPU hospital quality data that we may use for the functions described in § 422.153 will address the concerns about the timeliness and reliability of this data. We are also modifying § 422.153 to indicate that we will acquire RHQDAPU data from QIOs and may use it for the limited functions described in § 422.153. As proposed, we do not plan to disclose any beneficiary identifiable information. We also do not plan to disclose any provider or practitioner identifiable information.

*Comment:* Many comments supported our proposal to obtain and use QRS information that is generated, collected, or acquired by QIOs. Commenters also supported CMS's proposal to use these data to enable beneficiaries to compare health coverage options and select among them, measure performance under the plan, and ensure compliance with plan requirements under Part 422, and other purposes related specifically to MA plans as specified by CMS. Commenters agreed that CMS should not plan to disclose any beneficiary identifiable information.

Some of these commenters asked CMS to consider additional recommendations with respect to our proposals. Some of the recommendations were that CMS should ensure that an adequate sample of QIO data for dual eligibles is reviewed; allow plans to review the information the QIO intends to submit to CMS in order to give plans the opportunity to correct errors; ensure appropriate procedures are available for plans that may dispute the data that CMS intends to make available to beneficiaries before those data are released; provide ample notice to plans of the specific data that CMS intends to collect to allow for programming and testing of data collection tools prior to submission to CMS; and make Original Medicare data available to beneficiaries, where available, along with MA plan data.

One commenter indicated that CMS should develop a methodology to stratify the data so that MA organizations would be grouped by local or regional MA organizations, and defined by statewide or selected geographic areas such as number of counties within a State, benefit design, and plan type. This commenter also indicated that data provided to beneficiaries would be misleading if CMS compared all MA organizations in a State without classifying these organizations by type and service area.

*Response:* As we refine our work plan for using the data collected under section 1886(b)(3)(B)(viii) of the Act (RHQDAPU data) for the functions described in § 422.153, we will consider these commenters' recommendations to ensure we achieve our goals of providing meaningful information to beneficiaries, developing minimum performance levels and requirements that address clinical and non-clinical areas from the data collected by QIOs, and ensuring plan compliance with MA contract requirements.

*Comment:* Commenters recommended that CMS ensure that the measures it develops are based on nationally endorsed measures, are collected in a uniform fashion, and have large enough sample sizes to support public reporting as well as any value based purchasing decisions. One commenter recommended that CMS specify that

plans will have multiple opportunities to comment on any performance measures proposed for the MA program.

*Response:* We will identify measures and standards using internal CMS methods as well as nationally recognized methodologies. The process for developing measures based on data collected by the QIOs is not subject to the PRA review process since it does not represent a new data collection requirement for MA plans.

2. CAHPS Survey Administration Under Parts C and D (§ 417.472, § 422.152, and § 423.156)

In the October 22, 2009 proposed rule, under the authority of sections 1857(e)(1), 1860D–12, and 1876(i)(3)(D) of the Act to impose additional contract requirements that the Secretary finds "necessary and appropriate," we proposed to revise the regulations to require that MA organizations, Part D sponsors, and section 1876 cost contractors would pay for the data collection costs of the annual CAHPS survey beginning in 2011. As we noted in the preamble to the proposed rule, in the 2010 Call Letter to Part C and D sponsoring organizations, we informed all MA and Part D contracts with at least 600 enrollees as of July 1 of the prior calendar year that they would be expected to pay for the data collection costs of the CAHPS survey starting with the administration of the 2011 annual CAHPS survey. The proposed rule set forth this requirement in regulations at § 422.152 for Part C, § 417.472 for section 1876 cost contracts, and § 423.156 for Part D.

The proposed rule would require only MA organizations, Part D sponsors, and section 1876 cost contractors with 600 or more enrollees to pay for the data collection costs of the CAHPS survey. For reasons of statistical precision, a target minimum of 300 or more completed Medicare CAHPS Surveys must be received for each contract. In order to obtain 300 or more completed surveys, we determined that plans would need to have 600 or more enrollees because some enrollees will not be eligible to receive the survey, such as institutionalized enrollees, and not all enrollees selected to be surveyed will respond to the survey.

In making this proposal, we noted that we conduct other Medicare quality surveys, such as the Hospital CAHPS and the Medicare Health Outcomes Survey (HOS) for which the MAOs are responsible for the cost of the data collection, and that this model for data collection is standard industry practice. For example, Federal Employees Health Benefit (FEHB) plans pay for the administration of the CAHPS survey to their members. Under our proposal, Part C & D contractors and section 1876 cost contractors would select a vendor from a CMS list of approved vendors to conduct the survey on their behalf. We also noted that this change would provide the sponsoring organizations with the flexibility of adding their own questions to the Medicare CAHPS survey.

We also noted that the first survey using the new model of data collection would be conducted in early 2011. Contracts that were in effect on or before January 1, 2010, would use the number of enrollees in a plan as of July 1, 2010 to determine whether they are required to conduct the 2011 CAHPS survey. In late 2010, all MA and Part D contracts that are subject to the CAHPS survey requirement in 2011 would need to select an approved Medicare CAHPS survey vendor to administer the survey.

Finally, we noted that, in addition to approving a list of survey vendors to conduct the survey on behalf of all MA and Part D contracts, we would select the sample of enrollees to be surveyed for each contract, approve survey vendors, provide oversight of survey vendor activities, analyze the CAHPS data for plan ratings, and produce individual-level reports for quality improvement use by MA and Part D contracts. Vendors will be trained by CMS to collect and submit data within specified timeframes.

After reviewing the comments received in response to this proposal, we are adopting the proposed CAHPS data collection requirements as final. However, we are revising § 417.472 and § 422.152 to clarify the distinction between cost contracts under section 1876 and coordinated care plans. Specifically, the revised wording is: "All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with specifications and submit the survey data to CMS."

*Comment:* CMS received comments concerning the proposed requirements for Part C and D contracts regarding the CAHPS survey. A few commenters noted that CMS did not provide any estimate of, or other information related to, the costs associated with collection of data for the CAHPS survey, asserting that this information is necessary in order to appropriately account for the costs in their annual bid submissions.

*Response:* We respectfully disagree. Both the estimated CAHPS costs and burden were addressed in the proposed rule. As stated therein, the estimated mean annual cost per contract is approximately $5,000 for MA organizations, cost contracts, and Part D sponsors with more than 600 enrollees for the CAHPS annual survey. (74 FR 54711). Data collection is to be performed by a contractor hired by the MAO or Part D sponsor.

*Comment:* A few commenters noted that proposed § 422.472(i) would require section 1876 cost contractors to contract with approved CAHPS survey vendors to conduct the Medicare CAHPS satisfaction survey for "MA plan enrollees." However, they assert that cost plans do not have MA plan enrollees. Moreover, cost plans are not "coordinated care plans," which is a term that describes certain MA plans. The commenters recommend that CMS delete the references to coordinated care plans and other MA references.

*Response:* We appreciate the commenters' suggestions and are revising § 417.472 and § 422.172 as follows: "All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with specifications and submit the survey data to CMS."

*Comment:* Several commenters expressed approval and support for CAHPS, applauding CMS's efforts to provide enrollees with consumer-tested, standardized information about plan choices. The commenters also support changes that will increase data collection, provide beneficiaries with additional information with which to make plan comparisons, and overall improve quality of plans.

*Response:* We appreciate these commenters' support of our quality efforts.

3. Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

In the October 22, 2009 proposed rule, under the authority of sections 1857(e)

and 1860D–12 of the Act, we proposed to amend § 422.516 and § 423.514 to state that each Part C and Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by us.

Additionally, in the preamble we noted that our rationale for making this proposed change, which was also announced in the 2010 Call Letter to Part C and D sponsoring organizations, was that only an independent data validation audit conducted by an external entity under contract to the MAO or PDP sponsoring organization would ensure that the results of the audit are in accordance with CMS specifications, that data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable. We noted that we were working with a contractor to develop data validation specifications to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the data validation audit. We intend that these specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify the sponsor's calculations, computer code, and algorithms. In addition, the specifications will be used to inform CMS as to how the MAOs, cost plans, and Part D sponsors collect, store, and report data. We expect that these specifications will be utilized by the auditors hired by MAOs and Part D sponsors to conduct the data validation audits, the results of which will be forwarded to us. We indicated that we expected to make these specifications available on our Web site for public comment early in 2010. We solicited comment on this approach.

Subsequent to publication of the proposed rule, in an HPMS memorandum dated December 23, 2009, we noted that after careful review of the reporting requirements and CMS' continued data needs, the amount of data required to be reported to CMS for CY 2010 and contract years contract beyond was to be reduced. We noted that the reason for the reduction in reporting was that some of the data could be derived from other means (that is, through analyses of prescription drug event data already collected by CMS). We believe these adjustments reduce the overall burden on sponsoring organizations while maintaining the integrity of the CMS data collection, plan reporting, and plan validation processes so that needed data for monitoring and public reporting are timely, reliable, valid, and comparable among organizations. Specifically, the following changes became effective January 1, 2010:

- Part C Reporting Requirements

++ Reporting of the Agent Compensation and Agent Training and Testing measures will be suspended.

++ The frequency of reporting of two Part C measures will be reduced.

— Only annual reporting for Plan Oversight of Agents will be required; the quarterly reporting will be suspended.

— Only annual reporting for Employer Group Plan Sponsors will be required; the semiannual reporting will be suspended.

++ Validation of PFFS Provider Payment Dispute Resolution and PFFS Plan Enrollment verification calls will not be required.

- Part D Reporting Requirements

++ Reporting of five sections will be suspended: Vaccines, Generic Drug Utilization, Transition, Drug Benefit Analyses, and Agent Training and Testing.

++ The frequency of reporting of six Part D sections will be reduced as follows:

— Only annual reporting for Employer/Union-sponsored Group Health Plan Sponsors, Fraud, Waste and Abuse Compliance Programs, Long Term Care (LTC) Utilization, and Medication Therapy Management Program (MTMP) will be required; the semi-annual reporting will be suspended.

— Only annual reporting for Plan Oversight of Agents and P & T Committees/Provision of Part D Functions will be required; the quarterly reporting will be suspended.

++ Validation of eight sections will not be required: Enrollment, Access to Extended Days.

— Supply, Prompt Payment by Part D Sponsors, Pharmacy Support of Electronic Prescribing, P&T Committees/Provision of Part D Functions, Pharmaceutical Rebates, Discounts and Other Price Concessions, Licensure & Solvency, and Fraud, Waste and Abuse Compliance Programs.

We are also excluding PACE organizations from CY 2010 Part D Reporting Requirements, which is consistent with Part C Reporting Requirements.

These changes will be incorporated in the final CY 2010 Part D Reporting Requirements document and the Part C and D Reporting Requirement Technical Specifications documents, which will be updated and posted to our Web site. The data validation standards will also be updated and provided for comment as part of a PRA package in 2010. We note that these changes do not affect our proposal to require an annual independent audit of Part C and Part D measures. Rather, because these changes reduce the amount of data that must be submitted by plan sponsors, they will make the data validation audits somewhat less time-consuming.

After considering the comments received in response to the proposed rule, in this final rule, we adopt the requirements as proposed.

*Comment:* Several commenters argued that plans need information regarding the data validation requirement in a timelier manner to allow for consideration during preparation of the 2011 bids. They also noted that CMS should provide plans with sufficient information and time to modify their operations to incorporate any new requirements prior to the data validation mandates taking effect.

*Response:* With this final rule, we believe that we are providing plans with information in sufficient time to allow for consideration in their 2011 bids. A regulatory impact analysis for this proposed requirement was included in the October 22, 2009 proposed rule. The proposed rule also contained the information collection requirements. Plans should be able to use the burden and cost estimate information to develop an estimate of any increase in resources and costs associated with the implementation of these provisions. Additionally, two HPMS memoranda were released this fall: Part C and Part D reporting requirements and data validation dated November 23, 2009 and Implementation changes in the Medicare Part C and Part D Reporting Requirements and Data Validation dated December 23, 2009. These memoranda contain detailed, updated information on changes in implementation of the data validation requirement. The first memorandum clarified the timing of implementation (that is, the data validation needs to occur in the spring of 2011 for reported 2010 data), while the second memorandum reduced the overall data validation and reporting requirements for Part C and Part D measures.

*Comment:* While one commenter supported the implementation of the data validation audit requirements for 2011, others recommended we delay codifying the data validation audit requirement. They argued that codifying the requirement before the process has

been evaluated and finalized is premature and will take away CMS' flexibility to refine the requirements as it gains experience with the process. The commenters were also concerned that the validation mechanisms are very preliminary and should be vetted through the subregulatory process. They noted that the validation approach stipulated in the proposed regulation places the full cost burden of the audit on the health plan. One commenter specifically recommended that the proposed new paragraphs (g) be revised by striking Each Part C [Part D] sponsor must and inserting instead, CMS may require each Part C [Part D] sponsor to * * * and strike independent audit and insert audit.

*Response:* We disagree with the recommendation to delay codifying the data validation audit. We have begun evaluating the data validation audit process and will have completed a pilot evaluation by May 2010, that is, approximately 10 months before the implementation of the data validation audits. Therefore, we believe we will have sufficient time to perform any needed refinements of the requirements well before actual implementation of the data validation process. We strongly believe that it is important to have the data validation audit process in place by 2011 since there is a need to monitor the Part C and D programs effectively and to respond to questions from Congress, oversight agencies, and the public with data that are timely, reliable, valid, and allow for comparisons among plans.

We also disagree that the data validation audit requirements should be provided only in subregulatory guidance. We proposed to implement these requirements through notice-and-comment rulemaking in order to ensure that, if they were adopted, they would be enforceable with the full force and effect of law. Detailed procedures for meeting the regulatory requirements will be provided through sub-regulatory guidance and will also undergo the PRA process. As a result, we believe we will retain sufficient flexibility to make necessary changes before the requirements are implemented as well as to update the procedures in the future as necessary. We further believe that it is necessary to conduct the data validation audit on all plans so that there is assurance that all the data are reliable, valid, and can be used to compare health plan performance. If we find through the data validation audit process that some plans are not reporting accurate data, then it will be possible to take this factor into account when reporting plan performance and in comparing performance among plans.

*Comment:* Several plans expressed concern that the cost of implementing the data validation audit will be high or excessive.

*Response:* We do not agree that the costs of implementing the data validation audit will be excessive. In the October 22, 2009 proposed rule (74 FR 54711), we estimated that the costs of these independent audits would be approximately $5,200 per plan. Because the costs on a per plan basis are not excessive, they will likely be reflected in only minimally higher bid prices across the board.

*Comment:* Two commenters stated that plans should have the option of using their own internal auditing staff.

*Response:* We disagree that plans should have the option of using their own internal auditing staff in lieu of an independent, external auditor. The data validation needs to be credible to stakeholders, including Congress and the American public. We believe that only an external independently conducted audit can establish this credibility.

*Comment:* One commenter requested clarification as to whether CMS intends to issue a list of certified contractors from which an organization may select a vendor. This commenter also recommended that the validation and testing of a plan's compliance with Fraud, Waste, and Abuse (FWA) programs regulations include the use of a certified fraud investigator.

*Response:* At this time, we do not expect to issue a list of certified contractors from which an organization may select a vendor to conduct data validation audits. Instead, we will be issuing standards for selected vendors. A draft of these standards was issued for informal comments last fall and a revised version will be issued with the PRA package associated with the data validation specifications that will be available for public comment. We also note that the commenter's second recommendation is likely in reference to a CMS program audit. Because this proposal relates to a data validation audit, we do not believe that plans should be required to use a certified fraud investigator.

*Comment:* One commenter stated that flexible criteria should be considered in the data validation audit's report specifications, that is, CMS should consider using flexible criteria in developing the specifications for the data validation report.

*Response:* We agree that the criteria used in developing the specifications for the data validation report should accommodate different types of reportable data that a plan collects for each Part C and D measure. We believe that the standards and procedures under development for the data validation effort provide sufficient flexibility to accommodate different types of available reportable data.

*Comment:* One commenter states that any final rule on data validation requirements should take into consideration the plan's state regulatory requirements and the plan's processes required to comply with state mandates, laws, and regulations and consider deeming in areas of overlap.

*Response:* We appreciate that plans may also have state reporting requirements with respect to licensure and solvency. We believe, however, that deeming with respect to issues subject to state reporting requirements is outside the scope of this proposal, which is to require an independent data validation audit of information reported to CMS.

*Comment:* One commenter questioned whether CMS needed to define performance benchmarks so plans can manage and monitor data before they are submitted to CMS.

*Response:* We will be defining the data validation standards prior to the data validation audit. Performance benchmarks relevant to these standards will be made available prior to the data validation audit.

*Comment:* One commenter offered to review the measures on behalf of CMS and explore ways for including them in the HEDIS measurement set and audit program.

*Response:* Although we appreciate the commenter's interest in this issue, we are not committing to the inclusion of the new Part C and D measures as part of the HEDIS measurement set and audit program at this time.

4. Collection of Additional Part D Claims Elements for Nonpayment-Related Purposes (§ 423.505)

In the October 22, 2009 proposed rule, we proposed to use the authority under section 1860D–12(b)(3)(D) of the Act to collect all additional elements added to the prescription drug event (PDE) record beyond the original 37 elements currently collected under section 1860D–12(b)(3)(D) of the Act. As a result, we would be able to use these data elements for nonpayment-related purposes.

As we explained in the preamble to the proposed rule, section 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) of the Act, provides the Secretary with authority to include in Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate, including

requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. We noted that under this authority, in the May 28, 2008 **Federal Register** (73 FR 30664), we published a final rule that allowed the Secretary to collect Part D "claims" data from the prescription drug event (PDE) record and use the information gathered for non-payment purposes. However, this rule limited what data (hereinafter referred to as PDE elements) we may collect and use for nonpayment purposes to the original 37 elements reported on the PDE record. The rule also described circumstances under which we may disclose the data to other government and external entities, and the limitations associated with any such release.

In the October 2009 proposed rule, we also noted that in 2008 the number of PDE elements collected was expanded from the original 37 elements to 39 elements. The additional PDE elements are "Rebate Amount Applied to the Point-of-Sale Price" and "Vaccine Administration Fee." The "Rebate Amount applied to the Point-of-Sale Price" is generally the standard amount of a rebate that the plan sponsor has elected to apply to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale. The "Vaccine Administration Fee" is the amount charged for the administration of a vaccine separate from the actual vaccine.

In the 2010 Call Letter to Part C and D sponsoring organizations, we noted that we were planning to make mandatory the collection of a new (40th) element to the PDE record, referred to as the "Prescription Origin Code." (at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf*). The prescription origin code is designed to capture the frequency with which providers use e-prescribing.

Under our proposal, we would be able to utilize these data for non-payment related purposes. Similarly, we would be able to release these elements to governmental and external entities, under the authority of section 1106 of the Act, using the same process that we now use to release the original 37 elements, namely our minimum necessary data policy, our data sharing procedures, and the encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors.

Our proposal would allow us to collect and use for non-payment-related purposes any data obtained as a result of the addition of new elements to the PDE record without undertaking rulemaking for each additional element added in the future. We believe that the May 28, 2008 Part D Claims Data final rule (73 FR 30664) resolved any statutory ambiguity surrounding our broad authority to collect PDE data under section 1860D–12(b)(3)(D) of the Act. Accordingly, we may use this same authority to collect additional elements that have been added to the PDE record since 2007. Once data have been collected under section 1860D–12(b)(3)(D) of the Act, we may use these data for nonpayment-related purposes and may release PDE data consistent with our minimum necessary policy and our data sharing procedures.

We also noted in the preamble to the proposed rule that we believe the ability to analyze new claims-related elements added to the PDE record will increase both specific and general knowledge of Medicare beneficiaries' healthcare and the operation of the Part D program and would aid our ability to conduct program oversight, support operational tasks, and provide more information for use in internal and external healthcare research studies. Moreover, as a result of the proposal, we would not be required to undertake a separate rulemaking and public comment process each time new elements are added to the PDE record, but rather would automatically begin collecting for nonpayment purposes elements added to the PDE record using our authority under section 1860D–12(b)(3)(D) of the Act and § 423.505(f)(3) of the regulations. However, because we did not propose any change to our data sharing procedures or our minimum data necessary policy, we will continue to—

- Ensure that beneficiary, prescriber, or pharmacy identifiers are not released unless absolutely necessary for a project (for example, to link to another database);
- Encrypt Part D plan identifiers and aggregate cost data elements (ingredient cost, dispensing fee, and sales tax) when sharing PDE data with external requesters; and
- Subject each request to our data sharing procedures which includes ensuring that requestors have the appropriate experience and are working for, or on behalf of, a reputable institution and that, when appropriate, make their project results public. External requests concerning beneficiary identifiable data would continue to be reviewed by the CMS Privacy Board, and would require the requestor to sign a data use agreement.

We also noted our current policy of protecting various Part D elements when responding to external research requests. Thus, the beneficiary ID, plan ID, prescriber ID, and pharmacy ID are encrypted prior to release to external entities. However, in the case of beneficiary ID, prescriber ID, and pharmacy ID, this information may be provided in an unencrypted format when needed to link to another data set. In contrast, under the current rule, there is no exception to the requirement that plan identifiers be encrypted for all external research requests. Under the current regulation, grantees of HHS agencies are treated as external entities and may not access plan identifiers. However, contractors acting on behalf of HHS are not considered to be external entities and may receive unencrypted plan identifiers when necessary for a particular project.

Because some HHS agencies accomplish their mission through grants, rather than contracts, and hence cannot rely on the access that is provided to HHS contractors and the fact that research performed by HHS grantees will advance the interests of Medicare beneficiaries, who may also be served by other HHS programs, we proposed to revise § 423.505(m)(iii)(C) to permit CMS disclosure to HHS grantees of unencrypted plan identifiers when certain conditions are met. The conditions we proposed to be met include—

- The plan identifier is essential to the study and there is no other source of CMS data that would substitute for plan identifiers in order to carry out the study;
- The study is key to the mission of the sponsoring agency;
- The study provides a benefit to the Medicare program; and
- The requestor attests that any public findings or publications will not identify plans or plan sponsors.

In evaluating requestors' proposals to determine whether these conditions are met, we propose the following evaluation standards:

- Plan identifier, we will evaluate the requestor's rationale to determine whether an encrypted plan identifier would be sufficient for the study design or if the real identifier is necessary for the study.
- Agency mission, we will review the requestor's agency's rationale for the study and how the study would help the agency achieve its mission.
- Medicare program benefit, we will review the requestor's rationale for the importance of study findings to the Medicare program.
- Public reporting, we require an attestation from the requestor that the requestor will not identify specific plans

or plan sponsors in any public reporting.

In the proposed rule, we indicated that we believed that these conditions would mitigate the risk of unauthorized use or disclosure of commercially sensitive plan information. We also solicited comments on whether it would be appropriate to extend the proposal to permit grantees of other Federal agencies to have access to plan identifiers when this access may be necessary for a particular research project and that project otherwise meets the conditions described above. After considering the comments received in response to our proposals, we are finalizing the proposed changes to § 423.505(f) and (m) without modification.

*Comment:* Some commenters questioned CMS' authority to share PDE data for non-payment purposes given the limiting language in section 1860D–15 of Act. One commenter alleges the approach outlined in the proposed rule would result in a potential violation of the Trade Secrets Act. Another commenter mentioned that section 1927(b)(3)(D) of the Act protects pricing, rebates and other financial information from disclosure except to very specific recipients (such as CBO or the Comptroller), which does not extend to HHS grantees. One commenter does not want the release of rebate data, estimated or otherwise, stating that rebates at point of sale reflect proprietary business information.

*Response:* We respectfully disagree with the commenters' assertions. In the May 28, 2008 **Federal Register** (73 FR 30664), we published a final rule regarding the collection and use of Part D claims data. This regulation resolved the statutory ambiguity between sections 1860D–12(b)(3)(D) and 1860D–15 of the Act, noting that section 1860D–12(b)(3)(D) of the Act (and its incorporation of section 1857(e)(1)) of the Act) provide broad authority to the Secretary to require Part D sponsors to provide the Secretary with "such information as the Secretary may find necessary and appropriate" and that when information is collected through a statutory authority independent of section 1860D–15 of the Act, the restrictions of section 1860D–15 of the Act would not apply. Following the issuance of this Part D claims data final rule, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 181 of MIPPA added clause (ii) to section 1860D–12(b)(3)(D) to provide that any Part D data collected under the authority of section 1860D–12(b)(3)(D) "shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title." While section 181 of MIPPA did not directly address the issues of statutory ambiguity associated with Part D claims data collected by CMS, it can be read as an implicit Congressional ratification of the arguments presented by CMS, in the Part D claims rule, as the legislation only overrides one provision of that rule. Specifically, under section 181 of MIPPA the Secretary must make data collected under section 1860D–12(b)(3)(D) available to Congressional support agencies, without regard to CMS' minimum data necessary standard. Accordingly, for reasons detailed in our May 29, 2008 final rule, we believe the restrictions of section 1860D–15 of the Act do not apply to PDE data collected under the authority of 1860D–12(b)(3)(D) of the Act. As a result, these data may be used for purposes other than payment.

In response to concerns about releasing proprietary data to external entities, we note that this rule pertains to additional elements added to prescription drug event data and does not extend to plan bid or reconciliation payment data provided outside of the PDE. Because PDE data are collected under section 1860D–12(b)(3)(D), rather than section 1860D–2(d)(2), they are not subject to the limitations on disclosure under section 1927(b)(3)(d). In addition, as we explained in the May 28, 2008 final rule (73 FR 30680), because § 423.505(m) was issued under the authority of section 1106 of the Act, any release of potentially proprietary data pursuant to this provision would be also be authorized by law under the Trade Secrets Act. Furthermore, we also note that rebates applied at point of sale are not the same as aggregate rebates estimated by plans as part of their bid or actual rebates received from manufactures that are submitted outside of the claim for payment reconciliation purposes. Rather, they most often reflect a standard amount that the manufacturer is providing to a particular sponsor for a specific drug that is then passed through to consumers as part of the plans' price at point of sale, the net amount of which is available to beneficiaries as an estimate on the drug plan finder tool. We also remind commenters that we place certain limitations on PDE data when released outside of CMS. Through the application of our "minimum data necessary policy," additional restrictions to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, and our data sharing procedures (which ensure the agency's compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Act of 1974, and other applicable laws), we limit the use and disclosure of Part D claims data to ensure that the data are only used or disclosed as permitted or required by applicable law, and not inappropriately disclosed in a manner which could undermine the competitive nature of the Part D program.

*Comment:* We received a number of varied comments on the sharing of PDE data. Several commenters provided recommendations related to the sharing of Part D PDE information for non-payment purposes, suggesting that CMS—

- Use only non-identifiable information for any public analysis, arguing that research can be done without an actual plan ID;
- Exclude data elements that could because of geographic information, and/or other aggregated information indirectly identify plan sponsors; and
- Share information (especially plan IDs, or PHI) *only* with written approval from the sponsor and publish guidance well before adding another element *to* the PDE format.

Another commenter stated that despite the restrictions in sharing plan IDs, certain plans could easily be identified. A few other commenters stated that CMS has no specific restrictions in the regulation protecting price information.

*Response:* We believe these comments are outside of the scope of the proposed rule, which was issued not to reopen our May 28, 2008 final rule on Part D claims data but rather to address the use and disclosure of additional PDE data elements beyond the original 37 elements that were the subject of the May 28, 2008 final rule. To the extent the comments are applicable, we disagree with the recommendations on using only aggregate data and obtaining written plan approval prior to use of the PDE data. Our rationale is the same as the one we expressed in response to a similar comment to the May 28, 2008 final rule on Part D claims data: if PDE data are collected only under the authority of section 1860D–15 of the Act CMS, HHS and external entities can never use the data for evaluations, analyses, and research important to public health, and vital to program oversight. In the Part D claims data final rule we provided a detailed description

of the potential purposes for which these data might be used, including evaluating the effectiveness of the prescription drug benefit and its impact on health outcomes, performing Congressionally mandated or other demonstration and pilot projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs. Balancing these important objectives with the potential sensitivity of PDE data, we implemented a rule that ensures that, subject to many safeguards put in place to guard against inappropriate use and disclosure of commercially sensitive and beneficiary identifiable information, Part D PDE data are available for research purposes under similar data sharing processes to those used for sharing Parts A and B claims data. While we agree with the commenter that in some situations, even if we provide samples of PDE data with masked plan identifiers, public information may be added to the PDE record to identify the particular plan, we believe that our data sharing procedures mitigate against any inappropriate use or disclosure. Under these procedures, we require each researcher to sign a Data Use Agreement (DUA) that spells out the multiple restrictions on the use of the data and the penalties for any failure to comply with the terms of the agreement. In addition, we require research using beneficiary identifiable data to be conducted by an experienced entity at a reputable organization, with an appropriate research design, and with assurances to protect beneficiary confidentiality. Research is to be made available to the public and identifiable data is not released for commercial purposes. Further we will only release beneficiary identifiable data for research purposes if the CMS privacy board approves the data release and then, will only release the minimum data necessary for the study. We believe these procedures allow us to safely balance the need to support legitimate research while at the same time guarding against the misuse or inappropriate disclosure of data that is sensitive in nature.

*Comment:* A commenter asked to what extent are PDE data uses and disclosures subject to requests under the Freedom of Information Act (FOIA).

*Response:* Requests for Part D PDE data should be directed through our contractor, the Research Data Assistance Center, at *http://www.resdac.umn.edu/,* as opposed to FOIA. However, as noted in our May 28, 2008 final rule on Part D claims data, if a FOIA request is received for PDE data used for non-payment purposes, we will follow our ordinary FOIA procedures and not release under FOIA data the agency determines are trade secrets, or commercial or financial information protected by FOIA Exemption 4 (5 U.S.C. 552(b)(4).

*Comment:* Commenters opposing the rule pointed out that it does not place any perimeters on the type of additional data CMS may classify as claims data, and thereby make available for disclosure. The commenters expressed concern that nothing in the proposed regulation would require confidentiality of rebate and pricing information if it were collected under section 1860D–12 of the Act.

One commenter also questioned CMS' conclusion that we could use section 1860D–12(b)(3)(D) of the Act to collect new elements to the PDE record without undertaking rulemaking for each additional element added in the future.

*Response:* We reiterate that our authority to collect PDE elements for non-payment purposes has already been decided with the clarification of our authority under 1860D–12(b)(3)(D) of the Act, as set forth in Medicare Part D Claims Data rule published on May 28, 2008. Because that final rule was expressly limited to the 37 original elements of the PDE claim, it was necessary for us to undertake further rulemaking in order to collect new elements that have been added to the PDE record. Rather than proposing to collect only the 3 new elements that have been added to the PDE record since 2007, we concluded that it was appropriate to propose to collect all elements that are currently part of the PDE record or that may be added to the PDE record in the future. As we stated in the preamble to the October 22, 2009 proposed rule, we believe that the ability to analyze new claims-related elements added to the PDE record would increase both specific and general knowledge of Medicare beneficiaries' healthcare and the operation of the Part D program and would aid in our ability to conduct program oversight, support operational tasks, and provide more information for use in internal and external healthcare research studies. These rationales apply not only to the collection of the 3 new PDE elements that have been added since 2007, but also to the collection of any new elements that may be added in the future. Furthermore, the addition of more PDE elements beyond those that are currently collected is at the Secretary's discretion and will be diligently reviewed and accorded the proper protection consistent with the principle outlined in the May 28, 2008 final rule. Plan sponsors will be notified of any changes to the collection of PDE data through the CMS Call Letter to Part D plan sponsors, or via HPMS memoranda. Therefore, we do not believe it is necessary to undertake a separate rulemaking to authorize CMS, to use section 1860D–12 of the Act to collect each new element that we may add to the PDE record in the future.

*Comment:* Some commenters opposed sharing the Plan identification element from the PDE record in an unencrypted form with HHS grantees expressing concern about the data security and the need to protect sensitive data, and arguing that encrypted data should satisfy most research needs. Other commenters supported the PDE data sharing provisions in the proposed rule, with some supporting a proposed option in the preamble of the proposed rule that would also permit grantees of non-HHS Federal agencies access to plan identifiers. One commenter supporting the rule asked that we go further and with proper restrictions allow access to plan identifiers to all legitimate researchers.

*Response:* After the Part D Data rule was published in May 2008, we limited the use of actual plan identifiers, but after gaining experience in releasing Part D data it soon became apparent that there was a compelling need for other HHS (such as FDA and NIH) agencies to use plan identifiers in their linking, oversight and research (for example, influence of brand name recognition, and benefit design on consumer choice) under certain conditions. These agencies cannot possibly conduct all of their own research. Accordingly, they engage grantees to perform approved studies. These studies often assist CMS in better understanding and improving the Medicare program. Furthermore, HHS is able to affect more oversight of its own grantees through the threat of future withdrawal of funding—a great disincentive for researchers—should any terms of the data use agreements be broken (as opposed to a study independently funded by a University). Therefore, with this final rule we are permitting access to plan identifiers HHS grantees for nonpayment purposes when the following conditions are present:

- The plan identifier is essential to the study and there is no other source of CMS data that would substitute for plan identifiers in order to carry out the study;

• The study is key to the mission of the sponsoring agency;

• The study provides a benefit to the Medicare program; and

• The requestor attests that any public findings or publications will not identify plans or plan sponsors.

While we believe that similar benefits may accrue to grantees of non-HHS entities and to many external researchers conducting studies of beneficiary plan choices, we believe that additional time is needed to evaluate this issue. Therefore, for now, we will limit the exception to the prohibition against releasing unencrypted plan identifier elements to external entities in § 423.505(m)(1)(C) to HHS grantees at this time.

*Comment:* One commenter asked for clarification on whether or not CMS intended to allow unencrypted data to be transmitted to requesters of data. The commenter had concerns with regard to potential risk of violation of the security rules under HIPAA.

*Response:* We ensure that any data transmission is done only after undergoing an approval process that requires requesters to detail their security procedures during transmission, storage of and access to Part D data.

*Comment:* Another commenter wanted clarification as to whether the fields discussed in the proposal had already been added to the PDE layout.

*Response:* We note that the vaccine administration fee and the rebate at point-of-sale were added to the original 37 elements for CY 2008, and that in the 2010 Call Letter we notified sponsors that a 40th element, Prescription Origin Code, collected on an optional basis in 2009, would be part of the mandatory reporting requirements beginning January 1, 2010.

*Comment:* A commenter asked about downstream entities, noting that the rule does not specify who may have access to this sensitive data.

*Response:* We share the commenter's concerns over the re-release of data to entities not included on the DUA. Under our current data sharing procedures, researchers or other external entities wishing to re-release Part D data must notify us and receive express permission for any subsequent release, with appropriate modifications made to any DUAs.

*F. Changes To Implement New Policy*

This section addresses two policies under Parts C and D respectively. Under Part D, we proposed new regulatory requirements pertaining to the required inclusion of protected drug categories and classes on Part D formularies. While our proposals initially were intended to implement provisions in section 1860D–4(b)(3)(G) as in effect at the time of our October 22, 2009 proposed rule, since that time on March 23, 2010 section 3307 of the PPACA was enacted.

Rather than specifying statutory criteria for identifying protected classes of drugs, as did section 1860D–4(b)(3)(G)(i) of the Act at the time of the proposed rule, section 1860D–4(b)(3)(G) of the Act now provides that the Secretary shall establish criteria for determining "classes of clinical concern" and until such time as the Secretary establishes such criteria, the following six classes of drugs shall be protected: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. As there are many provisions in the PPACA affecting Medicare Part D beneficiaries, we believe it is important to take some time to thoughtfully consider how best to establish appropriate criteria. As such, and in accordance with 1860D–4(b)(3)(G) of the Act, we are protecting the six statutorily-specified drug classes and categories of drugs of "clinical concern" and will turn in the future to consider the criteria the Secretary would issue under the statute.

Under Part C, we proposed to revise our rules to allow beneficiaries who elect MSAs as a type of health insurance plan to pay only a pro-rated deductible if their MSA deposit is pro-rated because they enroll after January 1. These revisions are detailed in Table 6.

TABLE 6—REVISIONS TO IMPLEMENT NEW POLICY

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Provide Criteria and a Process for identifying Protected Classes of Drugs. | N/A ..... | N/A | Subpart C ..... | § 423.120(b)(2)(v) |
| Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period. | Subpart C ..... | § 422.103 | N/A ..... | N/A |

1. Protected Classes of Concern Under Part D (§ 423.120(b)(2)(v))

In the October 22, 2009 proposed rule, based on comments that we received on an earlier January 16, 2009 interim final rule with comment period (IFC) (74 FR 2881), we proposed criteria and procedures for identifying "protected classes" of drugs, within which all covered Part D drugs must be included in Part D formularies. While we had previously identified six such classes under our authority in section 1860D–11(e)(2)(D) of the Act to ensure that formularies were not discriminatory, section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act which required the Secretary, effective plan year 2010, to address the issue of protected classes and undertake to identify classes of drugs that met two criteria specified statutory criteria:

• Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class.

• There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class.

Under section 176 of MIPPA, the Secretary was provided discretion to establish exceptions permitting Part D sponsors to exclude from their formularies, or to otherwise limit access to (including utilization management restrictions or prior authorization), certain Part D drugs in the protected categories and classes. Section 176 of MIPPA required that such exceptions be subject to a public notice and comment process.

In the October 22, 2009 proposed rule, we proposed interpreting several of the statutory terms used in the criteria set forth in section 176 of MIPPA to better define the scope of the protections afforded under that section. To that end, we proposed to add several new definitions at § 423.100, including: "restricted access," "major or life-threatening clinical consequences," "significant need for access to multiple

drugs," "a short period of time," and "multiple drugs." Further, we proposed that the MIPPA protections did not apply to non-Part D drugs and their exclusion from the formulary requirements would not be based on the exceptions authority under section 1860D–4(b)(3)(G)(iii) of the Act.

We also proposed to add a new paragraph to § 423.120(b)(2) to identify exceptions to the inclusion of all drugs meeting the criteria set forth in section 176 of MIPPA and our implementing regulations. Under proposed § 423.120(b)(2)(vi), exceptions would include the following:

- Drug products that are determined to be therapeutic equivalents under the FDA's Orange Book.
- Edits that limit the quantity of drugs due to safety.
- Other drugs that we may specify through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents) and which permits public notice and comment. We welcomed comment on these proposed definitions and clarifications.

Finally, we noted in the preamble to the October 22, 2009 proposed rule that we continue to believe that the best way to determine which drug classes and categories should be identified as a protected class and category is through a data-driven process, which includes an analysis of prescription drug event data, a review of widely used treatment guidelines, validation of the results by a expert committee of clinicians, and acceptance by the Secretary.

We also offered two approaches for consideration, and solicited comment on which option the public believed would allow us to make timely determinations in a transparent manner. Those options were—

- *Option 1:* Announce protected classes through subregulatory guidance (for example, the Call Letter) that provides a notice and comment process but does not entail formal **Federal Register** notice and comment rulemaking; and
- *Option 2:* Announce the protected classes through formal notice and comment rulemaking.

Since issuance of the October 22, 2009 proposed rule, the PPACA was enacted. Accordingly, new section 1860D–4(b)(3)(G) of the Act replaces section 176 of MIPPA. Section 1860D–4(b)(3)(G) of the Act requires a PDP sponsor to include "all" covered part D drugs in the categories and classes identified by the Secretary as classes and categories of "clinical concern." It requires the Secretary to establish criteria to determine, as appropriate, categories and classes of drugs of "clinical concern." It provides for an exceptions authority similar to the one included in section 176 of MIPPA. Section 3307 of PPACA further requires that until the Secretary establishes criteria to determine classes of "clinical concern," the following categories and classes of drugs shall be identified and protected as classes of "clinical concern": anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

Given that PPACA was recently enacted and there are many provisions affecting Medicare Part D beneficiaries, we need time to thoughtfully consider how best to establish criteria to identify classes and categories of drugs of "clinical concern." Accordingly, consistent with the PPACA, at this time we are requiring that PDP sponsors include all covered part D drugs in the following categories and classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. This requirement will be in effect for plan year 2011 and until such time as we undertake additional notice-and-comment rulemaking to establish the criteria for identifying classes and categories of drugs of "clinical concern." Continuing to protect the current six classes of "clinical concern" will ensure that beneficiaries will continue to have access to the medications they need and will not experience a disruption in care. We note that PPACA requires that sponsors cover "all" Part D drugs rather than "all or substantially all" as required under section 30.2.5 of the Prescription Drug Manual.

Consistent with this approach, we have decided to adopt, in regulatory text, neither the criteria we proposed in the October rule which were specified by MIPPA for identifying classes and categories of drugs of "clinical concern," nor the definitions used to interpret the MIPPA criteria. However, we are retaining the exceptions process in the regulatory text, as new Section 1860D–4(b)(3)(G) of the Act retains the exceptions process established under MIPPA.

*Comment:* Several commenters expressed opposition to our exception that inclusion of "all covered Part D drugs" on formulary from a protected class or category does not extend to the inclusion of all brand-name drugs and generic versions of a covered drug in question. They argue that this exception is inconsistent with other CMS formulary requirements, namely our midyear formulary change policy for which they argue that CMS makes it clear that a brand-name drug and its generic counterpart are different "drugs" for the purpose of submitting formulary changes. In addition, one commenter expressed concerns about different exceptions in therapeutic equivalent products, stating that some may not provide the same benefit in the physician's judgment.

*Response:* We disagree with the commenters' arguments. It is important to distinguish our formulary change policy from the definition of a "drug" for the purpose of explaining therapeutic equivalence. For the protection of beneficiaries who may experience cost sharing changes, we require that when a new generic equivalent is released into the market and a plan sponsor proposes to add the new generic to its formulary and remove the brand-name drug, we approve the change and notice be sent to affected beneficiaries to make them aware that a generic equivalent is available and that there may be a change in their cost-sharing if they continue to take the brand-name.

For the purpose of formulary submission to us, our regulations specify at § 423.120(b)(2)(i) that two therapeutically equivalent drugs cannot be used to satisfy our requirement that there be at least two drugs per category and class on formulary. Contrary to the commenters' assertions, we believe this existing formulary requirement is consistent with our proposal in that both standards acknowledge that therapeutically equivalent products are the same drug. Further, as stated in our January 28, 2005 Part D final rule (70 FR 4260), inclusion of "all covered Part D drugs" within a class or category of clinical concern does not extend to inclusion of all brand-name drugs and generic versions of the covered drug in question. The Orange Book, published by the FDA, is a widely accepted standard for determining therapeutically equivalent drugs within the same class/category (*see http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm*). Therefore, we disagree that our policy stating that inclusion of "all covered Part D drugs" on formulary from a protected class or category does not extend to the inclusion of all brand-name drugs and generic versions of a covered drug in question is somehow inconsistent with other formulary policies.

Finally, with regard to the one comment that some therapeutically equivalent drugs may not provide the same benefit in the physician's judgment, we note that a beneficiary, working with his or her physician, may pursue an exception if they believe that a drug considered to be a therapeutic equivalent is not providing the same benefit as the brand drug originally prescribed.

*Comment:* Several commenters oppose the application of any utilization management edit applications for protected class drugs. Other commenters contended that our proposal undermines the benefits of formulary and utilization management processes. A few commenters in particular oppose our exception for drugs "with very limited applicability to the Medicare Part D population and non-Part D drugs" to be included on formulary under the regulatory protected classes provision, arguing that if a drug fits the criteria, it should be protected.

*Response:* We disagree with these commenters. Consistent with the definition of a Part D drug under § 423.100, we do not require inclusion on formularies those drugs that are paid for under Part B (for example, "incident to" drugs supplied and administered by physicians during patient visit and paid for under Part B), and drugs whose regulatory status under the definition of a Part D drug is unknown. To do so when they are not payable under Part D would lead to beneficiary confusion. Therefore, we are maintaining this policy in this final rule.

*Comment:* A few commenters expressed concern over CMS's proposal permitting the use of utilization management processes that limit the quantity of drugs under protected classes due to safety. One commenter argues that this policy would create a significant opening for plans to expand "restrictive policies" and that CMS should be clear on what we mean by safety edit. The commenter asserted that it is important for CMS to further define what a valid safety edit is and to specifically link it to prevention of imminent harm to the health of the beneficiary. Another commenter asserted that the safety of any course of drug therapy is a clinical concern and it is critical for utilization controls not to interfere with appropriate clinical decisionmaking. This commenter notes that the imposition of safety-based quantity limitations—even where well-intentioned—may harmfully interfere with patient needs if his or her clinical context is not fully taken into account. The commenter suggested that in evaluating safety-based exceptions, CMS should not rely only on information contained in the package insert, but should also consider clinical trial data and accepted standards of care.

*Response:* We have been clear on what is meant by a safety edit. As indicated in section 30.2.2.1of Chapter 6 of the Medicare Prescription Drug Manual (*see http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf*), safety edits refer to point-of-sale (POS) edits implemented to satisfy concurrent drug utilization review (DUR) requirements set forth in § 423.153(c)(2). Examples include screening for therapeutic duplication, age or gender-related contraindications, over-utilization, under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse. For the protection of beneficiaries, we continue to believe that the protected classes provision must not interfere with this POS DUR to help ensure that adverse events do not occur. We believe that such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. To the extent that an individual's clinical needs require a quantity greater than permitted under the FDA labeling, we believe that the exceptions process is the appropriate vehicle for resolution of such cases. Finally, in response to the comment that permitting the use of safety edits would create a significant opening for plans to establish restrictive policies, we disagree. Rather, our guidance is clear that edits need to conform to FDA labeling. To the extent that a plan sponsor would establish safety edits that were more restrictive than FDA labeling contrary to our guidance, we would likely uncover such edits through complaints or through a review of exceptions and appeals data and would instruct the plan to revise its processes immediately.

*Comment:* A commenter requested that CMS clarify what is meant by "scientific evidence" and specify how the use of such evidence would be validated with respect to CMS' proposed language that we may identify other exceptions "through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents) and which permits public notice and comment)." Another commenter urged CMS to establish any exception to the inclusion of all drugs and biologicals in a protected category or class only when warranted by scientific evidence and medical standards of practice, and only after a notice and comment period.

*Response:* We will undertake future rulemaking to identify additional exceptions, as necessary. Further, where appropriate, we will provide the citation for the supporting scientific evidence and medical standards of practice to support our findings. We note that an example of scientific evidence may include information contained in the FDA drug approval records or may include evidence referenced in widely-used treatment guidelines, such as those approved by the Agency for Healthcare Research and Quality (AHRQ).

2. Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period (§ 422.103)

In the October 22, 2009 proposed rule, we proposed to revise the regulations to provide for the pro-rating of the plan deductible under an MA MSA plan in the case of enrollments occurring during an initial coverage election period at a time other than the beginning of the year. As we noted in the preamble to the proposed rule, section 1851(a)(2)(B) of the Act provides that Medicare Advantage Medical Savings Account (MSA) plans are a type of MA plan that a MA-eligible Medicare beneficiary can elect to receive his or her Medicare Part A and B benefits. An MSA plan combines both a tax advantaged Medical Savings Account (MSA) and a high-deductible health insurance policy. Under this MA plan option, Medicare pays the MA organization offering the MA plan the premium amount charged by the organization for a high-deductible insurance policy and the remainder of the MA payment amount is deposited in the enrollee's MSA. If an individual enrolls in such a plan midyear, under section 1853(e) of the Act, a pro-rated share corresponding to the number of months remaining in the calendar year is placed into the individual's savings account. However, as provided under § 422.103(d) beneficiaries newly eligible for Medicare who enroll in MSAs midyear pursuant to an initial coverage election period (ICEP) are currently required to pay the full "high deductible" for the calendar year. For example, an enrollee whose 65th birthday is in May and who chooses to enroll May 1 will be given 8/12ths of the deposit that has been approved for the plan for the year, but this enrollee is required to pay the full deductible approved for the plan for the

entire calendar year. An enrollee whose 65th birthday is later in the year could enroll, for example, on September 1 and would receive a pro-rated deposit representing only 4/12ths of the year; however, this enrollee would also be required to pay the full calendar year deductible.

The deductible under an MSA plan is governed by section 1859(b)(3)(B) of the Act, which specifies the maximum amount of what the statute refers to as the "annual deductible" under an MSA plan. In the October 22, 2009 proposed rule, we proposed to infer from the statute's use of the term "annual" that the deductible amount at issue was intended to apply to a full 12-month period, and thus to specify in a proposed revised § 422.103(d) that an individual who enrolls in an MSA plan under an ICEP other than at the beginning of the calendar year would only be subject to that portion of the "annual" deductible corresponding to the number of months in which the individual is enrolled. Interested beneficiaries would be able to inquire with organizations sponsoring MSA plans about their options prior to enrollment, and, upon enrollment, would receive a confirmation of enrollment letter that would inform them of both their pro-rated deposit amount and their pro-rated deductible. As the result of our review and consideration of commenter support for our proposal, we are modifying § 422.103(d) in this final rule to provide for a pro-rated deductible in the case of any beneficiary enrolling in an MSA plan after January 1, not just an enrollment pursuant to an ICEP.

*Comment:* A commenter supported as "positive" our proposal to "revise the regulations to specify that beneficiaries who enroll in a Part C MSA during the year" be required to "pay only a pro-rated deductible consistent with a pro-rated deposit."

*Response:* While the commenter's point in support of the policy rationale for our proposed revision to § 422.103(d) was made in the context of our proposal to pro-rate deductibles for beneficiaries who enroll after January 1 under an ICEP, the commenter's point in support of symmetry between a pro-rated deposit and a pro-rated deductible would apply to any situation in which a beneficiary enrolls in an MSA plan after January 1. It is noteworthy that the language in section 1853(e) of the Act limiting the Medicare payments to months in which the individual is enrolled is not limited to a late enrollment under an ICEP. We thus believe that the symmetry supported by the commenter should apply in all cases of midyear enrollment in an MSA plan. For example, a beneficiary who receives a special election period for relocating, and enrolls in a MSA plan after January 1, should be required to pay only a pro-rated deductible. Therefore, we are modifying § 422.103(d) in this final rule to allow all beneficiaries who enroll in a MSA plan midyear to pay a pro-rated deductible.

### *G. Changes to Clarify Various Program Participation Requirements*

This section addresses proposals from the October 22, 2009 proposed rule that would either clarify existing regulations or implement new requirements consistent with existing policy guidance, to assist MA organizations with and PDP sponsors in attaining the goals envisioned by the Congress when the legislation implementing the Medicare Advantage and Prescription Drug Benefit programs was first passed. These clarifications are detailed in Table 7.

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Clarify what we mean by uniform benefits. | Subpart C | § 422.100(d) | Subpart C | § 423.104. |
| Ensure security of protected health information and other personally identifiable information. | Subpart K | § 422.504 | Subpart K | § 423.505. |
| Require plans to report other payer information to support coordination of benefits (COB). | Subpart C | § 422.108 | Subpart C | § 423.464. |
| Visitor/Traveler Benefit under Part C for the Purpose of Extending Enrollment up to 12 Months. | Subpart B | § 422.74 | N/A | N/A. |
| Codify authority to establish (MTM) Program requirements. | N/A | N/A | Subpart D | § 423.153(d). |
| Clarify Pharmacy & Therapeutics (P&T) Committee requirements. | N/A | N/A | Subpart C | § 423.120. |
| Generic equivalent disclosure. | N/A | N/A | Subpart C | § 423.132. |
| Application of access standards at application level. | N/A | N/A | Subpart C | § 423.120. |
| Standard Timeframe for coverage determinations. | N/A | N/A | Subpart M | § 423.568. |
| Clarify Novation requirements. | N/A | N/A | Subpart L | § 423.551. |

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS—Continued

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Cost Contract Program revisions: Appeals and Marketing Requirements. | Subpart O | § 417.428<br>§ 417.492<br>§ 417.494<br>§ 417.500<br>§ 417.640 | N/A | N/A. |

1. Uniform Benefits Under Parts C and D (§ 422.100(d) and § 423.104(b))

In the October 22, 2009 proposed rule, we proposed to revise § 423.104(b) to mirror the language at § 422.100 to specify that Part D sponsors apply uniform premiums and cost-sharing. As we noted in the proposed rule, section 1852(d)(1)(A) of the Act requires a MA organization offering a plan to select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan's service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. Section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean access to standard or actuarially equivalent prescription drug coverage and access to negotiated prices (in accordance with section 1860D–2(d) of the Act). We codified these sections of the statute in our regulations at § 422.100(d) and § 423.104(b) prior to the proposed rule, but believed that § 423.104(b) should be further clarified in regards to the PDP sponsor's imposition of uniform premiums and cost sharing. In this final rule, we adopt this provision as proposed with a minor revision.

*Comment:* One commenter is concerned about how the uniform requirement would be applied in unusual circumstances that may not be in the enrollee's best interests. For example, the commenter asked what would happen if an enrollee has already paid the applicable cost sharing amount once, but by no fault of the beneficiary, the drug is either no longer usable, or available because of a natural disaster. Waivers should be considered in these special circumstances.

*Response:* The circumstance the commenter refers to is more appropriately addressed by our emergency access policy and not by a revision to, or waiver of, the uniform benefit requirement. Our emergency access policy is currently provided in Chapter 5 of the Medicare Prescription Drug Benefit Program Manual and outlines our expectations of Part D sponsors when administering the Part D benefit during a natural disaster or public health emergency.

2. Ensuring the Security of Protected Health Information (PHI) and Other Personally Identifiable Information (§ 422.504 and § 423.505)

In our October 2009 proposed rule (74 FR 54690), we specified that we interpret the Secretary's right to audit or inspect the facilities of MAOs and Part D sponsors to monitor compliance with MA and Part D program regulations as including the evaluation of compliance with our requirements for maintaining the privacy and security of protected health information (PHI) and other personally identifiable information of Medicare enrollees. In order to clarify our policy that beneficiaries' PHI and other personally identifiable information must remain secure, we proposed to revise § 422.504 and § 423.505 to make this interpretation explicit. In a related change, we proposed to clarify that we interpret the term "facilities" to include an MAO's or Part D sponsor's computer or other electronic systems. We proposed to implement these proposed changes at § 422.504(e)(1)(ii) and § 423.505(e)(1)(ii). We also proposed conforming changes to the contract requirements related to downstream entities at § 422.504(i)(2)(i) and § 423.505(i)(2)(i), respectively. We noted in the preamble to the proposed rule that we may review systems and computer information generated by downstream and related entities for compliance with privacy and security requirements. Such information includes, but is not limited to, backup tapes, print outs of screen shots, CDs, and similar information, whether in the possession of a downstream or related entity or obtained from such entities by the MAO or Part D sponsor. We are adopting the revisions to § 422.504 and § 423.505 as specified in the proposed rule.

*Comment:* Several commenters supported the proposed provisions with one commenter suggesting that CMS draw upon its expertise in evaluating and assessing plan compliance with personal health information-related requirements.

*Response:* We appreciate the suggestion and will consider this as we develop any additional guidance on PHI-related requirements.

*Comment:* A commenter questioned CMS' authority to request backup tapes and computer-generated information held by pharmacies as part of CMS' review of privacy/security of PHI requirements. The commenter writes that tapes and computer data can contain information beyond that normally submitted by plans and which is often unrelated to a pharmacy's Part D contract. If CMS is, in fact, asking for information outside of that provided as part of the pharmacies' contracts with Part D plans or claims data that pharmacies routinely submit, the commenter requests that CMS clarify its authority for doing this.

*Response:* Although we have the authority to review information generated in connection with the downstream or related entity's contract with an MAO or Part D sponsor, including information related to compliance with privacy and security requirements, it has never been our intent to review documents or information unrelated to a pharmacy's or other downstream or related entity's Part C or Part D contract.

3. Requirement for Sponsoring Organizations Under Parts C and D to Report Other Payer Information to the Coordination of Benefits Contractor (§ 422.108, § 423.462, and § 423.464)

In the October 22, 2009 proposed rule, under the authority of sections 1852(a)(4) and 1860D–2(a)(4) of the Act, we proposed to require the reporting of other coverage information in § 422.108 for MA organizations and § 423.462 and § 423.464 for PDP sponsors. Our rationale for proposing these changes was the importance of the other payer information for Medicare Seconday Payer (MSP) procedures and for prescription drug program coordination of benefits. We proposed to limit required reporting to that information

which is reported to the sponsor as being inconsistent with existing information on the COB file.

As we noted in the October 22, 2009 proposed rule, MA organizations are responsible for identifying payers that are primary to Part C of Medicare, determining the amounts payable by those payers, and for coordinating the benefits the plan offers with the benefits of such payers. Additionally, MA organizations must take into account Part C costs that could have been recovered or avoided due to MSP when determining costs in the base period for purposes of their MA plan bids. MA organizations must account for Part C MSP amounts in one of three ways. MA organizations must—

- Recover from liable third parties;
- Avoid Part C costs by directing providers to bill liable third parties directly; or
- Account for Part C costs that could have been recovered or avoided, but that were actually not recovered or avoided, by not including them in Part C base period costs.

MA organizations and PDPs are required to follow the same rules regarding—

- Their responsibilities under the MSP statutory and regulatory provisions;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

A Part D sponsor must also coordinate with SPAPs, as well as other drug plans, including Medicaid programs, group health plans, FEHBP, military coverage, and other plans or programs providing prescription drug coverage. To support the required benefit coordination, section 1860D–2(b)(4)(D)(ii) of the Act permits Part D sponsors to request information on third party insurance from beneficiaries. In addition, we noted that the growing number of CMS data sharing agreements with other payers has improved the volume and quality of other payer information available to MA organizations and prescription drug sponsors on the COB data file provided by CMS. New mandatory insurer reporting of MSP group health plan coverage, liability insurance, no-fault insurance, and workers' compensation, required by section 111 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (P.L. 110–173) (MMSEA), further expands the other payer information available for MA organization and PDP MSP procedures and for Part D sponsor COB (see 42 U.S.C. 1395y(b)(7) and (8)). Most insurers will need to report their own coverage already. It is only when an MA organization becomes aware of coverage that is primary to Medicare offered by another insurer that it will need to report under this rule.

Accordingly, given the importance of the other payer information to MA organization and PDP MSP procedures and for prescription drug program coordination of benefits, we proposed to include in regulatory text the requirement that MA organizations and Part D sponsors, upon being notified of credible new information regarding other payers, or changes to existing other payer information, report this information to the CMS COB Contractor (COBC) in accordance with the processes and timeframes established by us. The proposed changes would change the requirement on MA organizations, but would not change current MSP and coordination of benefits policy for the prescription drug program.

We noted that by "credible" we mean information that is consistent with conventions for how group health insurance coverage is identified, for instance, information that includes the name and address of the insurance company and the policy identification number. We also proposed to extend the reporting requirements to MA organizations as they relate to other primary payers. We noted that original Medicare, MA organizations, or Part D sponsors should never be reported to CMS as a "primary" payer. In the absence of another (that is, non-Medicare) primary payer, original Medicare, an MA organization, or a Part D plan are always primary. This is not to say that if an enrollee has primary individual or employer group coverage with the same insurer or organization through which they also have MA or Part D coverage, such primary coverage should not be reported. In fact, such coverage must be reported. However, reporting original Medicare, an MA or Part D plan themselves as primary serves no purpose and merely causes confusion.

After reviewing the comments received in response to the proposed rule, we are adopting § 422.108(b)(3) and § 423.462(b) as proposed.

*Comment:* A commenter supported CMS' proposed Part C reporting requirement. Another commenter requested that we revise the new regulatory language to reference the fact that we will only require MAOs and PDPs to report "credible" new information and that CMS either revise the regulatory language or mention in the preamble discussion to the final rule that we will only require reporting on information that is inconsistent with that in the COB data file.

*Response:* In this final rule, we are reiterating that the portion of the preamble discussion in the proposed rule related to the requirement to report only MSP and COB information that is inconsistent with existing information on the COB data file. We have also repeated the preamble discussion of what we mean by "credible" new information and confirmed that we only expect MAOs and PDPs to report such "credible" new information to the COBC. We have not modified the regulatory language since we believe it is unnecessary to do so. However, we have added § 423.464(h), which we inadvertently omitted from the proposed rule. Operational guidance, in the form of our implementing instructions, will be consistent with preamble language in both the proposed rule and this final rule.

*Comment:* One commenter pointed out the apparent discrepancy between the 30-day timeframe for reporting credible MSP/COB information to the COBC we mentioned in the preamble of the October 2009 proposed rule, and the 45-day timeframe for correcting discrepancies in MSP status (with an additional 10 days to submit corrections) discussed in Chapter 5 of the MSP Manual. The commenter requested that CMS retain the existing 45-day timeframe, with an additional 10 days for submission to the COBC.

*Response:* As noted in the preamble of the proposed rule, section 50.2 of the Coordination of Benefits chapter of the Medicare Prescription Drug Benefits Manual (CMS Publication # 100–18, Chapter 14, last updated in September 2008) provides for reporting within 30 days of receipt and can be accessed on the Internet at: *http://www.cms.hhs.gov/prescriptiondrugcovcontra/12_PartDManuals.asp.*

We will consider this comment as we develop operational guidance related to the reporting of MSP information related to Part C by MAOs. However, we note that the timeframe for reporting MSP status in section 10.1 of Chapter 5 of the MSP manual is actually *the lesser of* 10 calendar days from completion of the evaluation or 45 calendar days from receipt.

*Comment:* A commenter asked if the requirements in § 422.108 and § 423.462 apply to only MA plans, or if these requirements also apply to Group Health Plans.

*Response:* The regulations at § 422.108 apply to MA organizations, while the regulations at § 423.462 apply

to both MA organizations offering Part D benefits as MA–PDs and free standing PDPs. Information on the rules related to Group Health Plan reporting of insurance coverage required by section 111 of MMSEA can be found on the following Internet Web site: *http://www.cms.hhs.gov/mandatoryinsrep/.*

*Comment:* A commenter noted an inconsistency between the preamble and the regulation language. The commenter stated that CMS seems to have failed to include regulation language at § 423.464 requiring Part D sponsors to report new or changed supplemental prescription drug coverage information.

*Response:* In the preamble of the proposed rule, we indicated our intention to revise § 423.464 to include a new requirement for Part D sponsors to report new or changed other prescription drug coverage information to the CMS COB Contractor. However, due to an oversight, the regulatory language for this requirement was not included in the proposed rule. However, the preamble discussion of this proposed requirement put interested parties on notice that we were considering imposing a new requirement on Part D sponsors to report new or changed prescription drug coverage information to the CMS COB contractor. Furthermore, we continue to believe that this reporting requirement is necessary to support the effective coordination of prescription drug benefits. Accordingly, we are including this new requirement at § 423.464(h) in this final rule.

4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending Enrollment Up to 12 Months (§ 422.74)

In the October 2009 proposed rule, we proposed to revise our requirements for MA visitor/traveler benefits under Part C. Section 422.74(d)(iii) currently provides that an MA plan can offer a "visitor" or "traveler" (V/T) type program which would allow its enrollees to remain enrolled in the MA plan while out of the plan's service area for up to 12 months. Although we stated in the preamble of the final rule in which § 422.74(d)(iii) was promulgated (August 22, 2003 (68 FR 50848)) that the visitor or traveler program must cover the "the full range of services available to other members," we did not specify in regulation text what we intended by "full range of services."

In order to clarify an MA organization's obligation to cover services out of the service area, we proposed to amend § 422.74(d)(4)(iii) to specify that an MA organization may offer an extended enrollment V/T benefit option under an MA plan if that plan furnishes all plan covered services, that is, Medicare Parts A and B services and all mandatory and optional supplemental benefits at in-network cost-sharing levels consistent with Medicare access and availability requirements at § 422.112. Under this proposed clarification, MAOs that offer a V/T benefit under an MA plan would be required to make the option available to all plan enrollees. We proposed that the V/T benefit must be available to all plan enrollees who are temporarily in the areas where the V/T benefit is offered for the 6 to 12 months the member may remain in the area and stay enrolled in the MA plan. We are adopting our proposed revision to § 422.74(d) (4) (iii) without further modification in this final rule.

*Comment:* A few commenters supported our proposed revisions to the V/T benefit requirements. They indicated that currently there is confusion surrounding the V/T benefit, and many beneficiaries have found the benefit does not provide them with access to Medicare-covered services they expected to have when outside their plan's network.

One commenter supported providing Medicare-covered services under the V/T benefit, but opposed our proposed requirement to also include optional supplemental benefits. The commenter believed that this change would require organizations to adjust plan premiums and could ultimately impact an organization's decision to offer optional supplemental benefits if a plan is not able to develop and meet network access requirements in the areas in which it intended to offer the V/T benefit.

Another commenter objected to the fact that the proposed revisions are less flexible than the existing rules governing V/T benefits and opposed the proposed requirement to provide supplemental benefits under the V/T benefit. The commenter indicated that it may be more feasible for MA organizations to enter into arrangements with providers in other areas of the country to provide access to Medicare-covered benefits than supplemental benefits. The commenter recommended that CMS defer incorporating the proposed changes into the MA regulations and instead issue draft sub-regulatory guidance for public comment.

*Response:* We agree with the commenters supporting our proposal to require MA organizations that offer a V/T benefit under an MA plan to furnish all plan-covered services (Medicare Parts A and B services and all mandatory and optional supplemental benefits) at in-network cost sharing in the areas where the V/T benefit is offered. We note that it is optional for MA organizations to offer a V/T benefit and that a V/T benefit gives MA organizations the flexibility to retain their members when they are outside the service area for extended periods of time when they might otherwise be required to disenroll them for residing outside the service areas for more than 6 months. We do not agree that supplemental benefits should be excluded from a V/T benefit. Since MA organizations will receive full capitation payments for enrollees that reside outside the plan's service areas for more than 6 months, we believe that requiring the plan to cover all plan-covered benefits will allow the enrollees to continue to realize the complete benefit package for which they enrolled in the plan. An MA organization that is not able to form a network of direct contracted providers to furnish supplemental benefits may, with CMS approval, allow its enrollees to obtain these services from non-contracted providers in the areas in which it offers the V/T benefit. We are therefore retaining our proposed changes to § 422.74(d)(4)(iii) in this final rule.

5. Medication Therapy Management Program Requirements (§ 423.153)

In the October 22, 2009 proposed rule, we proposed to codify our policy guidance regarding medication therapy management programs (MTMPs) in the Part D regulations at § 423.153. As we noted in the preamble to the proposed rule, based on the experience garnered from the first few years of the Part D program, and as we await further development of MTMP outcomes measures that can serve the Part D program, we have determined that it is necessary to have more specific Part D MTMP requirements for enrollment methods, targeting procedures, and MTM services. The 2010 Call Letter included policy guidance regarding the implementation of MTMPs that reflected common practices among Part D MTMPs that were derived from extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informational interviews with Part D sponsors, and other relevant literature and data. In the proposed rule, we indicated that codifying this MTM guidance in the Part D regulations would promote greater consistency across the Part D program, and allow for better evaluation and comparison of MTMPs when outcomes measures become available.

Specifically, in accordance with sections 1860D–4(c)(1)(C) and 1860D–4(c)(2) of the Act, we proposed to add the following regulatory requirements regarding MTMPs—

- Section 423.153(d)(1)(v) to require Part D sponsors to enroll beneficiaries in their MTMPs using only an opt-out method of enrollment. The opt-out method of enrollment is currently the preferred method of enrollment among Part D sponsors, used by approximately 85 percent of current MTMPs, and has increased enrollment of targeted beneficiaries into MTMPs;
- Section 423.153(d)(1)(vi) to require Part D sponsors to target beneficiaries for enrollment in the MTMP at least quarterly during each plan year. Currently, more than 95 percent of Part D sponsors target beneficiaries for enrollment in their MTMPs on a daily, weekly, monthly, or quarterly basis; and
- Section 423.153(d)(1)(vii) to require Part D sponsors to offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both beneficiaries and prescribers; annual comprehensive medication reviews; and quarterly targeted medication reviews.

In addition, we proposed to revise § 423.153(d) to clarify which beneficiaries should be targeted for MTMP services.

In this final rule, based on the public comments we received in response to the proposed rule, we adopt these provisions with some modification, as explained below. Specifically, at § 423.153(d)(2)(iii), we adopt a specific dollar threshold of $3,000 in incurred annual costs for covered Part D drugs, instead of, as proposed, relying on the Initial Coverage Limit (ICL) as the threshold at which plans must target beneficiaries for MTM services. The $3,000 cost threshold will be indexed using the annual percentage increase in average per capita aggregate expenditures for Part D drugs, which is found in § 423.104(d)(5)(iv). We note that these provisions are consistent with the changes made in PPACA.

*Comment:* One commenter is concerned that the proposed rule does not ensure adequate payment to pharmacies for MTM services. The commenter believes plan sponsors may shift costs associated with MTMPs to providers (specifically pharmacies) through lowered payments. The commenter urges CMS to require quarterly reporting of payment to pharmacies for MTM services and should ensure that pharmacies are paid adequately for furnishing these services.

*Response:* We disagree with the commenter's recommendation that CMS require reporting of MTM payment data to ensure payment adequacy. The non-interference provision at section 1860D–11(i) of the Act explicitly provides that the Secretary may not interfere with the negotiations between pharmacies and PDP sponsors, which would include payment negotiations between the Part D sponsors and pharmacies for MTM services.

*Comment:* One commenter encouraged CMS to require Part D sponsors to disclose to CMS their criteria for determining whether a comprehensive medical review (CMR) will be performed face-to-face or by phone.

*Response:* We appreciate this comment, but believe that as long as the CMR is interactive and person-to-person, plans continue to have the discretion to determine whether it can be achieved through a phone or other alternative real-time method. We will monitor MTM program outcomes and performance to ensure best practices are adopted. In the event we receive data revealing weaknesses in this approach to CMR, we may consider revising the CMR minimum requirements in future rulemaking.

*Comment:* One commenter suggests that when enrollees are provided with a written summary of the interactive consultation, such summary be provided promptly to all prescribers involved in an enrollee's care.

*Response:* We agree with the commenter and believe such written summaries should be provided promptly to the provider. However, we believe the timeframe for the release of such summaries to providers is better addressed in the agreements between the MTM providers and the plans. The written summaries from the CMR will vary in complexity, depending upon an individual's diagnoses and medication usage; therefore, the time needed for preparation of such summaries will vary.

*Comment:* A few commenters indicated that the outcomes of MTMPs would be enhanced by requiring at least one initial face-to-face consultation with a pharmacist to review the patient's drug regimen and by offering another face-to-face consultation at least quarterly. Another commenter indicated that the quarterly reviews should be done person-to-person as this interaction permits evaluation of cues that may otherwise be missed if performed through lower touch interventions. Furthermore, periodic re-evaluations must be conducted and MTMPs should initiate programs to detect proactively, on a monthly-basis, under-utilization of prescribed medicines for all chronic therapies. MTMPs should also be required to initiate interventions to address underutilization on at least a quarterly basis.

*Response:* We appreciate these comments, but not all beneficiaries can access the MTM services face-to-face or at the provider's location. Furthermore, we believe permitting alternative interactive methods (for example, by telephone or Web cam) will allow the sponsors to try innovative techniques that may better serve the beneficiary, especially when the beneficiary resides in a remote location or cannot travel to the provider's location. We emphasize, however, that when using alternative interactive methods, the CMR interaction must remain a real-time interaction.

We do not require the quarterly assessment to be interactive because we believe lower touch interventions, coupled with the annual comprehensive medication review will allow the patient to be adequately served. However, we encourage plans, to follow up with a person-to-person interaction if the quarterly review reveals that the patient is facing medication related problems.

*Comment:* One commenter indicated that CMS should clarify what it means by interactive, person-to-person consultation. For some hearing impaired or technically savvy beneficiaries the Internet is a valuable communication tool. CMS should allow the use of emerging technologies to conduct the CMR.

*Response:* As indicated in an earlier response, we agree that the use of alternative interactive methods be used by Part D sponsors, as long as the CMR is conducted in real-time.

*Comment:* One commenter recommends sponsors have the flexibility to determine if an MTMP intervention should be for member, prescriber or both. Another commenter indicated that additional clarification is needed about any and all prescriber interventions to ensure that MTM services are coordinated with and do not adversely impact on, or interfere with, the relationship between the enrollee and his/her prescriber.

*Response:* Section 423.153(d)(1)(vii), would require Part D sponsors to offer interventions to the enrolled beneficiary and his/her prescriber. As indicated in the preamble to the proposed rule, this does not mean that all interventions must be targeted to both the beneficiary and prescriber. Instead, sponsors must determine, based upon the specific nature of the intervention, whether it should be targeted to the beneficiary,

the prescriber, or both, in order to promote coordinated care.

*Comment:* One commenter indicated that it is important that CMS clarify how the MTM requirements will be applied, if at all, in the long-term care setting. Furthermore, this commenter asked how Part D sponsors will coordinate their efforts with the consultant pharmacists who conduct monthly drug regimen reviews for all residents in Medicare/Medicaid certified facilities.

*Response:* The same MTM program requirements apply to long-term care residents as apply in the outpatient setting, except that Part D sponsors are not required to offer an interactive CMR to targeted beneficiaries in an LTC setting. The Part D sponsor will still be required to do the quarterly medication reviews and offer interventions targeted to the individual's prescribers. Part D sponsors are not required to coordinate their MTM services with the monthly drug regimen reviews of the facilities' consultant pharmacists at this time.

*Comment:* We received several comments regarding performance measures for pharmacists. Commenters made the following recommendations:

• CMS should continue to use validated performance-based measures for pharmacy providers, such as the Pharmacy Quality Alliance (PQA) measures. These measures will give further definition to MTMPs, distinguish among different pharmacy providers and the types of MTMPs provided and appropriately compensate pharmacists that are able to improve quality of care.

• CMS should consider additional performance measures, in conjunction with participating pharmacists, and the performance measures should be made available publicly, on a yearly basis. The commenter suggested that CMS adopt only performance measures established by national voluntary consensus building.

• CMS should continue to allow as much flexibility as possible until evidence can demonstrate what aspects of an MTMP bring desired results.

• CMS should expand upon existing data collection and reporting requirements. At a minimum, reported data should include—

++ Number of adverse drug events avoided, categorized by reason;

++ Data on adherence and persistence by enrollees to their prescribed drug therapies;

++ Information on the form, frequency, and types of interventions; and

++ Data on the per capita administrative and drug costs under each program.

*Response:* We appreciate the commenters' interest in this issue. We will continue to utilize valid performance measures such as the measures developed by the PQA. In addition, we will evaluate MTM outcome data that we receive under the Part D reporting requirements to ensure that Medicare beneficiaries are receiving effective and appropriate MTM services. We will also continue to evaluate MTMPs to ensure consistent guidelines are applied, and issue best practices when necessary. We note that an MTM contract was awarded through 2010 to assist CMS in monitoring and evaluating sponsor's MTM programs.

*Comment:* Two commenters indicated that MTM services should be included as part of access standards for retail pharmacies. Another commenter requested that CMS ensure that pharmacists working in community pharmacy practice settings (network pharmacies), and pharmacists unaffiliated with network pharmacies, have the opportunity to contract with Part D plans to provide MTM services.

*Response:* These comments are outside the scope of this rulemaking and therefore we will not be addressing them in this rule.

*Comment:* A few commenters recommend that CMS consider requiring, or signaling a preference for, pharmacists to provide MTM services. Another commenter requested clarification regarding the characteristics of an "other qualified provider" in the regulation and at a minimum, a requirement that the provider have demonstrated expertise in medication use management.

*Response:* At present, 99 percent of the MTMPs are utilizing the services of pharmacists. While CMS believes pharmacists will continue to be the main provider of MTM services, the statute at 1860D–4(c)(2) of the Act permits plans the flexibility to use other qualified providers to perform the MTM. At this time, CMS does not believe it is necessary to issue regulations to govern the qualifications for providers of MTM services, but may consider rulemaking in the future, if further data reporting and experience reveal that additional refinement of the policy is needed.

*Comment:* Several commenters recommend that CMS not set specific program requirements in regulatory language, but continue to use the subregulatory mechanism offered by the annual industry call letter. They believe there is insufficient experience to include MTM policies in regulation, and the implications of the more detailed criteria for targeting beneficiaries for MTMPs are not yet clear.

*Response:* We disagree with these commenters regarding placing the requirements in regulation. This rulemaking process has afforded both Part D plans and the public the opportunity to comment on the MTMP requirements prior to any changes being made to the existing requirements. Furthermore, because the MTMP requirements are being incorporated in our regulations, in the event a Part D sponsor fails to meet its MTMP services requirements, our ability to enforce those requirements has been enhanced. Accordingly, we believe that including these MTMP requirements in our regulations will help to ensure that targeted beneficiaries receive appropriate MTM services.

*Comment:* One commenter recommends that CMS develop standardized billing and documentation data sets to eliminate the need for pharmacists to utilize specific platforms to obtain payment from different plans. A standardized data set should include a measure of a patient's clinical outcomes as well as the rates at which the patient's providers accept the pharmacist's recommendations.

*Response:* We agree that the adoption of standardized documentation for MTM could be helpful in measuring the outcome of MTM. However, we believe any such standard documentation or billing be developed via an industry standard-setting group, and not by CMS.

*Comment:* Several comments were received regarding the MTM targeting criteria. Specifically, commenters suggested that CMS—

• Decrease the maximum number of medications that a plan could require for a targeted beneficiary to be eligible for MTM services; currently that number is eight. One commenter recommended decreasing the number to six, to prevent patients taking combination drug products from being unintentionally excluded from the program because a single medication has replaced two separate drug products;

• Allow Medicare beneficiaries who do not qualify for MTM services to receive MTM services through a referral or prior authorization process initiated by their prescriber or pharmacist. Some patients with only one chronic disease or less than 8 medications may still have medication use issues that would benefit from participation in their plan's MTM program; and,

• Require MTM services upon discharge from the hospital or anytime a beneficiary undergoes a transition of care. In both situations beneficiaries

would benefit from receiving MTM services because MTM has the potential to reduce costly hospital readmissions due to medication misuse or non-adherence.

*Response:* The regulation governing the number of prescriptions an individual must take before he or she is targeted for MTM services sets both a ceiling and a floor on the number of prescriptions that may be required. Therefore, a plan sponsor has the discretion to determine whether to target beneficiaries taking anywhere from two to eight medications. Our data indicate that 85 percent of the plans reviewed targeted beneficiaries in a range of two to eight medications.

As for targeting certain other beneficiaries for MTMP services, our regulations provide that sponsors must provide a minimum level of MTM services to targeted beneficiaries. To the extent a Part D plan wants to offer additional MTM services, or provide MTM services to individuals who do not meet the targeting criteria, including those individuals who have undergone a transition in their level of care, they may do so. However, additional administrative reimbursement will not be available for the provision of these additional services.

*Comment:* We received some comments regarding MTM targeting frequency. One commenter indicated that CMS should consider increasing the minimum requirements regarding the frequency with which plans conduct outreach to eligible beneficiaries for enrollment in MTM programs, and specifically recommended that beneficiaries be targeted for enrollment at least monthly.

*Response:* The requirement of quarterly targeting that was included in the proposed rule, and that is being adopted into this final rule, is a floor that Part D sponsors may build upon. Sponsors may adopt more frequent targeting than the minimum quarterly outreach threshold required under the regulation. We will also continue to monitor and evaluate MTM programs to determine if there is any significant difference in MTM outcomes when beneficiaries are targeted more frequently and will consider making further changes to our requirements if warranted.

*Comment:* One commenter believed a better method for targeting beneficiaries would be to examine an individual's historical and expected aggregate health care spending using a cost threshold for eligibility that is based on total projected Medicare spending, rather than just Part D spending.

*Response:* We do not agree with this approach. Pursuant to section 1860D–4(c)(2)(A)(ii)(III) of the Act, targeted beneficiaries are defined as Part D eligible individuals who "are identified as likely to incur annual costs for covered Part D drugs that exceed a specified level by the Secretary." Accordingly, the statute does not afford CMS the flexibility to permit plans to target individuals for MTM services based upon their expected aggregate health care spending. Furthermore, given the complexity of this suggested alternative, we believe the collection and review of health care spending data prior to determining whether an individual will be targeted for MTM services would only delay access to MTM services.

*Comment:* One commenter indicated that a Part D sponsor's use of an opt-out only enrollment process for placing beneficiaries in its MTM programs must be carried out thoughtfully and carefully. CMS should require MTM program policies that promote patient collaboration with their physicians, provide adequate enrollment notification and include clear instructions on opt-out. CMS should also undertake an outreach initiative to physicians.

*Response:* We appreciate the commenter's concerns regarding the application of the opt-out method to enroll beneficiaries into MTMPs. However, we believe the opt-out approach is critical for the health and well-being of the Medicare population. The elderly and disabled populations are most at risk of polypharmacy consequences. Therefore, an opt-out enrollment policy that requires no further action by the enrollee helps to ensure that vulnerable individuals will be enrolled in MTMPs, which we believe will reduce adverse drug reactions and ensure safe prescription drug practices, before their health is at risk. In addition, CMS has found that the opt-out enrollment method is the preferred method among Part D sponsors to increase the number of beneficiaries participating in MTMPs. In 2008, fewer than 15 percent of MTMPs utilized an opt-in method. We will continue to monitor Part D plans to ensure they engage in best practices when applying the opt-out enrollment method to their plan members.

*Comment:* One commenter was concerned that the use of the initial coverage limit (ICL) as a targeting benchmark for Part D MTM may elevate cost considerations over clinical considerations in targeting beneficiaries for the Part D MTM program.

*Response:* To the extent that the commenter appears to be stating that it is improper to consider cost considerations in targeting beneficiaries for the MTM program, we disagree. As discussed above, section 1860D–2(c)(2)(A)(ii)(III) of the Act expressly instructs CMS to consider costs for Part D drugs when targeting beneficiaries for MTM. However, following further consideration of this issue, reliance on the ICL, which is specifically tied to the cost structure of the Part D benefit to target beneficiaries for MTM may be problematic. There have been further legislative proposals to restructure the Part D benefit, including revising the ICL, that may have unintended consequences for basing the MTM targeting criteria on the ICL. Accordingly, we believe the establishment of a specific dollar threshold is more appropriate and are reverting back to the $3000 limit, which we previously established in the 2010 call letter. Consistent with statutory requirement that drug costs be considered in targeting beneficiaries for MTM, we will apply an index that is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs. Specifically, we will adjust the $3000 threshold by the index used to increase the ICL, as originally proposed, which is currently found at § 423.104(d)(5)(iv).

The decision to apply a $3000 threshold is based upon program experience and our analysis of PDE data. We originally established the initial $4000 cost threshold at the inception of the Part D program. At that time, it was estimated that approximately 25 percent of the Part D eligible population would meet the three criteria and be targeted for MTM services. After two years of experience and analysis of plan reported data, we found that only 10.0 percent of beneficiaries enrolled in a Part D plan with an approved MTMP were eligible for MTMP in 2006 (13.1 percent were eligible for MTMP in 2007). In 2008, we conducted an analysis using PDE data from contract years 2006 and 2007 obtained from the Integrated Data Repository (IDR) system. The total gross drug cost and number of beneficiaries that incurred annual drug costs (below) or (greater or equal) to the $4000 cost threshold was determined. The average number of PDE fills and average cost per beneficiary was also calculated. Further analysis examined cost breakouts in $500 increments to determine the distribution of beneficiaries, as well as the number of fills, and gross drug cost for beneficiaries with annual drug costs

within these breakouts. It was determined that close to 25 percent of Part D enrolled beneficiaries with drug utilization (beneficiaries with at least one PDE during the study period) during 2006 and 2007 had annual gross drug costs of at least $3000. Therefore, CMS lowered the cost threshold to $3000 in the 2010 Call letter. Based upon our analysis of the most recent data, it appears that this threshold will continue to ensure that approximately 25 percent of these beneficiaries utilizing the Part D benefit receive MTM services. Accordingly, we are adopting the $3000 cost threshold in this final rule.

6. Formulary Requirements—Development and Revision by a Pharmacy and Therapeutics Committee (§ 423.120)

In the October 22, 2009 proposed rule, we offered further clarifications surrounding our formulary requirements associated with pharmacy & therapeutics (P&T) committees. As we explained in the preamble to the proposed rule, section 1860D–4(b)(3)(A) of the Act requires Part D sponsors to use a P&T committee to develop and review the formulary if the Part D sponsor uses a formulary. In developing and reviewing the formulary, section 1860D–4(b)(3)(B) of the Act requires the P&T committee to base clinical decisions on the strength of scientific evidence and standards of practice, including accessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate. The P&T committee must also consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

Based upon our experience with the formulary development process since the beginning of the Part D program, we have come to recognize that the application of prior authorization (PA) criteria, step therapy, and quantity limits are as important to the clinical soundness of a formulary as the drugs that are included. Access to Part D drugs may be influenced as much by the application of PA criteria, step therapy requirements, or quantity limit restrictions as it can be by exclusion of a Part D drug from a Part D formulary. Therefore, in accordance with section 1860D–4(b)(3)(A) and (b)(3)(B) of the Act, we proposed adding new paragraph § 423.120(b)(1)(ix) to require P&T committees to review and approve all clinical PA criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

In this final rule, we adopt these provisions as proposed.

*Comment:* One commenter is concerned that utilization management (UM) requirements have become barriers to timely access, especially for the low-income population for whom the exceptions, reconsideration, and appeals processes are difficult to navigate. While UM tools may be used appropriately by a Part D plan, they may also result in impeding appropriate and timely access to prescribed medications and in themselves, can be discriminatory in beneficiary selection of the Part D plans to the extent that beneficiaries are even aware of the restrictions.

*Response:* It is our intention that the changes adopted specifying the responsibilities of the P&T committee in this final regulation will address this commenter's concern regarding potentially discriminatory practices that may affect beneficiary protections. We believe P&T committees are in the best position to ascertain whether certain UM tools, when applied to covered Part D drugs, will inappropriately impede access to these drugs, since the committee's membership includes independent practicing pharmacists and physicians with the clinical knowledge necessary to provide an unbiased review of the impact of UM tools on the Part D sponsor's formulary.

*Comment:* One commenter indicates that it supports CMS' improvement of the rigor of evidence supporting decisions of P&T committees, but encourages CMS to strengthen its evidence requirements even further. This commenter is concerned that the widely used treatment guidelines or clinical literature standard may not be specific enough and recommends that CMS amend § 423.120 to provide that a Part D sponsor may require that beneficiaries try drugs supported solely by off-label indications only if the sponsor demonstrates that there are generally accepted, widely used and evidence-based treatment guidelines or substantial and credible clinical literature that recommend patients use an off-label indication.

*Response:* The policy regarding a plan member's use of drugs for off-label indications is out of the scope of this final rule. However, we have recently adopted in our guidance (see the 2010 Call Letter released on March 30, 2009) that as part of our assessment of a formulary's appropriateness, Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) unless the off-label indication is supported by widely used treatment guidelines or clinical literature that we consider to represent best practices. Generally, we require such authoritative guidelines to be endorsed or recognized by Federal government entities or medical specialty organizations.

*Comment:* One commenter indicated that they agree, theoretically, that the P&T committee should not have to approve administrative PA criteria, such as Part B versus Part D coverage, but their experience has been that plans utilize administrative criteria as excuses not to cover drugs. Therefore, they believe P&T committees should review the administrative criteria to make sure they are being applied properly. Another commenter indicated that CMS allow plan sponsors to implement non-clinical UM criteria without the input and prior approval of their P&T committees.

*Response:* Consistent with the operational guidance in Chapters 6 and 7 of the Medicare Prescription Drug Benefit Program Manual, we continue to require Part D sponsors to submit utilization management requirements, such as prior authorization, step therapy and quantity limits not based upon the FDA's maximum daily dose limits, as part of their Health Plan Management System (HPMS) formulary submission. We believe these UM tools should be reviewed by Part D sponsor P&T committees for the reasons stated above.

However, we continue to believe that the administrative criteria a plan uses should not be subject to the P&T committee review because they do not require clinical information or justification. Moreover, we believe that when a beneficiary is subject to an administrative UM tool (that is, one that is not a coverage determination) that the beneficiary believes unfairly denies access to his/her prescription drugs, such cases can be addressed through the plan's grievance process. In accordance with § 423.564, Part D sponsors must provide meaningful procedures for timely hearing and resolving enrollee grievances. Chapter 18 of the Medicare Prescription Drug Benefit Manual defines a grievance as any complaint or dispute other than one that involves a coverage determination or a low-income subsidy or late enrollment penalty determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D sponsor, regardless of whether

remedial action is requested. Because another avenue exists for redress of a beneficiary's concern about administrative criteria such as "B versus D" determination, we decline to adopt the commenter's suggestion.

*Comment:* One commenter questioned the value of committing the resources of a P&T committee to review and approve quantity limits.

*Response:* We believe there is value to P&T committees reviewing quantity limits since the imposition of quantity limits can affect clinical outcomes. As we previously stated in the preamble to the proposed rule, quantity limits are as important to the clinical soundness of a plan's formulary as the drugs that are included on the formulary. The P&T committee, as a body of clinicians, should review the quantity limits to ensure restrictions do not affect a plan member's access to covered Part D drugs that could lead to health or life-threatening outcomes, especially when quantity limits are not based upon the FDA's maximum daily dose limits.

*Comment:* One commenter indicated that CMS provide Part D sponsors with minimum standards for P&T committees' clinical review and make those standards publicly available to further strengthen the clinical appropriateness of formularies.

*Response:* We disagree with the commenter's suggestion that we dictate minimum standards for P&T committees' clinical review. Section 1860D–4(b)(3)(B) of the Act requires the P&T committee base clinical decisions on the strength of scientific evidence and standards of practice, including accessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the P&T committee determines to be appropriate. Since the statute specifically directs P&T committees to make these clinical decisions, we believe it does not have the authority, or the capability, to establish clinical review criteria for the P&T committees.

*Comment:* One commenter urged CMS to continue to engage in robust formulary review to ensure that a plan formulary appropriately reflects the clinical needs of Medicare beneficiaries.

*Response:* We appreciate the comment, but changes to CMS' formulary review are outside the scope of this final rule. We are not making any further changes to our current formulary review process at this time because we believe we already conduct a robust formulary review consistent with the statutory and existing regulatory parameters, and current guidance.

*Comment:* One commenter indicated that plans inform beneficiaries of utilization management criteria prior to selecting their plans.

*Response:* As provided in § 423.128(c)(2), a Part D plan, upon the request of a Part D eligible individual, must provide the procedures the Part D plan uses to control utilization of services and expenditures. CMS guidelines for marketing materials spell out that as part of a plan's formulary, Part D plans must indicate any applicable utilization management tools (such as, prior authorization, step therapy, and quantity limit restrictions) for the drug. Also, formulary and utilization management criteria must be appropriately displayed on the plan's Web site.

*Comment:* One commenter requested that CMS require that P&T committee decisions be in writing, including the rationale behind formulary and utilization management policies, and that the committee's decisions be made public.

*Response:* As stated in response to the previous comment, utilization criteria are made available to the public prior to enrollment, and to enrollees of the plan. Additionally, § 423.120(b)(1)(viii) requires the Part D sponsor's P&T committee decisions regarding formulary development or revision, as well as utilization management activities, be documented in writing. However, the Part D sponsors may consider decision by their P&T Committees to be proprietary and for this reason, we decline to require plans to make them public.

7. Generic Equivalent Disclosure Under Part D (§ 423.132)

In the October 22, 2009 proposed rule, we proposed revisions to part D requirements related to the disclosure to Part D enrollees who are residents of long term care institutions of any differential in pricing of drugs dispensed compared to generic equivalents. As we explained in the preamble to the proposed rule, section 1860D–4(k)(1) of the Act requires a Part D sponsor to have each of their network pharmacies inform enrollees of any difference between the price of the drug(s) they are purchasing via the plan and the price of the lowest priced therapeutically equivalent generic product available to the pharmacy. Section 1860D–4(k)(2)(A) of the Act requires that this information be provided at the time of purchase except for purchases delivered by mail when it must be provided at the time of delivery. Under section 1860D–4(k)(2)(B) of the Act the Secretary has the authority to waive this requirement for certain entities in certain cases as specified in § 423.132(c).

When we issued the January 28, 2005 (70 FR 4273) Part D final rule, we specified that for enrollees in long-term care pharmacy settings, the timing portion of the disclosure requirement (that is, the requirement that the enrollee be informed at time of purchase) may be waived. Accordingly, sponsors were required to disclose the differential (if any) in pricing for long-term care network pharmacies by requiring that this information be provided in the explanation of benefits (EOB). However, over time, we have heard from sponsors, as well as pharmaceutical benefit managers on behalf of sponsors, that providing this information in the EOB is unworkable from a plan operational standpoint.

We also came to realize that the generic equivalent information provided on the EOB is of no value to the long-term care beneficiary. Unlike the enrollee standing at the retail pharmacy counter at time of service, enrollees in long-term care institutions have limited opportunities to effect a switch to a lower-priced generic substitute before dispensing.

For the aforementioned reasons, we proposed revising § 423.132(c) by adding long-term care network pharmacies to the list of entities for which from the public disclosure requirement is waived, and revise § 423.132(d) to remove the requirement that long-term care network pharmacies provide the pricing differential information in enrollees' EOBs. In this final rule, we adopt these provisions as proposed.

*Comment:* A number of commenters supported this change. One commenter wanted to go even further and eliminate this requirement for all areas of pharmacy practice because it imposes an unreasonable administrative burden.

*Response:* We disagree that elimination of this requirement should be extended to all areas of pharmacy practice. Providing this information to the beneficiary at the time of purchase enables the beneficiary to choose the lowest priced product available at the pharmacy. The pharmacy can avoid the administrative burden by dispensing the lowest priced product.

*Comment:* Only one commenter did not support this change and thought that providing this information in the EOB would help identify fraud, waste, and abuse and enable the beneficiary to change at a later date.

*Response:* Although we agree that this information may have some value to a beneficiary in the long-term care setting,

the primary reason for removing this requirement is that it is unworkable from a plan operational standpoint considering the variable nature of generic pricing and the programming maintenance effort required, and we continue to believe that the value to the beneficiary, given the circumstances, does not justify the burden of maintaining the requirement.

8. Access to Covered Part D Drugs (§ 423.120)

In the October 22, 2009 proposed rule, we made corrections to current regulatory requirements that would align the regulations with the intent of the statute with regard to the level of analysis that should be conducted for access to Part D drugs, namely at the Part D sponsor level, rather than at the plan level. As we noted in the preamble to the proposed rule, the statute at sections 1860D–4(b)(1)(C) and 1860D–21(c)(1) of the Act establishes the standards for convenient access for network pharmacies for PDP sponsors and other Part D sponsors. This section of the statute requires that the sponsor of a PDP shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access consistent with the rules established by the Secretary, and as long as they are no less favorable than the TRICARE pharmacy access standards. These standards are—

- *Urban*—a pharmacy within 2 miles of 90 percent of the beneficiaries;
- *Suburban*—a pharmacy within 5 miles of 90 percent of the beneficiaries; and
- *Rural*—a pharmacy within 15 miles of 70 percent of the beneficiaries.

We adopted into regulation the TRICARE standards, but instead of specifying them at the contract or PDP sponsor level, erroneously established them at the plan level. Specifically, in § 423.120(a) of the regulation, which describes the requirements to assure pharmacy access, we inadvertently used the term "plans" instead of the correct terminology of PDP sponsor or other Part D sponsors. This error is problematic when considering the definitions outlined in § 422.2 (for MA) and § 423.4 (for Part D) because the term "plan" is intended to mean a specific benefit package offered to beneficiaries living in a geographic area. For any given service area, Part D sponsors frequently offer multiple plans under one contract with CMS, and any given plan may be offered within a subset of the Part D sponsor's total service area. For example, a Part D sponsor may offer a high and low option at one price in part of the contract's service area, and also offer a high and low option at a different price in the remaining portion of the contract's service area.

We noted that our intention has always been to ensure adequate access to Part D covered drugs at sponsor level, not at the plan level. For one, the statute explicitly states that access should be ensured at the PDP sponsor level. Further, assessing adequacy of pharmacy access is one of the most critical steps in the Part D application review process and determining access to Part D covered drugs at the plan level is not possible during application review. This is because plan service areas (potentially subsets of Part D sponsor or organization service areas) are not determined until the time of the bid submission, which occurs after applications are reviewed. However, sponsor service areas are known at the time of application submission.

Our correction would align our regulations with the intent of the statute with regard to the level of analysis that should be conducted for access to Part D drugs, namely at the Part D sponsor level, rather than at the plan level. We also noted in the preamble that as a practical matter and consistent with the current drafting of the regulation, if the Part D sponsor's entire service area is larger than one State, we will continue to ensure access at no greater than the State level for multistate regions. We noted that this approach is necessary to ensure that pharmacies are not unduly clustered in one part of the region.

Therefore, based on the preceding, we proposed to revise the text of the regulation that discusses pharmacy access in § 423.120(a)(1) through (a)(7) to refer to PDP sponsors, MA organizations offering local and regional MA–PD plans, and cost contracts rather than plans. Additionally, since § 423.120(a) (defining access requirements for Part D drugs) references a definition provided in § 423.112(a) (establishment of PDP service areas), it was necessary to correct the terminology in that location as well. Therefore, we proposed revising § 423.112(a) to specify the establishment of service areas for PDP sponsors. We are adopting the above changes without further modification into this final rule.

*Comment:* One commenter fully supported the proposed revision to the regulation clarifying access to Part D drugs be measured at the sponsor level, rather than at the plan level.

*Response:* We appreciate the support.

*Comment:* One commenter asked CMS to exercise its statutory authority to adopt regulations that would apply access standards more favorable to beneficiaries to Part D sponsors by increasing the urban and suburban percentages to 95 percent, and increasing the rural standard to 10 miles and 85 percent. This commenter believes that the current access standards are too lax, especially in rural areas. Additionally, this commenter noted that measuring distance "as the crow flies" when evaluating pharmacy access may not be representative of true driving distance in certain locations.

*Response:* Our proposed regulatory change addressed only the organizational level at which the pharmacy access standards would be applied, not whether a change in those standards is warranted. While we appreciate the comment, we will not address it at this time as it is outside the scope of our proposal.

However, we wish to allay the commenter's concern that measuring distance "as the crow flies" may actually underrepresent true driving distance. Presently, the software used by Part D sponsors to demonstrate they meet our retail pharmacy access standards has a feature that allows distance to be measured as estimated driving distance, and sponsors are instructed to use this feature.

*Comment:* One commenter suggested that CMS move toward a more automated and streamlined process for conducting the initial review and ongoing monitoring of Part D sponsor's retail pharmacy networks. The commenter suggests CMS consider establishing a certification process whereby a first tier entity, such as a PBM, may submit one set of access reports in support of its certification. If found acceptable by CMS, all Part D sponsors using that PBM could demonstrate their compliance with the pharmacy access standards by submitting an attestation that the network they are using is already CMS-approved.

*Response:* We appreciate the comment and note that we are working on developing a more automated system for the submission of pharmacy network information. That said, the issue of our review of network adequacy and the processes we use is outside the scope of our proposal, and we therefore decline to address it in this rule.

*Comment:* One commenter urged CMS to create retail pharmacy access standards to ensure that beneficiaries have the choice of obtaining medication therapy management (MTM) services from their retail community pharmacies.

*Response:* This comment concerns the administration of MTM programs, not the methodology for the calculation of retail pharmacy access standards.

Therefore, we will not address this comment as it concerns an issue outside the scope of our proposed regulatory change.

9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§ 423.568)

In the October 22, 2009 proposed rule, we proposed to make several changes to § 423.568 related to the standard timeframes and notice requirements for coverage determinations under Part D. The first change we proposed was a technical change that would require Part D plan sponsors to accept standard coverage determination requests orally and in writing. This change would not apply to standard requests for payment, which must be submitted in writing unless the plan sponsor adopts a policy for accepting those requests orally. As we explained in the preamble to the proposed rule, we proposed this change to § 423.568 because section 1860D–4(g) of the Act requires Part D sponsors to follow the same procedures as MA organizations with respect to organization determinations and reconsiderations, and we were proposing to make an identical revision to § 422.568 of the MA appeals regulations.

We also proposed to revise the timeframe for a Part D plan sponsor to notify an enrollee of a payment determination in § 423.568(b), and proposed to establish a regulatory timeframe for making payment to an enrollee when a decision is partially or fully favorable. The regulation currently requires a plan sponsor to notify an enrollee of its payment determination no later than 72 hours after receipt of a request, and manual guidance requires plan sponsors to make payment for fully or partially favorable decisions within 30 days of the request. The proposed revisions to § 423.568(b) would require a Part D plan sponsor to notify an enrollee of a payment decision no later than 14 calendar days after receiving a reimbursement request. If the decision is partially or fully favorable, the plan sponsor must also make payment within the same 14-day timeframe. For example, for partially and fully favorable decisions, a plan sponsor must both notify the enrollee of the decision and make payment no later than 14 calendar days after receiving the request). As noted in the preamble, we proposed to revise the reimbursement timeframes because we believe the existing 72-hour requirement is virtually impossible for plan sponsors to meet, and as a result, plan sponsors are issuing perfunctory denials. This outcome is not in the best interest of Medicare's Part D enrollees. We were also concerned that the existing requirement would in effect force enrollees into the Part D appeals process despite the fact that the majority of these claims could have been paid within the 30-day reimbursement timeframe. Based on our experience and previous discussions with Part D plan sponsors, we determined Part D plan sponsors generally are capable of making reimbursement decisions and payment within a 14-day period following receipt of reimbursement requests. We believe the proposed revision to the timeframes for notifying enrollees of payment determinations will significantly increase the number of timely payment-related decisions by plan sponsors, and the revised timeframes for making payment will be more meaningful for the typical Medicare beneficiary who often cannot afford to wait 30 days to be reimbursed.

Finally, we proposed to add new paragraphs (d) and (e) to § 423.568, to explain the form and content of favorable coverage determination decisions. In § 423.568(d), we proposed requiring plan sponsors to send written notice of fully favorable decisions to enrollees. We also proposed to allow plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to the enrollee within three calendar days of the oral notification. In § 423.568(e), we proposed to require notice of fully favorable decisions to include the conditions of the approval in a readable and understandable manner. We noted these changes were necessary because prescription drugs are often provided to beneficiaries on a recurring basis (unlike most MA services which are generally provided to beneficiaries only once), and requiring plans to provide the terms of an approval in writing helps ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D.

After reviewing the comments received in response to these proposals, in this final rule, we adopt the proposed changes without modification. In addition, as explained below, we are adding paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and retaining the documentation in the case file.

*Comment:* Several commenters supported the proposed technical change that would require Part D plan sponsors to accept standard coverage determination requests orally and in writing, except for standard requests for payment which must be submitted in writing. A commenter asked CMS to clearly articulate how plans are to record, track, and report oral requests. Another commenter suggested allowing plan sponsors to require the use of plan-specific forms for payment requests.

*Response:* We appreciate the comments we received in support of this proposal, and the commenter's concern about the processes plan sponsors should have in place to record, track, and report oral requests. We agree that it is important for plan sponsors to document and track requests that are submitted orally in order to determine if plan sponsors are processing requests in a timely manner. Therefore, in this final rule, we are adding a new paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and to retain that documentation in the case file. We do not agree with the suggestion to require the use of plan-specific forms for payment requests. We have, since the inception of the Part D program, required plan sponsors to accept any written request submitted by enrollees and prohibited plan sponsors from requiring the use of plan-specific request forms. We do not believe there is a compelling reason to depart from this standard. During this time, we have also received numerous requests to standardize the Part D coverage determination and appeals processes in order to create consistency and predictability for Part D enrollees, and we are continuously looking to improve the coverage determination and appeals processes. Allowing each plan to require the use of different forms for different requests moves us further away from creating a process that is easier for enrollees to navigate. Although we understand plan sponsors often need enrollees to submit specific information with reimbursement requests, requiring the use of a specific form does not guarantee that an enrollee will provide all information a plan sponsor needs to process the request (for example, an enrollee may not complete part of the form). When a reimbursement request is not complete, plan sponsors must either obtain the missing information or deny the request within the applicable decision making timeframe. Because we are extending the timeframe for resolving payment requests in this final rule, plan sponsors have more time to evaluate payment requests and obtain missing information when necessary.

*Comment:* We received many comments in response to the proposed revisions to § 423.568(b), which would require a Part D plan sponsor to notify an enrollee of a payment decision and,

if appropriate, make payment no later than 14 calendar days after receiving a reimbursement request. Some commenters that supported the 14-day timeframe for making a decision opposed the requirement to make payment within the same 14-day timeframe. The commenters objected because a 14-day payment cycle is not consistent with current industry standards, and moving the payment cycle to 14 days would require great expense to update current processes and systems, and would not offer any real benefit to enrollees who already have the prescription drugs in dispute. For these reasons, the commenters suggested maintaining the current 30-day payment timeframe. As an alternative, some of the commenters suggested allowing plan sponsors an additional 14 calendar days to make payment after a decision has been made. Other commenters suggested that CMS defer implementation of the 14-day timeframe until 2011.

We also received support for the proposed 14-day timeframe from a number of commenters, but the commenters also opposed extending the 72 hour decision-making timeframe. The commenters objected because extending the timeframe would cause an additional financial hardship for enrollees who pay out-of-pocket for prescriptions. The commenters argued the proposal would extend the appeals process by up to eleven days for enrollees who receive denials, and would prevent those enrollees from obtaining a decision by the Part D Independent Review Entity before a 30-day prescription runs out. For that reason, most of the commenters suggested retaining the 72-hour decision-making timeframe for reimbursement requests. As an alternative, a few of the commenters suggested that CMS maintain a 72-hour decision-making timeframe for payment requests that involve exceptions, and a 14-day decision-making timeframe for all other payment requests. Finally, one commenter believed that a 7-day timeframe would be acceptable for making payment-related decisions.

*Response:* After careful review and consideration of the numerous comments and suggestions we received about this provision, we continue to believe that the timeframes established in proposed § 423.568(b) strike the right balance between ensuring plan sponsors have enough time to properly adjudicate reimbursement requests, and creating a reimbursement timeframe that does not impose an undue hardship on Medicare beneficiaries who often cannot afford to wait 30 days before being reimbursed.

Some commenters raised concerns about plan sponsors not being able to make payment within 14 calendar days after receiving a reimbursement request in large part because most Part D plan sponsors process reimbursement requests under a 30-day billing cycle, which is the industry standard. However, we note that plan sponsors already have prior experience processing some reimbursement requests in less than 30 days. Pursuant to section 171 of MIPPA and the PDP Sponsor Application, Part D plan sponsors are required to make payment for certain reimbursement requests from out-of-network pharmacies within 14 calendar days. Although the 14 calendar day MIPPA requirement applies to reimbursement requests that are submitted electronically, we note the MIPPA requirement to illustrate that a 14-day timeframe for processing reimbursement requests is not unprecedented under the Part D program, and that plan sponsors currently have systems in place to accommodate billing cycles that are less than 30 calendar days. As noted in the preamble to the proposed rule, our experience and previous discussions with Part D plan sponsors on this issue led us to conclude that plan sponsors are capable of processing reimbursement requests and sending payment, when required, to enrollees within 14 calendar days after receiving a reimbursement request. In the 2009 Call Letter, we indicated that we would exercise our enforcement discretion to decline to bring an enforcement action for non-compliance with the 72-hour timeframe in § 423.568 if the plan sponsor processes a reimbursement request and submits reimbursement (when appropriate) within 14 calendar days after receipt of the request. As a result, plan sponsors have been permitted the option of either notifying enrollees of their reimbursement decisions within 72 hours and making payment within 30 days, or, providing notice of a reimbursement decision and sending payment (when a decision is partially or fully favorable) to the enrollee within 14 calendar days after receiving a reimbursement request.

We also understand the concerns about enrollees receiving decisions as quickly as possible. In particular, some commenters indicated the need for shorter timeframes when a request involves an exception. We agree, but note that the reimbursement process was intended primarily for use in resolving out-of-network issues. Consequently, we do not believe that it is the most efficient way to obtain coverage decisions for non-formulary drugs or drugs subject to a utilization management requirement. Furthermore, using the reimbursement process to obtain coverage decisions for non-formulary drugs or drugs subject to a utilization management requirement does not obviate the need to provide medical documentation either demonstrating that an exception is needed or that a utilization management requirement has been met. In the former case, if the reimbursement request is submitted without a prescriber's supporting statement, the plan sponsor's decision making timeframe is tolled until the statement is received. Thus, we believe enrollees who need prescription drugs that either are non-formulary, or are subject to utilization management requirements that they cannot meet, would be better served by using the exceptions process. Under § 423.568(a), a plan sponsor must respond to a standard exception request within 72 hours of receiving the request and the prescriber's supporting statement, and consistent with § 423.572(a), a plan must respond to an expedited request within 24 hours of receiving the request and the prescriber's supporting statement.

Finally, we appreciate some commenters' concerns that the 14-day timeframe may result in enrollees receiving unfavorable payment determinations beyond the current 72-hour timeframe. Thus, in order to ensure that enrollees are able to access the appeals process as quickly as possible, we encourage plan sponsors to issue unfavorable determinations sooner than 14 days.

Therefore, we are finalizing the proposed revisions at § 423.568(b) to require Part D plan sponsors to notify an enrollee of a payment decision no later than 14 calendar days after receiving a reimbursement request. If the decision is partially or fully favorable, the plan sponsor must also make payment within the same 14 calendar-day timeframe.

*Comment:* We received a number of comments supporting the proposal to allow Part D plan sponsors to make the initial notice of favorable standard coverage determination decisions orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. However, one commenter suggested revising the three calendar day requirement to three business days.

*Response:* For the reasons noted in our response to a similar comment about the timeframe for providing written follow-up of notice of a fully favorable expedited redetermination decision, we do not agree that it is

necessary to revise "calendar days" to "business days."

*Comment:* We received numerous comments supporting the proposal to require plan sponsors to include specific information (such as, the conditions of approval) in favorable coverage determination notices. However, one commenter opposed the proposed requirement and suggested allowing plan sponsors to provide the approval conditions on request.

*Response:* As noted above in our response to a similar comment relating to favorable redetermination decisions, we believe requiring plan sponsors to provide the condition(s) of approval in writing is an important enrollee protection that helps ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D, and the commenter's suggested approach would diminish that important protection.

*Comment:* We received several comments asking us to develop a model letter for fully favorable coverage determination decisions under § 423.568.

*Response:* As noted in our response to a similar comment regarding fully favorable redetermination decisions, we will explore developing either a model or standard notice for favorable decisions, and will publish any such notice in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

10. Expediting Certain Coverage Determinations (§ 423.570)

In the October 22, 2009 proposed rule, we proposed to make a technical change to § 423.570 by removing the cross reference to § 423.568(a) and inserting a cross-reference to § 423.568(b). This change is necessary to be consistent with the proposed revisions to § 423.568. We did not receive any comments with regard to our proposed revision. Therefore, this final rule adopts this revision without change.

11. Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)

The October 22, 2009 proposed rule includes a proposed revision to § 423.572(b) that would require plan sponsors to send written notice of fully favorable expedited coverage decisions to enrollees, and allow plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to the enrollee within three calendar days of the oral notification. We also proposed to add paragraph (c)(2), which would require notice of a fully favorable expedited coverage determinations to provide the conditions of the approval in a readable and understandable manner. As noted in the proposed rule, the rationale for adding these requirements is consistent with our rationale for adding form and content requirements for favorable standard coverage determination decisions, and in so doing, ensures enrollees are able to maintain continuity in their prescription drug treatment.

Finally, we proposed to revise § 423.572(c)(2)(i) by requiring plan sponsors to issue adverse expedited coverage determination decisions using CMS approved language in readable and understandable form. As noted in the preamble to the proposed rule, this proposed change would reconcile a discrepancy in the regulations by requiring plan sponsors to use the standardized denial notice (Form CMS–10146) for both standard and expedited adverse coverage determinations. Currently, the regulations require the use of the standardized denial notice only for standard adverse coverage determinations. The only comment we received on this provision was supportive of the change. Accordingly, we are adopting the proposed revision to § 423.572(c)(2)(i) as set forth in the proposed rule without change.

*Comment:* We received a number of comments supporting the proposal to allow Part D plan sponsors to make the initial notice of favorable expedited coverage determination decisions orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. However, one commenter suggested revising the three calendar day requirement to three business days, and another commenter recommended allowing plan sponsors to send the first notice in writing, but not requiring plan sponsors to send additional written notices when any related refills are approved.

*Response:* For the reasons noted in our response to a similar comment about the timeframe for providing written follow-up of notice of a fully favorable expedited redetermination decision, we do not agree that it is necessary to revise "calendar days" to "business days." Also, as previously noted, we believe a written notice should follow every favorable decision, including favorable decisions to approve refills. This policy will help to ensure continuity of care for Medicare beneficiaries who are obtaining refills of prescription drugs under Part D. We note that additional favorable decisions for refills are not necessary if the coverage determination or appeal decision specifically authorizes refills for the remainder of the plan year.

*Comment:* We received numerous comments supporting the proposal to require plan sponsors to include the conditions of approval in favorable decision notices. However, one commenter opposed the proposal and suggested allowing plan sponsors to provide the approval conditions on request. A different commenter asked CMS to exempt Special Needs Plans (SNPs) from the written-notice requirement for favorable decisions because SNPs hire nurse case managers to make sure an enrollee's medication supply is not interrupted. Thus, enrollees receiving medications from SNPs do not need to know the conditions of an approval.

*Response:* As noted in our responses to similar comments, requiring plan sponsors to provide the conditions of approval in writing is an important enrollee protection that helps ensure uninterrupted drug coverage for Medicare beneficiaries who receive prescription drugs under the Part D program. We believe implementing the commenters' suggestions would diminish this important protection because without this requirement, enrollees would likely not receive timely notice of the coverage limits for approvals. Without this information, enrollees may experience interruptions in coverage. Thus, the best way to ensure that enrollees receive timely notice and understand the conditions that apply to their approvals is to require plan sponsors to consistently provide this information, in writing, to all enrollees.

*Comment:* We received several comments asking us to develop a model letter for fully favorable decisions issued under § 423.572.

*Response:* As noted in our response to an earlier comment, we will explore developing either a model or standardized notice for use in issuing favorable notices and will publish any such notice in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

12. Clarify Novation Agreements Under Part D (§ 423.551)

In the October 22, 2009 proposed rule, we proposed revisions to § 423.551 and proposed adding a new paragraph § 423.551(g) to restrict the situations in which we will approve the novation of a PDP sponsor's contract. A change in ownership of an existing sponsor's PDP contract(s) can promote the efficient and effective administration of the Part D program. However, over the past few years several PDP sponsors have requested CMS approval of transactions that involve the sale of a piece of the

sponsor's contract with CMS or less than all of the PDP contracts held by that PDP sponsor. Therefore we have proposed these revisions in order to restrict a novation to those transfers involving the selling of the sponsor's entire line of PDP business, which would include all PDP sponsor contracts held by the legal entity. We believe that allowing the spin-off of just one contract (when the PDP sponsor has more than one PDP contract) or pieces of a single contract can have a negative impact on beneficiary election rights.

We recommended becoming more prescriptive in this area because our experience gained over the first 4 years of the program indicates this is necessary. As we noted in the preamble to the proposed rule, our policy goals are not served when a sponsor uses the novation process to purchase a piece of another sponsor's contract with CMS for less than the full line of PDP business. We do not agree that picking and choosing which markets a sponsor wishes to serve at any given time and to profit from its exit from a given PDP region is most efficient when a simple nonrenewal for that region is an option available to the sponsor. Moreover, this process should not be used as an instrument for moving LIS beneficiaries when a particular sponsor has missed the benchmark.

We believe that the change we proposed creates consistency between the Part C program and the Part D program, because the Part C regulations only permit novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity).

We adopt these provisions as proposed. As noted below, we amend § 423.551 to clarify that these provisions do not apply to changes of ownership between subsidiaries of the same parent organization.

*Comment:* Several commenters expressed concern that the proposed policy could cause greater disruption for beneficiaries by limiting sponsors' ability to divest and acquire certain Part D contracts in situations where those transactions would have few effects on beneficiaries. The commenters believe that the proposed change may result in Part D sponsors withdrawing plan benefit packages and bid submissions, prevent acquisitions and mergers, or cause mid-year terminations, if the novation option no longer is available in many situations. The commenters also believed that this change could impact CMS efforts to consolidate PBPs and service areas under one contract number.

*Response:* We believe that there are adequate PDP choices for beneficiaries, and that restricting novations as proposed is in the best interest of the Part D program. We do not believe that the proposed change would negatively impact a sponsor's ability to consolidate PBPs even if the plans are located in different geographical areas. To the extent that this comment concerns the application of this policy to novations among subsidiaries of the same parent organization, CMS agrees that those types of transactions should be permitted and would not require the transfer of an entire line of Medicare business. Novations between the subsidiaries of the same parent organization do not involve the buying and selling of beneficiaries; rather, they are usually undertaken to accommodate an organization's change to its internal corporate structure. Therefore, we have modified our proposed regulatory language to clarify that the new policy does not apply to changes of ownership between subsidiaries of the same parent organization.

*Comment:* One commenter stated that no change is needed in the current regulation to accomplish CMS' policy goal. The commenter, citing § 423.552(a)(3)(ii), believed that CMS already has authority to determine whether a proposed novation is in the best interest of the Medicare program and that CMS did not need to change the regulation to keep this authority. The commenter expressed concern, however, that the proposed change would limit CMS's flexibility to approve a novation of some but not all of an entity's Part D contract(s), even if CMS determined that it was in the best interest of the program to approve the novation. The commenter added, that if CMS does not retain the authority to approve a novation representing less than an organization's entire line of PDP business, the acquiring company would have to terminate the contract, causing substantial member disruption.

*Response:* We believe that a change to the regulation is necessary to provide clarity to sponsors regarding the circumstances under which a PDP novation would be approved by CMS. Additionally, we believe that beneficiary disruption in situations where a sponsor nonrenews a contract because it is not eligible to be novated, is minimized by comprehensive nonrenewal beneficiary rights and required notifications, and that beneficiary election rights trump any member disruption that occurs due to a nonrenewal.

*Comment:* One commenter stated that it agreed with CMS that the novation process should not be used, either in Part C or Part D, to pick and choose profitable markets, but it did not interpret the current Part C regulation related to the novation process to only allow novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity). The commenter stated that there are unique circumstances where a change of ownership may be specific to Special Needs Plans (SNPs) that may be better served under new ownership that has a specialized model. The commenter suggested that the proposed provision be modified (and our Part C regulations modified as well) to allow for exceptions, especially with regard to SNPs.

*Response:* We have consistently interpreted the Part C regulation to limit novations in situations involving the sale of less than an entity's entire MA line of business. Also, SNP plans do not present unique circumstances that would require an exception to our proposed policy change. If a SNP plan can no longer serve its enrollees, there is existing regulatory authority pursuant to which the failing SNP can non-renew or terminate its Medicare contract. CMS can then exercise its regulatory authority related to plan enrollment to ensure that affected beneficiaries either elect or are assigned to an appropriate new plan.

*Comment:* Several commenters supported this change to the regulation, and agreed with the underlying reasoning used by CMS to make this change and become more prescriptive in this area.

*Response:* We appreciate these comments.

*Comment:* A few commenters stated that CMS should allow novations of one contract, where a selling sponsor holds multiple contracts, because otherwise PDP sponsors will have to resort to holding PDP contracts under different legal entity names in order to avoid having to novate all contracts as required under the proposed requirement, or terminating a contract, which would result in beneficiary disruption.

*Response:* A sponsor is already afforded ample opportunity to leave a particular Medicare market through the contract non-renewal process. That process does not require that a sponsor non-renew all of its contracts, so there is no need for organizations to hold contracts through multiple legal entities. The beneficiary disruption in this instance would be no more than that already contemplated by the Congress and CMS when it adopted and implemented a program which featured

the right of beneficiaries to elect their own health and drug plan coverage. Therefore, we believe that limiting novation to the entire line of PDP business is the best interest of the Part D program.

*Comment:* One commenter asked CMS to clarify that the proposed change would not prevent a sponsor from novating its Part D contract in connection with sale of an MA–PD Plan while retaining the entity's stand-alone Part D Plan contract or vice versa.

*Response:* We agree that in the scenario described by the commenter, the organization would be permitted to retain a stand-alone PDP sponsor contract after it had transferred ownership of all of its Medicare Advantage contracts, including those through which it had been offering Part D benefits. We believe that the regulation makes this point clear on its face as the language specifically mentions only PDP contracts.

*Comment:* One commenter encouraged CMS to reconsider its proposed position that a Part D contract can only be novated when the "entire line of business" is involved. The commenter stated that there are important differences between Part C and Part D contracting including the notion that Part D contracts are national in scope and Part C contracts generally conform to State boundaries. The commenter stated that the suggested alignment between Part C and Part D contract novation policy as discussed in the preamble is not true when the practical impact of that policy is considered.

*Response:* The commenter has not made clear, and we are unable to determine on its own, how the stated difference between Part C and D service areas affects the novation policy we adopt in this regulation. Therefore, we retain our belief that a change to the regulation to limit PDP novations to the entire line of business is in the best interest of the Part D program.

13. Cost Contract Program Revisions: Appeals and Marketing Requirements (§ 417.428, § 417.494, § 417.500, and § 417.640)

Under the authority in section 1876(i)(3)(D) of the Act to impose "other terms and conditions" under contracts authorized by the statute that the Secretary finds "necessary and appropriate," and in implementation of the requirements in section 1876 of the Act set forth below, we proposed in our October 22, 2009 proposed rule to apply the following MA program requirements to cost contracts authorized under section 1876 of the Act:

- The MA program requirements on appeals processes for contract determinations and intermediate sanctions under the authority in section 1876(i)(1) of the Act to terminate or non-renew contracts, and the authority in section 1876(i)(6) of the Act to impose intermediate sanctions and CMPs (To the extent that the CMPs in section 1876(i)(6)(B) and (C) of the Act differ from those under Part C, the penalty amounts under section 1876 of the Act would continue to control); and
- The MA program's marketing requirements under the authority in section 1876(c)(3)(C) of the Act to regulate marketing of plans authorized under section 1876 of the Act and ensure that marketing material is not misleading.

The specific revisions we proposed are summarized below.

a. Cost Contract Determinations (§ 417.492 and 417.494), Civil Money Penalties (§ 417.500), and Intermediate Sanctions (§ 417.500)

We proposed requiring cost contracts to follow the contract determination appeal procedures under Subpart N of Part 422. We proposed codifying these requirements in § 417.492(b)(2), concerning notice of appeal rights, and § 417.494, concerning notice of termination.

We proposed revising § 417.500 to require cost contracts authorized under section 1876 of the Act to follow the MA programs requirements for appeals of CMPs at Subpart T of Part 422. The appeals process for CMPs specified at Subpart T allows for a hearing by an Administrative Law Judge (ALJ) and a review of the ALJ's decision by the Departmental Appeals Board. We proposed, in new paragraph (c), to specify that the amount of CMPs a cost contract may be assessed is governed by section 1876(i)(6)(B) of the Act, not by the provisions in part 422 of the MA program regulations.

Our proposed revisions to the cost contracts regulations authorized under section 1876 of the Act would ensure that these contracts follow the same requirements for intermediate sanctions appeals specified in § 422.750 through § 422.764 of the MA program regulations (subpart O). These sections concern—

- Types of intermediate sanctions and CMPs (§ 422.750);
- Bases for intermediate sanctions and CMPs (§ 422.752);
- Procedures for imposing intermediate sanctions and CMPs (§ 422.656)
- Collection of CMPs (§ 422.758);
- Settlement of penalties (§ 422.762); and
- Other applicable provisions (§ 422.764).

With respect to determinations of the amount of CMPs, the provisions in section 1876(i)(6)(B) and (C) of the Act would govern such amounts.

We are adopting our proposed changes to § 417.472, § 417.492, § 417.494, § 417.500, § 417.640, § 417.640, § 417.642 through § 417.694, and § 417.840 without further modification in this final rule.

*Comment:* Two organizations expressed concerns about extending the MA requirements for appeals of contract determinations to cost contract plans. Both commenters point to differences in cost contract plans and MA plans as their basis for seeking revisions to our proposals.

One commenter suggested that CMS' approach of cross referencing the MA appeals provisions in the cost plan requirements is unworkable for three reasons: (1) There are provisions of Part 422, Subpart N, that would not apply to Medicare cost plans, for example, organizations may not submit an application to obtain a new section 1876 contract; (2) there are termination/non-renewal provisions under part 417 that are not addressed under Part 422, for example, the obligation to non-renew a portion or all of the service area under the so called two-plan competition test at § 417.402(c); and (3) simply indicating that part 422 references should be read as Part 417 references does not provide the reader with guidance regarding the applicable provisions. This commenter asserts that, without specific cross references, the reader is left to guess which sections of part 417 would substitute for the sections of part 422 cited in part 422 subpart N and that, in some cases, there are no directly analogous provisions under part 417. Thus, it is unclear in this commenter's view whether CMS intended to create a new requirement for cost plans in a specific provision, or whether the provision does not apply. The commenter recommends that CMS not simply cross reference subpart N, part 422, in part 417 but revise the language in part 417 to incorporate structure that is similar to the part 422 rules for terminations, but includes relevant part 417 cross references and is modified to appropriately apply to Medicare cost plans.

The second commenter also believed that CMS' proposed approach would not provide sufficient clarity to cost contracts regarding the requirements that apply to them. For example, there are provisions of part 422, subpart N

that would not apply to cost contracts, and there are termination/non-renewal provisions under part 417 that are not addressed under part 422. Accordingly, the commenter recommended that CMS revise the language in part 417 to incorporate a structure that is similar to the part 422 rules and is modified to appropriately apply to Medicare cost plans.

*Response:* We agree with the commenters that there are differences between cost plan and MA plan procedures in this area but believe that the differences are minimal with respect to the application of the MA provisions concerning appeals of contract determinations. We stated clearly in the preamble of the proposed rule that the part 422 regulations concerning appeals of non-renewals, terminations, and imposition of intermediate sanctions and CMPs would apply to cost contracts. Therefore, we believe there should be no ambiguity in this regard. In other words, if there is no "analogous provision" under part 417, as one of the commenters wrote, cost plans would follow the part 422 requirements. Concerning the possibility of confusion resulting from different CMPs for cost plans and MA plans, we did acknowledge in the proposed rule, in both the preamble and regulations text at § 417.500(c), that CMPs for cost plans would be assessed according to the statutory requirements at section 1876(i)(6)(B) of the Act. We do not agree with the commenter that additional regulations for part 417 are necessary to capture this distinction.

With respect to the other discrepancies that the commenter asserts make incorporation of the part 422 regulations "unworkable," we do not believe that there should be any confusion about appeal of contract determinations as a result of cost plan competition requirements. The application of such requirements is statutory, and non-renewal of a cost plan based on the statutory requirement is not appealable. We note that the current regulations for Part 417 do not indicate that such a decision may be appealed. Concerning the commenter's other example of an allegedly unworkable discrepancy, the fact that there may be no new cost plans and thus no new applications, we note that the part 422 contract determinations include not only decisions on new applications, but determinations concerning non-renewals and terminations, and thus have relevance to cost contracts. The part 417 regulations are clear that there may be no new cost plans, as is CMS guidance, and we do not believe that the part 422 contract determination provisions would lead anyone to believe otherwise.

Finally, we believe it is most efficient to cross-reference the part 422 regulations as specified in the proposed rule and are, therefore, adopting the language in that rule.

b. Extending MA Marketing Requirements to Cost Program Plans (§ 417.428)

As noted above, based on the authority in section 1876(c)(i)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, we proposed to amend § 417.428, which governs 1876 cost contract program marketing requirements, to require cost contract plans to follow the MA marketing requirements in § 422.2260 *et seq.* (Subpart V).

We proposed that cost contracts authorized under section 1876 of the Act follow the same standards, with respect to definitions concerning marketing materials, as MAOs under § 422.2260, including how marketing materials are defined. We also proposed that the part 417 marketing regulations be revised to provide that, consistent with the requirements regarding review and distribution of marketing materials at § 422.2262, cost contractors authorized under section 1876 of the Act submit all such marketing materials to CMS at least 45 days before the date planned for distribution (10 days if plans use CMS model language, without any modifications), and that file and use materials, as designated by CMS under the MA marketing regulations, may be released 5 days following their submission to CMS.

We proposed to apply the same standards with regard to CMS review of marketing materials to cost contract plans as currently applied to MAOs at § 422.2264. Cost contractors authorized under section 1876 of the Act would be required to comply with MA regulations that specify the information that cost contract plans must include in marketing materials, and specify that the cost contract plan must notify the general public concerning the plan's enrollment period. Under section 1876(i)(3)(D) of the Act, we also proposed that, in markets with a significant non-English speaking population, cost contract plans be required to provide materials in the language of these individuals.

We proposed to specify that if we have not disapproved the distribution of marketing materials or forms submitted by a cost contract plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the cost contract plan and cost contract except with regard to any portion of the material or form that is specific to the particular area, as provided under § 422.2266.

*We proposed to extend to cost contract plans the following provisions at § 422.2268—*

- Plans may not offer gifts to potential enrollees, unless the gifts are of nominal value (as defined in the CMS Medicare Marketing Guidelines), are offered to all potential employees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates;
- Plans may not market any health care-related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment;
- Plans may not market additional health-related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment;
- Plans may not use a plan name that does not include the plan type. The plan type should be included at the end of the plan name;

We proposed to extend to cost contract plans authorized under section 1876 of the Act the following requirements for MAOs under § 422.2272:

- Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.
- Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the plan, and understand the rules applicable under the plan.
- Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the CMS Medicare Marketing Guidelines) in that State, and whom the cost program has informed that State it has appointed, consistent with the appointment process provided for under State law.

We proposed applying the MA limits on independent agent and broker compensation at § 422.2274 to 1876 cost contract plans. As with MA plans, compensation would be based on a 6-year compensation cycle. Agents and brokers would receive initial compensation (first year of the cycle) with compensation over each of the successive 5 years to be no more and no less than 50 percent of the initial aggregate compensation paid for the

enrollment. If an enrollee moves to plan type distinct from the one in which he or she is currently enrolled, the agent/broker would receive an initial commission and the cycle would begin anew. Distinct plan types include MA, MA–PD, PDP, and cost contract plans authorized under section 1876 of the Act.

We are adopting our proposed changes to § 417.428 without further modification in this final rule.

*Comment:* All commenters support applying the MA marketing requirements to cost contract plans. A few of these commenters note, however, that CMS is not applying one of the marketing sections (§ 422.2276) which exempts from the prior review and approval requirements marketing materials designed for members of an employer group. While one of the commenters on the employer group requirement notes that cost contracts are not eligible to offer 800-series plans for their medical benefits, the commenter notes that cost contracts have always been permitted to negotiate with employers to offer additional benefits to their employer group members. The commenter believes there is no statutory or policy reason for treating cost contracts differently than MA plans with respect to marketing materials furnished for employer groups and asks that all MA marketing provisions, including § 422.2276, apply to cost plans. Another commenter believed that while it makes sense, in general, to apply the MA marketing requirements to cost contract plans, there are several differences between MA and cost contract plans, and that these should be reflected in updated Medicare Marketing Guidelines.

*Response:* In order to permit employer group health plans to tailor plans best suited to their enrollees and to communicate such information to enrollees, we have permitted waivers of the requirement that MA-eligible individuals in an MA plan service area be eligible to enroll in the plan in order to permit an MA plan to be composed solely of members of an employer group plan (an "800 series plan"). Because non-employer group members are not eligible to enroll in such plans, and the employer generally provides information to group members, we have waived certain requirements, such as the prior review and approval requirement for marketing standards for 800 series plans based on the statutory authority to permit such waivers at 1857(i)(1) of the Social Security Act. There is no such general waiver authority with respect to other MA plans or cost plans that would permit such plans to limit enrollment to a particular group, or to waive statutory marketing requirements, and CMS thus would not have the authority to exempt cost plans from such marketing requirements. We are, therefore, adopting the language from the proposed rule. Concerning the suggestion that CMS update the Medicare Marketing Guidelines to reflect any difference between cost plans and MA plans, we are unsure to which specific provisions, if any, the commenter is referring but in revising the guidelines, will point out any necessary distinctions between MA and cost plan procedures and policies.

*Comment:* One commenter recommends that CMS amend the cost plan enrollment regulations to allow beneficiaries the option of electronic enrollment into cost plans in the same manner as MA organizations.

*Response:* This comment is outside the scope of this rulemaking, and therefore, is not addressed in this final rule.

14. Out of Scope Comments

*Comment:* A number of commenters asked CMS to revise § 423.562(a)(3) to eliminate the option of posting Form CMS–10147 Medicare Prescription Drug Coverage and Your Rights, also known as the Pharmacy Notice, in network pharmacies. The notice instructs enrollees to contact their plan sponsors to request coverage determinations or exceptions when they disagree with the information provided at the pharmacy counter. The commenters recommended requiring plan sponsors to arrange with network pharmacies to give enrollees copies of the Pharmacy Notice whenever prescription drugs are not covered or are covered but subject to utilization requirements that cannot be resolved at the point-of-sale, or if an enrollee pays out-of-pocket for prescription drugs for either of these reasons.

*Response:* The commenters' suggestion is outside the scope of the proposed rule. However, we agree that receiving a written copy of the Pharmacy Notice in any of the situations described by the commenters is more beneficial for an enrollee than being referred to a copy of the notice posted in the pharmacy. We will consider this suggestion for future rulemaking.

*Comment:* A number of commenters asked CMS to allow an enrollee to send an appeal request to the Part D Independent Review Entity (IRE) when a coverage determination or redetermination decision is not received timely. The commenters also asked CMS to closely monitor plan compliance to determine if coverage determination and redetermination requests are timely forwarded when appropriate, and impose sanctions on plan sponsors that are not meeting these requirements.

*Response:* The commenters' suggestion is outside the scope of the proposed rule. However, we want to note our disagreement with the commenter's proposal to allow enrollees to request appeals when plan sponsors fail to make timely decisions. We currently require plan sponsors to automatically forward redetermination requests that are not timely decided to the Part D Independent Review Entity for review once the decision-making timeframe has expired, and we have processes in place to monitor and plan performance in this area and impose sanctions when necessary. Furthermore, the Part D IRE currently tracks the volume of cases that are automatically forwarded from plan sponsors. The current auto-forwarding rate of 30 percent is not insignificant, so it appears that plans are appropriately auto-forwarding cases when they miss the decision-making timeframes.

*Comment:* Numerous commenters asked CMS to allow public access to the prescription drug compendia used to determine if a drug may be approved under the Part D exceptions process.

*Response:* The commenters' suggestion is outside the scope of the proposed rule. We note that any private or public entity may obtain access to the prescription drug compendia by contracting with the publishers.

*Comment:* A commenter, in response to the revisions proposed to § 423.590, requested clarification that the Part D Independent Review Entity is responsible for completing expedited reconsideration reviews.

*Response:* We did not propose to revise any of the regulatory provisions pertaining to the Part D reconsideration process, which is conducted by the Part D Independent Review Entity for both expedited and standard appeals. However, we did propose to revise the Part D expedited redetermination process conducted by the Part D plan sponsor. In the related preamble discussion, we referenced the expedited reconsideration process conducted by MA organizations under § 422.590 to illustrate a discrepancy between that process and the expedited redetermination process conducted by Part D plan sponsors under § 423.590. We believe the reference to the MA expedited reconsideration process may have confused the commenter, and given the impression that we were proposing changes to the Part D

reconsideration process when we were not.

*H. Changes To Implement Corrections and Other Technical Changes*

In this section, we address six technical changes to the regulations proposed in our October 22, 2009 proposed rule outlined in the Table below.

TABLE 8—CHANGES TO IMPLEMENT CORRECTIONS AND OTHER TECHNICAL CHANGES

| Provision | Part 422 | | Part 423 | |
|---|---|---|---|---|
| | Subpart | Section | Subpart | Section |
| Applications of Subpart M to Health Care Prepayment Plans. | Subpart M | § 417.840 | N/A | N/A. |
| Generic Notice Requirements | Subpart M | § 422.622<br>§ 422.626 | N/A | N/A. |
| Revision to Definition of Gross Covered Prescription Drug Costs. | N/A | N/A | Subpart G | § 423.308. |
| Application Evaluation Procedures | Subpart K | § 422.502(c) through (d). | Subpart K | § 423.503(c) through (d)). |
| Intermediate Sanctions | Subpart O | § 422.750(a) | Subpart O | § 423.750(a). |
| Basis for Imposing Intermediate Sanctions and Civil Money Penalties. | Subpart O | § 422.752 | Subpart O | § 423.752. |

1. Application of Subpart M to Health Care Prepayment Plans (§ 417.840)

In the October 22, 2009 proposed rule, we proposed a technical correction to the regulations governing Health Care Prepayment Plans (HCPP) intended to ensure that HCPP enrollees have access to fast-track appeals for comprehensive outpatient rehabilitation facility (CORF) services furnished by an HCPP. As we explained in the preamble to the October 22, 2009 proposed rule and in the January 28, 2005 MA final rule, we required cost plans (HMOs), including HCPPs, that are established under section 1876 of the Act (Part E) and regulated under part 417, to follow the MA appeals requirements in subpart M of part 422. In applying the MA appeals procedures to HCPPs by regulation, we adapted and implemented the section 1869 appeal rights that apply to Original Medicare beneficiaries to the circumstances of beneficiaries enrolled in an HCPP. Because HCPPs only provide Part B services, in our January 28, 2005 final rule (70 FR 4194), we explicitly limited the application of subpart M, for the HCPPs, to those provisions affecting Part B services delivered to HCPP enrollees, and intended to encompass all Part B services. However, in doing so, we inadvertently failed to include the fast-track appeal rights regarding Part B services provided by a CORF. In a proposed revision to § 417.840, we proposed to correct this oversight, and ensure that HCPP enrollees have access to fast-track appeals for CORF services furnished by an HCPP. This revision would also ensure that HCPP enrollees received the fast track appeal rights provided for under section 1869 of the Act with respect to such services (which parallel those available to section 1876 cost enrollees and Part C enrollees).

We received only one comment on this clarification, and the commenter supported our proposed technical revision. Accordingly, we are revising § 417.840 as set forth in the proposed rule without change.

2. Generic Notice Delivery Requirements (§ 422.622 and § 422.626)

In the October 22, 2009 proposed rule (74 FR 54700), we proposed to make technical revisions to § 422.622 and § 422.626 to ensure that the MA regulations accurately state when plans and providers are responsible for delivering certain notices to enrollees. Section 422.622 currently states that when a QIO determines that an enrollee may remain in an inpatient setting, the MA organization must again provide the enrollee with a copy of the Important Message from Medicare (IM) when the enrollee no longer requires inpatient hospital care. However, our intent was to make delivery of the IM the hospital's responsibility, and the form instructions for the IM state this. Similarly, § 422.626 of subpart M inadvertently states that delivery of the Notice of Medicare Non-Coverage (NOMNC) is the MA organization's responsibility. Again, consistent with the form instructions for the NOMNC, our intent was to make delivery of the notice the provider's responsibility. To address these technical errors, we proposed replacing "MA organization" with "hospital" in § 422.622, and "provider" in § 422.626.

The only comment we received regarding these provisions was supportive of the proposed technical revisions. Thus, we are making these revisions as set forth in the proposed rule without change.

3. Revision to Definition of Gross Covered Prescription Drug Costs (§ 423.308)

In the October 22, 2009 proposed rule, we proposed to revise the definition of "gross covered prescription drug costs" in § 423.308 to correctly reference both "negotiated prices" paid to network pharmacies and "usual and customary prices" paid to out-of-network pharmacies. Specifically, we proposed to replace the term "negotiated price" with the term "actual cost," which is defined at § 423.100 as "the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out of network pharmacy consistent with § 423.124(a)." With this correction, the definition of "gross covered prescription drug costs" would include "the share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy or other dispensing entity."

As we noted in the preamble to the October 22, 2009 proposed rule,, the January 12, 2009 final rule (74 FR 1494) included revisions to the definition of "gross covered prescription drug costs" in the Part D regulations at § 423.308. In amending § 423.308 in that final rule, we made a technical error in the definition of "gross covered prescription drug costs" (74 FR 1545) by referencing "negotiated price" as the prices made available to Part D beneficiaries at network pharmacies, and not also referencing "usual and customary prices," the prices for drugs purchased at out-of-network pharmacies. When we revised the definition of "gross covered prescription drug costs" in that final

rule, our intent was to clarify that Part D sponsors must use the amount received by the dispensing pharmacy or other dispensing provider as the basis for determining the drug costs that must be reported to us. The use of the term "negotiated prices" as defined at § 423.100 (74 FR 1544) in the definition of "gross covered prescription drug costs" clarifies this requirement with regards to covered Part D drugs purchased at network pharmacies. However, by not also referencing "usual and customary prices" for covered Part D drugs purchased at out-of-network pharmacies, we inadvertently omitted from the definition of "gross covered prescription drug costs" the share of drug costs actually paid by Part D sponsors to out-of-network pharmacies. Since section 1860D–15(b)(3) of the Act defines "gross covered prescription drug costs" as "the costs incurred under the [Part D] plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs * * *," these costs must include costs incurred for covered Part D drugs at out-of-network pharmacies, as well as costs incurred at network pharmacies. Therefore, we needed to revise the definition of "gross covered prescription drug costs" to correctly reference both "negotiated prices" paid to network pharmacies and "usual and customary prices" paid to out-of-network pharmacies. We received two comments, both of which supported the proposed revision to the definition of "gross covered prescription drug costs." The commenters agreed with our proposed correction to add a reference to "usual and customary prices" paid to out-of-network pharmacies in the definition of "gross covered prescription drug costs." Therefore, we are adopting this revision to the definition of "gross covered prescription drug costs" in § 423.308 as proposed.

4. Application Evaluation Procedures (§ 422.502(c) and (d) and § 423.503(c) and (d))

In the October 22, 2009 proposed rule, we proposed two amendments to regulations governing the application evaluation procedures at § 422.502(c) and (d), and § 423.503(c) and (d). In addition, at § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) we proposed to make a technical correction and delete the language "right to reconsideration" and replace it with "right to request a hearing".

As we noted in the preamble to the proposed rule, currently, § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) state that if we deny the application, CMS gives written notice to the contract applicant indicating the applicant's right to request reconsideration. In our December 5, 2007 final rule, we modified the appeal rights for initial applications and eliminated the reconsideration process. However, in the final regulations we did not update § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) to state that the applicant has a right to request a hearing and as a result the existing regulations incorrectly provide for a right to reconsideration.

In the October 22, 2009 proposed rule, we also proposed to delete § 422.502(d) and § 423.503(d). Sections 422.502(d) and 423.503(d) currently provide that we have the ability to oversee the sponsoring organization's continued compliance with our requirements and that if the sponsoring organization no longer meets those requirements, we will terminate the contract in accordance with § 422.510 and § 423.509. We noted that this regulation is not an appropriate regulation for a section dedicated to the evaluation and determination procedures for approving or denying a contract application.

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

5. Intermediate Sanctions (§ 422.750(a) and § 423.750(a))

In the October 2009 proposed rule (74 FR 203), we made three technical changes to each intermediate sanction regulation at § 422.750 (a) and § 423.750(a) to more accurately reflect the statute. First, we changed § 422.750(a)(1) and § 423.750(a)(1), which stated that we may impose a suspension of enrollment of Medicare beneficiaries. This regulation did not adequately reflect the statutory language which specifies that the enrollment suspension applies to the "sponsoring organization's enrollment of Medicare beneficiaries.

We also changed the language of § 422.750(a)(2) and § 423.750(a)(2), which stated that we may impose a suspension of payment to the sponsoring organization for Medicare beneficiaries who are enrolled in the MA plan. This language does not conform to the statutory language, which states that suspension of payment may be imposed for Medicare beneficiaries enrolled after the date we notify the organization of the imposition of an intermediate sanction.

We also proposed to change § 422.750(a)(3) and § 423.750(a)(3), which stated we may suspend all marketing activities to Medicare beneficiaries by a sponsoring organization for specified MA or Part D "plans." We deleted the words "for specified" MA or Part D "plans" because those did not conform to the statutory language that applies intermediate sanctions at the organization level.

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

6. Basis for Imposing Intermediate Sanctions and Civil Money Penalties (§ 422.752 and § 423.752)

In the October 22, 2009 proposed rule, we proposed conforming changes to our regulation at § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) to more accurately reflect statutory language and to ensure accuracy, consistency, and uniformity. Specifically, we proposed to amend § 422.752(a)(1) and § 423.752(a)(1) to conform with statutory language and state that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

We also proposed to amend § 422.752(a)(3) and § 423.752(a)(3) to conform with statutory language and stated that we may impose an intermediate sanction if the sponsoring organization "acts" to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

Additionally, we proposed to amend § 422.752(a)(4) and § 423.752(a)(4) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

As we noted in the proposed rule, sections 1857(g) and 1860D–12 of the Act provide a list of the bases for intermediate sanctions and civil money penalties. Existing regulations at § 422.752(a) and § 423.752(a) provide a similar list of bases for intermediate sanctions and civil money penalties. However, the language provided in § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) does not adequately conform to the statutory language in section 1857(g)(1)(A), (C), and (D) of the Act, respectively.

First, § 422.752(a)(1) states that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide, to a sponsoring organization enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a sponsoring organization enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee. This language is slightly different than the language provided in the statute at section 1857(g)(1)(A) of the Act.

Second, § 422.752(a)(3) and § 423.752(a)(3) states that we may impose an intermediate sanction if the sponsoring organization expels or refuses to reenroll a beneficiary in violation of the provisions of this part. This language does not include the word "acts" to expel which is mentioned in the statute at section 1857(g)(1)(C) of the Act.

Third, § 422.752(a)(4) and § 423.752(a)(4) states that we may impose an intermediate sanction if the sponsoring organization engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services. This language does not match the exact language contained in section 1857(g)(1)(D) of the Act.

Finally, we made conforming changes to § 422.752(c) and § 423.752(c). Currently § 422.752(c)(1) and § 423.752(c)(1) state that we may impose civil money penalties for any of the determinations at § 422.510(a) and § 423.509(a), except § 422.510(a)(4) and § 423.509(a)(4). Also, § 422.752(c)(2)(ii) and § 423.752(c)(2)(ii) state that OIG may impose civil money penalties for a determination made pursuant to § 422.510(a)(4) and § 423.509(a)(4). Since we are proposing elsewhere in these proposed regulations to redesignate § 422.510(a)(4) and § 423.509(a)(4) to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii), we need to conform § 422.752 and § 423.752 to these changes. Therefore, for regulations § 422.752(c)(1), § 422.752(c)(2)(ii), § 423.752(c)(1), and § 423.752(c)(2)(ii) we are deleting the reference to § 422.510(a)(4) and § 422.509(a)(4) and replace with a reference to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii).

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

## III. Provisions of the Final Rule

*Except as otherwise noted below, this final rule adopts the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows:*

- Changes to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers.
- Notice of Intent to Apply. We modified § 422.503(b)(2) and § 423.502(b)(2) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.
- Compliance Programs under Parts C and D—

++ We made changes made to § 422.502(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and clarify that they may not be an employee of a first tier, downstream or related entity of the sponsoring organization and must be accountable to the governing board of the sponsoring organization.

++ At § 423.504(b)(4)(vi)(C)(3), we adopt a new regulation for the Part D program to specify that first tier, downstream, and related entities have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program and accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier are deemed to have met the training and educational requirements for fraud, waste, and abuse.

- Termination of Contracts under Parts C and D. We did not finalize the modifications to § 422.510(a)(2)(i), § 423.509(a)(2)(i) (failure to comply with regulatory requirements), § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii) (failure to comply with performance standards).
- Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services. At § 422.100(f)(4) with one modification regarding its applicability to all MA plans.
- Transition Process Under Part D (§ 423.120(b)(3)). At § 423.120(b)(3), we are modifying proposed paragraph (iii) to clarify that transition notices must be sent to beneficiaries within 3 business days of adjudication of a temporary fill.
- Beneficiary Communications Materials Under Parts C and D

++ Revised paragraph § 422.2260(5)(vii) to retain materials about membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification materials) in the definition of marketing materials.

++ Added a new paragraph § 422.2260(6) to specifically exclude from the definition of marketing ad hoc customized or situational enrollee communications from the definition of marketing materials.

- Use of Standardized Technology under Part D. At § 423.120, we clarify that the effective date for the requirement for a unique RxBIN or RxBIN/RxPCN combination and a unique Part D Rx identifier for each individual Part D member will be January 1, 2012.
- Notice of Alternative Medicare Plans Available to Replace Nonrenewing Plans Under Parts C and D.
- Revised § 422.506 and § 423.507 to require that both Part C and Part D organizations inform beneficiaries of both MA and PDP available options.
- Made minor technical changes to § 422.254(a)(4), § 423.265(b)(2), § 422.256(b)(4)(i) and § 423(b)(3)(i).
- RADV Appeals Processes.

++ In § 422.2 we are—

— Removing the definition of documentation dispute process; and

— Adding the definition of initial validation contractor (IVC).

++ In § 422.311 we are revising the audit dispute and appeals processes.

- Changes to Improve Data Collection for Oversight and Quality Assessment

++ At § 480.140(g), we clarify that QIOs must disclose quality review study information collected by the QIOs as part of the RHQDAPU program, as defined in section 1886(b)(3)(B) of the Act, to CMS.

++ We also modify § 422.153 to indicate that we will acquire quality review study information from QIOs as defined in part 475.

- CAHPS Survey Administration Under Parts C and D. At § 417.492 and § 422.152, we clarify that all cost contracts under section 1876 of the Act with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.
- Protected Classes of Concern under Part D. We are not finalizing our proposed revisions to § 423.120(b)(2)(v).
- Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring

During an Initial Coverage Election Period. We are modifying § 422.103(d) in this final rule to allow beneficiaries who enroll in a MSA plan mid-year to also pay a pro-rated deductible.

Medication Therapy Management Programs Under Part D—At § 423.153(d)(2)(iii), we adopt the establishment of a specific threshold of $3,000 for MTM eligibility, instead of relying on the ICL as the proposed target for MTM eligibility.

• Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D. We add paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and maintaining the documentation in the case file.

• Novations. We amended § 423.551 to provide clarity to sponsors regarding the circumstances under which a PDP novation would be approved by CMS, noting that they do not apply to changes of ownership between subsidiaries of the same parent organization.

## IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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.

The following sections of this document contain paperwork burden but not all of them are subject to the information collection requirements (ICRs) under the PRA for reasons noted.

### *A. ICRs Regarding Basic Contract Requirements (§ 417.472)*

Proposed § 417.472(i) states that HMO or CMP must comply with the requirements at § 422.152(b)(5). Proposed § 417.472 states that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications and submit the survey data to CMS. The burden associated with the requirement in § 417.472(i) and (j) is detailed in our discussion of § 422.152.

### *B. ICRs Regarding Apportionment and Allocation of Administrative and General Costs (§ 417.564)*

We are not imposing any new reporting requirements. We are simply clarifying what costs an HCPP may report in its cost report as administrative costs for reimbursement from the government. We do not believe that our proposal will result in additional burden on cost plans; therefore, we have not incorporated a burden increase in the PRA section.

### *C. ICRs Regarding Medicare Secondary Payer (MSP) Procedure (§ 422.108 and § 423.462)*

Section 422.108(b)(3) proposes that MA organizations must coordinate benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained in accordance with requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions. Similarly, § 423.462 proposed that Part D plan sponsors must report creditable new or changed primary payer information to the CMS COB Contractor in accordance with the processes and timeframes specified by CMS. In the proposed rule, we estimated the burden associated with this requirement to be the time and effort necessary to report the specified information to CMS on an ongoing basis. We estimated that 624 MA organizations and 456 Part D plan sponsors would need to comply with these requirements, a total of 1,080 entities. We also estimated that, on average, each entity would produce one report thereby yielding a total of 1,080 reports annually for involved entities. We estimated that it would take each entity an average of 2,885 hours to report the required information to CMS. The estimated annual burden associated with these requirements was 3,115,800 hours, and the cost associated with meeting these requirements was $77.9 million.

We have now determined that the information collection burden imposed by § 422.108 and § 423.462 is generally part of the information being captured in CMS–10265—Mandatory Insurer Reporting information collection request (ICR). The OMB control number (OCN) is 0938–1074. Therefore, no new ICR is required.

The collection approved under OCN 0938–1074 takes care of virtually all of an MAO's MSP reporting responsibilities; the MAO is now reporting on their own primary, commercial insurance coverage. The small number of cases where an MAO will need to report either a new primary carrier or the termination of such coverage, that is not captured by OCN 0938–1074 is covered by existing authority under OCN 0938–0753. Under our previous Part C coordination of benefits policy, we required MAOs to survey members annually and to report results to CMS.

The reporting burden under our previous Part C coordination of benefits policy was to report both survey non-responders (approximately 10 percent of enrollees) and those who reported that they had other third party health insurance coverage (less than 2 percent). MAOs were not required to report to us on members that responded to the survey and said that they did not have other third party health insurance coverage—over 85 percent. Under the new system MAOs will only have to report to CMS those for whom MSP status changes from what is showing on the current COB file. We estimate this will be less than 1 percent. The burden of reporting is less now than it was before the change, but the actual reporting process is new. The new reporting process is slightly more burdensome than the old process and we believe the overall burden will be similar to what it was before this change.

### *D. ICRs Regarding Disclosure Requirements (§ 422.111)*

Proposed § 422.111 states that we may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

Our intent is to invoke this disclosure authority when we become aware that an MA organization has serious compliance and performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to

promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. The burden associated with this requirement would be the time and effort necessary for the MA organization to make the aforementioned disclosures. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 10 organizations per any 12 month period. We have based this assumption on past experience. For example, while this requirement does not just apply to those organizations who have been sanctioned, in 2009, CMS imposed intermediate sanctions on a total of 4 sponsoring organizations (which is the highest number of intermediate sanctions imposed in any year or 12 month period from 2006 through 2009) and, it is important to note, that not all of the organizations sanctioned in 2009 were required to make such a disclosure. Additional organizations (not under sanction) experience compliance deficiencies, however we intend to utilize this disclosure requirement in instances where we become aware of serious deficiencies which may lead to the imposition of intermediate sanctions and/or require immediate correction. For any of these instances, we will then evaluate and determine whether it is appropriate that beneficiaries be specifically notified of the underlying deficiencies to achieve our stated goals of promoting transparency and/or informed choice. Therefore, we do not believe that we will impose the disclosure requirement on 10 or more sponsoring organizations within any 12-month period which would not require the development of a burden estimate.

*E. ICRs Regarding Quality Improvement Program (§ 422.152)*

Section 422.152(b)(3)(ii) states that MA coordinated care plans must collect, analyze and report quality performance data indentified by CMS that are of the same type as those specified under paragraph (b)(3)(i) of this section. Section 422.152(e)(2)(ii) states that MA organizations offering an MA regional plan or local PPO plan must collect, analyze and report quality performance data identified by CMS that are of the same type as those described under § 422.152(e)(2)(i). The burden associated with these requirements is the time and effort necessary for an MA coordinated care plan to collect, analyze and report quality performance data to CMS. In the proposed rule, we estimated that it would require 1,000 hours per MA coordinated care plan to comply with these requirements. There are 624 MA coordinated care plans. The estimated annual burden associated with these requirements was 624,000 hours. The estimated annual cost associated with these requirements was $36.9 million. The new quality measures will be identified during CY 2011 at which time it will go through the PRA review and approval process. CMS has begun drafting the PRA package for the new quality measures. However, the PRA package cannot be completed until the measures have been developed.

Section 422.152(b)(5) requires that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act in Section 417.472, private fee-for-service contracts, and PDPs under Section 423.156 with 600 or more enrollees in July of the prior year) must contract with approved Medicare CAHPS survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications, and submit the survey data to CMS. The burden associated with this requirement is the time and effort necessary to conduct the CAHPS survey and submit the corresponding data to CMS. The associated burden is currently approved under OMB control number 0938–0732. For the CAHPS requirements, the requirement will go into effect in 2011 when the contracts select approved vendors to collect and submit CAHPS data on their behalf. The data collection begins in February 2011. We have revised the currently approved ICR to include the requirements contained in this section. The burden associated with these requirements is the time and effort necessary for an MA organization, Section 1876 Cost Plan, or PDP sponsor to collect, analyze and report quality performance data to CMS. We estimate that it will require 54 hours per MA organization or per PDP, to comply with these requirements. The 54 hours includes the time to select a CAHPS survey vendor and the survey administration time of the CAHPS survey vendor for which the MA or PDP contract pays. There are 624 contracts (both MA and PDPs). The estimated annual burden associated with these requirements is $54 \times 624 = 33{,}696$ hours for the affected contracts.

*F. ICRs Regarding Risk Adjustment Data Validation (RADV) Appeals (§ 422.311)*

We received comments from an MA organization disputing CMS's burden estimate associated with RADV audit appeals. This organization contends that CMS has underestimated the amount of time, effort, and cost associated with complying with CMS's RADV appeals processes, as proposed.

While we acknowledge that there can be differences regarding the exact burden estimate CMS developed for RADV appeals, we continue to believe that the overall impact analysis we provided regarding RADV appeals-related procedures is reasonable. To date MA organizations have not been afforded appeal rights under RADV audits and CMS has no historical data to verify what we believe is an inherently reasonable level of effort and associated burden-estimate. Also, since invoking an MA organization's appeal rights is entirely voluntary on the part of MA organizations, we likewise have no altogether accurate way to estimate the level of activity that MA organizations will undertake in appealing eligible RADV-related audit provisions. Indeed, we think it is entirely possible that various MA organizations could take altogether different approaches in requesting an RADV appeal. For example—some organizations might employ internal resources to process an appeal request (for example, employ in-house medical record and legal staff) while other organizations could hire external medical record consultants and/or law firms to process their appeals requests. Given this uncertainty, CMS must rely upon what we believe are reasonable level of effort and burden-estimates, as described in our proposed rules and finalized here.

In section § 422.311 of the proposed rules, CMS proposed a multi-step Risk Adjustment Data Validation (RADV) dispute and appeals process. One important change to the RADV dispute and appeal process that we have implemented pursuant to public comment is removal of the documentation dispute process described at § 422.311(c)(2)(ii) and development of a process that would allow MA organizations to appeal medical record review determinations that occur at the IVC level of medical record review. We describe this new process that we are implementing at § 422.311(c) (2). In effect, the new medical record review appeal procedures provides MA organizations with two opportunities to appeal—first, to appeal RADV medical record review determinations and second, to appeal the RADV payment error calculations. It's our belief that the level of effort necessary to process a request for documentation dispute will be roughly the same level of effort necessary to request Medical record review appeal

since both processes involve sending CMS medical record documentation to support identified RADV errors identified pursuant to CMS's initial level of medical record review. However, the scope of the eligibility criteria for what CMS will allow MAOs to appeal under medical record review appeal could be broader when compared with what CMS would have allowed under the now removed documentation dispute process. We therefore have calculated a new burden estimate for medical record review appeal.

Whereas under documentation dispute, RADV contract-level audit statistics indicated that approximately 55 percent of RADV audit errors would have been of the type that could be eligible for documentation dispute, we estimate that fully 100 percent of RADV audit errors will be eligible for medical record review appeal. The historical contract-level RADV audit error rate to date is approximately 15 percent. Utilizing the statistics regarding the number of organizations that we expect to undergo RADV audit (70) annually, we estimate that 100 percent of these organizations will invoke their medical record review appeal rights and appeal their medical record review errors. On average, CMS audits approximately 200 beneficiaries per contract; and each beneficiary selected for testing has approximately 2.5 Hierarchical Condition Categories (or HCCs, which are the base-level unit of analysis under RADV audits) equating to roughly 500 HCCs tested per annual RADV contract-level audit. Applying the 15 percent contract-level RADV audit error rate to the 500 tested HCCs renders an estimate of 75 HCCs (500 × .15) eligible for medical record review appeal per audit. This equates to approximately 5,250 HCCs (70 audits × 75 HCCs/audit) that could be appealed annually under medical record review appeal. Each HCC that is appealed will require production of one medical record to overturn the RADV testing error. We continue to estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via medical record review appeal. This equates to 5,250 burden hours at approximately $59.20/hour (based on U.S. Dept. of Labor statistics for hourly wages for management analysts)—or, an annual dollar burden on the MA industry of $310,800.

CMS also estimates that beyond product of medical records, MAOs pursuing medical record review appeal would incur legal costs in the preparation of the formal request for appeal. Again, we assume all MAOs will appeal their medical record review determinations found to be in error (70 MAOs). We estimate 40 hours by an attorney costing $60 per hour (Bureau of Labor Statistics, 1/28/2010), and 20 hours by a health care administrator costing $30 per hour (Bureau of Labor Statistics, 1/28/2010); for a total cost of $3,000 in labor costs per MAO per appeal. This equates to an additional aggregate annual dollar burden of $210,000 ($3000 × 70 audits).Total estimated aggregate annual dollar burden to the MA industry annually equals $520,800 ($310,800 for medical record preparation + $210,000 for legal preparation of appeal case). The total aggregated burden is 9,450 hours.

*G. ICRs Regarding Application Requirements (§ 422.501 and § 423.502)*

Section 422.501(b) and § 423.502(b) require that an organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. We will not accept applications from organizations that do not submit a timely Notice of Intent to Apply. The purpose of these requirements is to facilitate CMS systems access earlier so that the contract number may be given out and applications may be submitted electronically. While the burden associated with the requirements contained in § 422.501(b) and § 423.502(b), the Notice of Intent to Apply, are subject to the PRA, the burden associated with these requirements is already approved under the OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

Section 422.501(c) and § 423.502(c) propose to revise the current regulation, making clear the application standards for becoming an MA organization or Part D plan sponsor. Specifically, § 422.501(c) and § 423.502(c) require that applicants complete all parts of a certified application. The burden associated with the aforementioned requirements is the time and effort necessary for an application to complete all parts of a certified Part C or Part D application. While the burden associated with the requirements contained in § 422.501(c) and § 423.502(c) are subject to the PRA, the burden associated with these requirements is already approved under OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

*H. ICRs Regarding General Provisions (§ 422.503 and § 423.504)*

Section 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) propose to expand on the existing requirements by providing clarification and additional guidance with respect to the requirements for developing, implementing and maintaining effective compliance programs. The burden associated with this requirement is the time and effort put forth by the sponsoring organization to prepare a compliance plan that meets the requirements of this section. While these requirements are subject to the PRA, it is currently approved under OCN 0938–1000.

*I. ICRs Regarding Contract Provisions (§ 422.504 and 423.505)*

Section 422.504 and § 423.505 explicitly state our existing authority to find sponsors out of compliance with either MA requirements, Part D requirements, or both when the sponsor's performance represents an outlier relative to the performance of other sponsors. Specifically, § 422.504(e)(2) and § 423.505(e)(2) state that HHS, the Comptroller General or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to our contract with the MA organization. These sections contain recordkeeping requirements. The burden associated with § 422.504(e)(2) and § 423.505(e)(2) is the time and effort necessary for MA organizations or Part D sponsors to maintain the information on file and make it available to CMS upon request. While these requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2).

*J. ICRs Regarding Nonrenewal of Contract (§ 422.506 and § 423.507)*

Section 422.506 and § 423.507 contain notification requirements for MA organizations and Part D plan sponsors. Section 422.506(a)(2) and § 423.507(a)(2) require that when an organization does not intend to renew its contract, it must notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. An organization will also have to provide information about alternative enrollment options by complying with at least one of the requirements specified in § 422.506(a)(2)(ii) or § 423.507(a)(2)(ii). In addition, § 422.506(b)(2) and § 423.507(b)(2) state

that an organization must notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process. We believe that fewer than 10 contracts will be terminated on an annual basis, and therefore, these requirements are exempt from the PRA process.

*K. ICRs Regarding Request for Hearing (§ 422.662 and § 423.651)*

With respect to Medicare contract determinations and appeals, § 422.662 and § 423.651 provide the methods and time period for when an MA organization or Part D plan sponsor may request a hearing after a contract determination or intermediate sanction has been imposed. The request for hearing must be submitted in writing and must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction. This is an existing regulation and in this rule we are only modifying the language "after receipt of the hearing decision" to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

*L. ICRs Regarding Time and Place of Hearing (§ 422.670 and § 423.655)*

Section 422.670 and § 423.655 state that CMS, an MA organization or a Part D plan sponsor may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing. The burden associated with these requirements is the time and effort necessary for an MA organization or a Part D plan sponsor to submit a written extension request to the presiding hearing officer. Furthermore, we believe the associated burden is exempt from the PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action is not subject to the PRA.

*M. ICRs Regarding Review by the Administrator (§ 422.692 and § 423.666)*

Section 422.692 and § 423.666 state that CMS, an MA organization or a PDP plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision. The burden associated with these requirements is the time and effort necessary to submit a request for the Administrator to review a hearing decision. This is an existing regulation and in this rule we are only modifying the language "after receipt of the hearing decision" to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

*N. ICRs Regarding Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties (§ 422.756 and § 423.756)*

Section 422.756 and § 423.756 state before CMS imposes intermediate sanctions, MA organizations and Part D plan sponsors may request a hearing before a CMS hearing officer. A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice of sanction. The burden associated with these requirements is the time and effort necessary to draft and submit a hearing request to the designated CMS office. This is an existing regulation and we are only modifying the language "after receipt of the hearing decision" to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

*O. ICRs Regarding Disclosure Requirements (§ 423.128)*

Proposed § 423.128 states that we may require a Part D Plan Sponsor to disclose to its enrollees or potential enrollees, the Part D Plan Sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

Our intent is to invoke this disclosure authority when we become aware that a Part D sponsor has serious compliance and performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. The burden associated with this requirement would be the time and effort necessary for the Part D sponsor to make the aforementioned disclosures. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 10 organizations per any 12 month period. We have based this assumption on past experience. For example, while this requirement does not just apply to those organizations who have been sanctioned, in 2009, CMS imposed intermediate sanctions on a total of 4 sponsoring organizations (which is the highest number of intermediate sanctions imposed in any year or 12 month period from 2006 through 2009) and, it is important to note, that not all of the organizations sanctioned in 2009 were required to make such a disclosure. Additional organizations (not under sanction) experience compliance deficiencies, however we intend to utilize this disclosure requirement in instances where we become aware of serious deficiencies which may lead to the imposition of intermediate sanctions and require immediate correction. For any of these instances, we will then evaluate and determine whether it is appropriate that beneficiaries be specifically notified of the underlying deficiencies to achieve our stated goals of promoting transparency and informed choice. Therefore, we do not believe that we will impose the disclosure requirement on 10 or more sponsoring organizations within any 12-month period which would not require the development of a burden estimate.

*P. ICRs Regarding Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)*

In this final rule, we are amending § 422.516 and § 423.514 to state that each Part C and Part D sponsor will be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. The burden associated with this provision is the time and effort of the MA organizations and Part D sponsors in procuring an auditor and in supporting the auditor as well as the time and effort of the auditor in conducting the yearly audit.

In the proposed rule, we estimated the total burden hours related to the time and effort for all auditing organizations to perform the annual audit for both Part C and Part D data validation to be 215,840. In addition, we estimated the total yearly burden for procuring and supporting the auditor would be 85,200 hours (120 hours per sponsor × 710 sponsors). Therefore, the total estimated burden was 301,040 hours. At that time, we assumed that the auditing organizations would audit all thirteen measures that comprised the Part C reporting requirements and all 21 sections that comprised the Part D reporting requirements. For Part C, two of the original thirteen reporting

requirements were suspended—agent compensation structure and agent training and testing. Additionally, two of the remaining eleven Part C measures will not undergo the data validation—PFFS Plan enrollment Verification Calls and PFF Provider Payment Dispute Resolution Process. We estimate that Part C reductions alone will reduce the annual hourly burden for all auditing organizations to perform the annual audit by 66,412 hours (215,840 × 4/13). This reduction leads to an estimate of 149,428 hours to perform the annual audit for Part C measures. The CY2010 Part D Reporting Requirements PRA package approved by OMB in October 2009 included burden estimates for data validation and auditing activities. The PRA package included the burden for plans to audit 17 of the 21 Part D reporting sections. This number has now been decreased because only 8 reporting sections will be audited. The elimination of 9 reporting sections from the requirements for data validation and auditing for Part D will result in the following reduction in labor hours: 0.5 hours × 9 sections × 715 plans = 3,218 hours.

The combined Part C and Part D reductions in data validation requirements from those in the proposed rule will result in 69,630 fewer labor hours. The total estimated labor hours is therefore 301,040 − 69630 = 231,410.

*Q. ICRs Regarding Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)*

The revisions to § 423.153 state that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes, but is not limited to, annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. Additionally, there must by quarterly targeted medication reviews with follow-up interventions when necessary.

The burden associated with these requirements is the time and effort necessary for Part D sponsors (both MA–PDs and PDPs) to conduct the medical reviews with written summaries. We estimate that each medical review will take an average of 30 minutes to conduct. Similarly, we estimate that there will be 1,875,000 reviews conducted by 456 Part D sponsors on an annual basis. The total annual burden associated with this requirement is 937,500 hours.

*R. ICRs Regarding Timeframes and Notice Requirements for Standard Coverage Determinations (§ 423.568)*

The Part D plan sponsor must, under paragraph (a)(3), establish and maintain a method of documenting all oral requests for standard coverage determinations and retain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that, on an annual basis, 90 percent of all coverage determination requests will be standard requests, and three percent of those requests will not involve reimbursement issues. Of the estimated 1,013,881 requests received annually, we estimate that approximately 90 percent (912,493) will be made orally. We estimate that it will take a Part D plan sponsor 3 minutes to document and retain the required documentation in the case file. Thus, it will take each of the 456 Part D plan sponsors 100 hours to maintain the required documentation on an annual basis, for a total annual burden of 45,625 hours.

If a Part D plan sponsor makes a completely favorable standard decision under paragraph (d) of this section, it must give the enrollee written notice of the determination. Pursuant to paragraph (d) of this section, the initial notice of a favorable decision may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

The burden associated with the requirement in paragraph (d) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of a completely favorable standard decision for benefits. We estimate that each year, the 456 Part D plan sponsors will issue a total of approximately 760,411 written favorable standard notifications for benefits. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.568(d) is 380,206 hours. For § 423.568, we will update 0938–0964 to include the burden estimates associated with this requirement.

*S. ICRs Regarding Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)*

If a Part D plan sponsor makes a completely favorable expedited decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification. The burden associated with the requirements listed in § 423.572(b) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of completely favorable expedited decision. We estimate that the 456 Part D plan sponsors will issue a combined 87,103 written favorable expedited notifications per year. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.572(b) is 43,552 hours.

*T. ICRs Regarding Access To Covered Part D Drugs (§ 423.120)*

Section 423.120(b)(3)(iv) requires sponsors to provide enrollees with appropriate notice regarding their transition process within three business days after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide a notice to beneficiaries regarding the transition process. We estimate this will result in 1.35 million notices that would take an average of 15 minutes to prepare. We then estimate the total burden to be 337,500 hours.

Section 423.120(c)(4) requires Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary. Section 423.120(c)(4) requires the approximately 28 pharmacy claims processors currently responsible for the electronic adjudication of pharmacy benefits to change their RxBIN or RxBIN and RxPCN combination if such identifiers are not already unique to its Medicare line of business, and the Part D cardholder identification number if it is not already unique to each Medicare

Part D enrollee. We estimate the annual hourly burden to be 1,380 hours per processor to make the coding changes necessary to implement this requirement. We estimate the yearly burden to be 38,640 hours for CY 2010. This is a one time only burden for programming. The collection burden for these provisions will be reflected in a revised submission of the ICR approved under OMB control number 0938–0964.

*U. ICRs Regarding Timeframes and Responsibility for Making Redeterminations (§ 423.590)*

Section 423.590(d)(2) states that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to follow up an initial oral notification to an enrollee with a written notification. In the proposed rule, we estimated a burden. We subsequently discovered that appeals notices, including those for Part D, are exempt from PRA under 5 CFR 1320.4. We will update 0938–0964 to include the § 423.590 exclusion language.

*Comment:* A commenter questioned our evidence of costs or time that support CMS' burden estimates and questioned the basis of the estimates.

*Response:* We believe that we provided evidence for both the cost and time estimates in the COI and regulatory impact analysis sections of the October 2009 proposed rule. The commenter did not provide any cost estimates that would call into question the validity of these estimates.

**V. Annual Information Collection Burden**

Table X shows our estimates of the annual reporting and recordkeeping burden based on the discussion detailed in sections III.A. through III.V. of this final rule.

TABLE 9—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

| Regulation section(s) | OMB Control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting ($) | Total labor cost of reporting ($ millions) | Total capital/ maintenance costs ($ millions) | Total cost ($ millions) |
|---|---|---|---|---|---|---|---|---|---|
| § 422.108 and § 423.462 | 0938–1074 | 1,080 | 1,080 | 2,885 | 3,115,800 | 25.00 | 77.9 | 0.0 | 77.9 |
| § 422.152(b)(3)(ii) and § 422.152(e)(2)(ii) | 0938–New | *624 | 624 | 1,000 | 624,000 | 59.13 | 36.9 | 0.0 | 36.9 |
| § 422.152(b)(5) and § 423.156 | 0938–0732 | 624 | 624 | 54 | 33,969 | 91.26 | 3.1 | 0.0 | 3.1 |
| § 422.311(c)(2) | 0938–New | 9,450 | 9,450 | 1 | 9,450 | 52.91 | .5 | 0.0 | .5 |
| § 422.516(g) and § 423.514(g) | 0938–New | *710 | 710 | 327.1 | 231,410 | 138.71 | 32.1 | .1 | 32.2 |
| § 423.120(b)(iv) | 0938–0964 | 710 | 1,350,000 | 0.25 | 337,500 | 21.93 | 7.4 | 0.0 | 7.4 |
| § 423.120(c)(3) | 0938–0964 | 28 | 28 | 1,380 | 38,640 | 25.88 | 1.0 | 4.8 | 5.8 |
| § 423.153 | 0938–0964 | *456 | 1,875,000 | 0.5 | 937,500 | 120.00 | 112.5 | 0.0 | 112.5 |
| § 423.568(a)(3) | 0938–0964 | 456 | 912,493 | 0.05 | 45,625 | 39.45 | 1.8 | 0.0 | 1.8 |
| § 423.568(b) | 0938–0964 | 456 | 760,411 | 0.5 | 380,206 | 41.03 | 15.6 | 0.0 | 15.6 |
| § 423.572(b) | 0938–0964 | 456 | 87,103 | 0.5 | 43,550 | 41.33 | 1.8 | 0.0 | 1.8 |
| Total | | 12,348 | 4,997,523 | | 5,797,650 | | 290.6 | 4.9 | 295.5 |

**Note:** Provisions regarding § 422.152(b)(5) and § 423.156 and § 422.516(g) and § 423.514(g) will not go into effect until contract year 2011. They are included here because they will be in effect for the period of 2010–2015. Therefore, the totals in this table will not agree with the totals for CY 2010 in the RIA Table of costs (Table 10) in the section V.C of this final rule.

## V. Regulatory Impact Analysis (RIA)

### *A. Need for Regulatory Action*

This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policy such as a Part D formulary policy, and clarify program policy.

### *B. Overall Impact*

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs 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).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. MA organizations and Part D sponsors, the only entities that will be affected by the provisions of this rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in non-urban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. We do not believe that this threshold would be reached by the requirements in this final rule because this rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we believe and the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently $135 million. This final rule is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. We do not believe that this final rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We estimate this rule is "economically significant" as measured by the $100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis.

Because there are costs to plans and sponsors associated with several provisions of this rule, we indicate general areas affected and specify the associated costs. For specific burden associated with the requirements and the bases for our estimates, see section IV. of this final rule.

### *C. Increase in Costs to MA Organizations and Part D Sponsors*

The provisions of this final rule would require MA organizations and Part D sponsors an estimated cost of approximately $260.3 million for CY 2010.

We believe the following requirements will result in costs to MA organizations and Part D sponsors between 2010 and 2015: Medicare Secondary Payer Procedures (§ 422.108), CAHPS Survey Costs for MAs and PDPs (§ 422.152(b)(5) and § 423.156), Quality Improvement program (§ 422.152(b)(3)(ii), § 422.152(e)(2)(ii)), and § 423.156,Validation of Reporting Requirements (§ 422.516 and § 423.514), Access to Covered Part D Drugs (§ 423.120(b)(iv)), Pharmacy Use of Standard Technology under Part D (§ 423.120(c)(3)), Drug Utilization Management, Quality Assurance, and Medication Therapy Management (§ 423.153), Documenting Oral Requests for Standard Coverage Determinations (§ 423.568(a)(3)), Timeframe and Notice Requirements for Standard Coverage Determinations (§ 423.568), and Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572(b)). It is true that all of the costs, besides those associated with MIPPA 176, are labor or capital, primarily labor. We expect that these costs will all be reflected in higher bid prices that will be federally-funded. Therefore, all the requirements, except MIPPA 176, will result in costs to MA organizations and Part D sponsors between CY 2010 and CY 2015.

We believe that the regulatory provisions implementing the MIPPA 176 provision will result in savings to the Medicare Program.

TABLE 10—ESTIMATED COSTS AND SAVINGS BY PROVISION FOR CYS 2010–2015

[$ in millions]

| Provision(s) | Regulation section(s) | Calendar year | | | | | | Total (2010–2015) |
|---|---|---|---|---|---|---|---|---|
| | | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | |
| Medicare Secondary Payer Procedures. | § 422.108 and § 423.462 | 77.9 | 77.9 | 77.9 | 77.9 | 77.9 | 77.9 | 467.4 |
| Quality Improvement | § 422.152(b)(3)(ii) and § 422.152(e)(2)(ii). | 36.9 | 36.9 | 36.9 | 36.9 | 36.9 | 36.9 | 221.4 |
| CAHPS Survey Costs for MAs and PDPs. | § 422.152(b)(5) and § 423.156. | 0 | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | 15.5 |
| RADV | § 422.311 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 3.0 |
| Data Validation | § 422.516 and § 423.514 | 0.1 | 32.1 | 32.1 | 32.1 | 32.1 | 32.1 | 160.6 |
| Transition Notification | § 423.120(b)(iv) | 7.4 | 7.4 | 7.4 | 7.4 | 7.4 | 7.4 | 44.4 |
| Pharmacy Use of Standard Technology. | § 423.120(c)(3) | 5.8 | 0 | 0 | 0 | 0 | 0 | 5.8 |
| Drug Utilization Management | § 423.153 | 112.5 | 112.5 | 112.5 | 112.5 | 112.5 | 112.5 | 675.0 |
| Documenting Oral Requests for Standard Coverage Determinations. | § 423.568(a)(3) | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 10.8 |
| Standard Coverage Determinations Notification. | § 423.568(b) | 15.6 | 15.6 | 15.6 | 15.6 | 15.6 | 15.6 | 93.6 |
| Expedited Coverage Determinations Notification. | § 423.572 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 10.8 |
| MIPPA 176 | | 0 | −160 | −340 | −460 | −520 | −570 | −2,050 |
| Total | | 260.30 | 129.60 | −50.40 | −170.40 | −230.40 | −280.40 | −341.70 |

*D. Expected Benefits*

Beginning in CY 2013, we expect net savings due to the combined impact of these new final provisions. We expect that the net impact across the 6-year period from CY 2010 through CY 2015 will be a cost of $308.3 million.

Many of the new requirements involve clarifications of existing regulations and policies. As such, they should help plans to improve their administrative operational functions which will streamline the Medicare Advantage and Medicare Prescription Drug programs and strengthen beneficiary protections within these programs. Specifically, we believe that the requirements in this final rule will improve coordination of care, increase quality of data reporting, increase ability to comply with existing regulations and policies, enhance appeal and grievance procedures, and curtail illegal marketing practices. Additional benefits include clarification of timeframes and notification requirements. Some of the new requirements may lead to changes in health plan service areas.

We anticipate that several of the requirements in this final rule will be beneficial to PBMs in administering the Part D benefit for Part D sponsors. Proposed codification of the transition process requirements and establishment of the protected classes will assist PBMs in applying the Part D requirements consistently across Part D plans and managing the Part D sponsor's benefit packages more efficiently. Establishing cut-off limits for COB and requiring Part D sponsors to report other payer information in a timely fashion to CMS' COB contractors will improve the administrative burden of the payment reconciliation process. The technical correction to the definition of "gross covered prescription drug costs" will also help PBMs calculate a beneficiary's gross covered prescription drug costs.

The original Medicare savings in 2007, resulting from the Medicare Secondary Payer (MSP) Procedures were estimated at $6.5 billion. This included $2.9 billion recovered or avoided for working-aged individuals, $1.9 billion for working-disabled individuals, $877 million for workers' compensation, $278 million for ESRD beneficiaries, and another $485 million recovered or avoided for liability and other insurers. In 2007, there were approximately 8.5 million MA enrollees and 44 million total Medicare enrollees (an MA penetration rate of approximately 19 percent). The $6.5 billion in MSP savings can be attributed to the 35.5 million original Medicare enrollees and thus equates to approximately $183 per original Medicare enrollee. In 2009, MA penetration was higher consisting of 11 million MA enrollees out of approximately 45 million total Medicare enrollees. This translates to an estimated 24 percent MA penetration. We assume a similar MSP take up rate for MA enrollees as that obtained in the original 2007 Medicare savings and therefore project a total MSP savings of approximately $2 billion by 2010.

The estimated impact of MSP on 624 MA organizations and 456 PDPs based on 3.1158 million burden hours at approximately $25 per hour (based on U.S. Department of Labor (DOL) statistics for the hourly wages of claims analysts of $22.20 per hour and for management analysts of $59.20/hour), is approximately $77.9 million. All labor rate calculations in the RIA are derived from the May 2008 wage statistics supplied by the Department of Labor (DOL), Bureau of Labor Statistics and include fringe benefits and overhead costs. We expect an MA organization to use approximately 1.5 FTEs to implement Part C MSP procedures related to avoiding costs, reporting data, and collecting from liable third parties related to MSP. We estimate the work mix to be completed to be 90 percent by the claims analyst and 10 percent by the management analyst.

We note that MAOs expenses for processing claims related to MSP recoveries are considered part of their administrative overhead costs. MA organizations that faithfully pursue and recover from liable third parties will have lower medical expenses. Lower medical expenses make such plans more attractive to enrollees. The lower the medical expenses in an MA plan, the higher the potential rebate. The rebate is calculated as the difference between the cost of Medicare benefits and the benchmark for that plan. The benchmark is a fixed amount. Therefore, as the cost of Medicare benefits decreases with the benchmark remaining constant, the rebate amount increases. That is, as more MSP dollars are collected or avoided, medical expenses go down and rebates go up, allowing the sponsoring MA organization to offer potential enrollees additional non-Medicare benefits funded by rebate dollars. Such non-Medicare benefits include reductions in cost sharing. Since cost sharing is

generally expressed as a percentage of medical costs, it will be proportionally lower as overall medical costs go down, providing MA organizations offering such plans with an additional competitive edge.

In sections 422.152(b)(3)(ii) and 422.152(e)(2)(ii), we require MA organizations to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that MA organizations are currently required to collect and report to CMS. The mean estimated burden per MA contract as indicated in section IV. E of this final rule is 1,000 hours. The estimated mean cost per hour for these MA contracts is $59.20. The mean cost per MA contract is $59,200. Since the number of MA contracts is estimated to be 624, the overall estimated cost across all contracts is $36.9 million (624 × $59,200).

In § 422.311 we describe the Risk Adjustment Data Validation (RADV) dispute and appeals process that audited MAOs can voluntarily choose to participate in. In our proposed rule, we estimated that upwards of 100 MAOs would be selected for contract-level RADV audits annually. We now believe that a more accurate estimate of the number of MAOs that will be selected for contract-level RADV audits is between 60 and 80 MAOs. Here, we will assume that CMS selects 70 MAOs for contract-level RADV audit. On average, CMS audits approximately 200 beneficiaries per contract; and each beneficiary selected for testing has approximately 2.5 Hierarchical Condition Categories (or HCCs, which are the base-level unit of analysis under RADV audits) equating to roughly 500 HCCs tested per audit. To date, the average contract-level RADV error rate has been approximately 15 percent. Thus, we assume a total burden to audited MAOs of approximately 5,250 HCCs ((500 × .15) 70) that will require validation medical records (each HCC is typically associated with one medical record.)

We continue to estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via medical record review appeal. At a per plan-level estimate, this equates to $4,440 per medical record review appeal. Annualized across all audited MAOs, this in turn equates to 5,250 burden hours at approximately $59.20/hour (based on U.S. Dept. of Labor statistics for hourly wages for management analysts)—or, an annual dollar burden on the MA industry of $310,800.

We also estimate that beyond production of medical records, MAOs pursuing medical record review appeal would incur legal costs in the preparation of the formal request for appeal. Again, we assume that all MAO will appeal their medical record error determinations (70 organizations.) We estimate 40 hours by an attorney costing $60 per hour (Bureau of Labor Statistics, 1/28/2010), and 20 hours by a health care administrator costing $30 per hour (Bureau of Labor Statistics, January 28, 2010); for a total cost of $3,000 in labor costs per MAO per appeal. When annualized across all contract-specific RADV audits, this in turn equates to an additional aggregate annual dollar burden of $210,000 ($3000 × 70 audits). Total estimated aggregate annual dollar burden to the MA industry annually equals $520,800 ($310,00 for medical record preparation + $210,000 for legal preparation of appeal case).

The validation of reporting requirements (§ 422.516 and § 423.514) focuses on how the sponsor collects, stores, and reports the new Part C and Part D data requirements. Standards and procedures will also focus on how sponsors compile data, and verify calculations, computer code, and algorithms. The estimated mean hourly burden per affected Part C and Part D sponsor to procure an auditing organization and to support the auditing organization in its data collection efforts including staff interviews is 120 hours, as indicated in section IV.O. of this final rule. We believe the auditor, who is hired by the plan, will typically have a team consisting of a management analyst, two senior auditors, a senior claims analyst, a senior statistician, an IT systems analyst, a computer programmer, and a word processor. We used May 2008 wage statistics supplied by the DOL, Bureau of Labor Statistics to develop estimates of direct wages. We also added fringe benefits, overhead costs, and general and administrative expenses using percentages that are consistent with CMS contracts. Based on our experience and discussions with program experts, we developed an estimate of the blended hourly burden. The estimated mean cost per hour for these sponsors is $43.14 (wages, fringe benefits, and overhead). The estimated mean number of hours per sponsor is 120. Thus, the mean cost per sponsor to procure and support the auditor is $5,177 (1200 × $43.14). Furthermore, with the 710 estimated number of sponsors, the overall cost across all sponsors to complete the work involved in procuring and supporting the auditing contractors is $3.7 million (710 × $5,177). The number of hours is 85,200.

The total estimated burden hours related to the time and effort for all auditing organizations to perform the annual audit for both Part C and Part D data validation is estimated to be 146,210 hours. The mean cost per hour is estimated to be $194.21. Therefore, the estimated annual cost for auditing contracts involving all 710 sponsors is $28.4 million. The estimated total annual cost for auditing contracts and for the procurement and audit support time and effort of the sponsors is $32.1 million ($28.4 million + $3.7 million). The total estimated burden hours, including the hours for sponsors to procure contractors, is 231,410. Lastly, there is a one-time cost to develop the software that will allow data entry into HPMS. This is a Federal cost estimated at $100,000 or $0.1 million for CY 2010.

Beginning in 2011 MA organizations under § 422.152(b)(5), section 1876 Cost plans under § 417.472, and Part D sponsors under § 423.156 will begin paying for the data collection costs of the CAHPS annual survey. Data collection is to be performed by a contractor hired by the MAO, section 1876 Cost plan or Part D sponsor. The mean estimated burden per contract, as indicated in section IV. of this final rule, is 54 hours. The 54 hours includes the time to select a vendor and the survey administration time of the survey vendor that the contract pays. The estimated cost per contract is $5,023. Beginning in 2011, the overall estimated annual cost across the 624 contracts is $3.1 million.

Section 423.120(b)(iv) requires sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). In section IV.S. of this final rule, we estimated that 1.35 million notices would be required with an average preparation time of 15 minutes. As a result, the estimated total burden is calculated at 337,500 hours. At an estimated $20.15 in hourly labor cost of reporting, the total cost is $6.8 million (337,500 × $20.15). In addition, we estimated an additional cost of printing, supplies, and postage of $0.475 per notice. This yields a cost of $641,250 for the 1.35 million notices. Therefore, the total cost for sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of

nonformulary Part D drugs is estimated at $7.4 million.

As indicated in section IV.R of this final rule, developing 760,411 written notices outlining favorable standard coverage determinations (§ 423.568(d)) is estimated to result in an annual burden of 380,206 hours. At an estimated cost of $40.00 per hour, the total annual cost of this change is $15.2 million. In addition, the aggregate cost of printing, supplies and postage associated for all the notices is $361,195. Therefore, the overall total cost for providing written notices of a favorable standard coverage determination (§ 423.568(d)) is estimated to be $15.56 million.

Section § 423.120(c)(3) requires the approximately 28 pharmacy claims processors currently responsible for the electronic adjudication of pharmacy benefits to change their RxBIN or RxBIN and RxPCN combination if such identifiers are not already unique to its Medicare line of business, and the Part D cardholder identification number if it is not already unique to each Medicare Part D enrollee. We estimate the annual hourly burden to be 1,380 hours per processor to make the coding changes necessary to implement this requirement. The yearly burden is therefore estimated to be 38,640 hours for CY 2010 (1,380 × 28). This is a one-time burden for programming. At an average labor cost of $150.00 per hour, we estimate the overall cost in CY2010 to be $5.8 million.

The revisions to § 423.153 state that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes but is not limited to annual comprehensive medication reviews with written summaries. The burden associated with this requirement was estimated at 937,500 hours, as reflected in section IV.P of this final rule. At an estimated average hourly labor cost of $120.00, the total cost is $112.5 million for 2010 (937,500 × $120.00).

Establishing and maintaining a method of documenting all oral requests for standard coverage determinations and retaining the documentation in the case file (§ 423.568(a)(3)), are estimated to result in an annual burden of 45,625 hours. At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $1.8 million.

As indicated in section IV.S of this final rule, developing 87,103 written notices for favorable expedited coverage determination (§ 423.572(b)) is estimated to result in an annual burden of 43,552 hours. At an estimated cost of $40.00 per hour, the total annual cost of this change is $1.74 million. In addition, the aggregate cost of printing, supplies and postage associated for all the notices is $41,374. Therefore, the overall total cost for providing written notices of an expedited coverage determination (§ 423.572(b)) is estimated to be $1.78 million.

Since issuance of the October 22, 2009 proposed rule, PPACA was enacted. Accordingly, new section 1860D–4(b)(3)(G) of the Act replaces section 176 of MIPPA. Section 1860D–4(b)(3)(G) of the Act requires a PDP sponsor to include "all" covered part D drugs—in the categories and classes identified by the Secretary as classes and categories of "clinical concern." It requires the Secretary to establish criteria to determine, as appropriate, categories and classes of drugs of "clinical concern." It provides for an exceptions authority similar to the one included in section 176 of MIPPA. Section 3307 of PPACA further requires that until the Secretary establishes criteria to determine classes of "clinical concern," the following categories and classes of drugs shall be identified and protected as classes of "clinical concern": anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Consistent with this approach, we are removing from the regulatory text the criteria specified by section 176 of MIPPA for identifying classes and categories of drugs of "clinical concern," as well as the definitions used to interpret the MIPPA criteria. We are retaining the exceptions process in the regulatory text, as new section 1860D–4(b)(3)(G) of the Act retains the exceptions process established under section 176 of MIPPA.

The estimated cost of implementing section 176 of MIPPA for FY 2010 budget baseline projections was $4.9 billion for FY 2010 through 2019. The removal of the section 176 MIPPA criteria eliminates the cost included in the baseline generating savings of $4.9 billion for FYs 2010 through 2019.

*E. Anticipated Effects—Effects of Maximum Out-of-Pocket Cost (MOOP) Limit and Cost Sharing Thresholds*

We are finalizing our proposal to establish and require local MA plans to have a maximum out-of-pocket (MOOP) limit on members' out-of-pocket cost sharing, the amount of which will be established annually by CMS. In addition, we are finalizing our proposal to require cost sharing thresholds for Parts A and B services, the amounts of which will be determined annually by CMS. These changes provide significant protection for MA enrollees from out of pocket costs and will lend greater predictability and transparency to benefit packages, so that beneficiaries will better understand and anticipate their out-of-pocket expenditures. However, we do not believe these changes will, by themselves, have a significant impact on plan participation or significantly increase plan premiums.

We believe the impact on enrollee premiums will be limited for several reasons. First, we have made a voluntary MOOP available for the past years (2008, 2009, and 2010). For CY 2010, the voluntary MOOP for all Parts and B services was set at $3,400. About 40 percent of current MA plans have adopted the voluntary MOOP while remaining competitive (and enrolling approximately one-third of all MA enrollees), and they do not appear to have incurred significant costs in administering a MOOP limit.

Second, as we described elsewhere in this preamble, it is our intention to set both the MOOP and Parts A and B cost sharing thresholds at levels that, while affording reasonable financial protection for those beneficiaries with high health care needs, do not result in significant new operating costs for MA plans or increased out-of-pocket costs for beneficiaries to the extent that MA plans pass along any increased costs to their enrollees in the form of premium increases. We will develop the MOOP and Parts A and B cost sharing thresholds using data provided by our Office of the Actuary (OACT) to ensure this result. In addition, given a competitive marketplace and Medicare beneficiaries' sensitivity to premium amounts, we believe that MA plans may choose instead to modify their benefit packages to reduce costs elsewhere. Furthermore, we estimate that beneficiaries in plans that currently offer the CY 2010 voluntary MOOP limit of $3,400 (about 40 percent of MA plans) will experience no cost increases as a result of these provisions. In fact, to the extent they instead choose the higher, mandatory MOOP limit, we would expect a net decrease in costs. We estimate that the maximum impact of these requirements on beneficiary premiums for those plans that currently have no MOOP limit of any kind (31 percent of all CY 2010 MA plans) would average $5. The average impact on premiums would be lower for plans that currently have a nonqualified MOOP—one with an amount higher than the voluntary MOOP limit of $3400 established for CY 2010 and/or that does not include all Parts A and B services. Approximately 29 percent of all CY 2010 plans had such a MOOP. However,

given competitive market pressures, we believe MA plans may instead choose to modify their benefit packages rather than increase premiums.

Finally, we believe that the many advantages for beneficiaries as a result of the new MOOP and cost-sharing threshold requirements will outweigh any small premium increases that may result. All MA plan enrollees will be protected against high out of pocket costs, and will be better able to compare plans by focusing on differences in premium and plan quality. Furthermore, enrollee cost-sharing will be more predictable and transparent. As we have explained in the preamble of the final rule, our goal is to set cost-sharing limits at a level that should not result in significant new costs for MA plans or beneficiaries.

*F. Alternatives Considered*

1. Strengthening CMS' Ability To Take Timely, Effective Contract Determinations or Intermediate Sanctions (Part C and D)

We are finalizing our modifications to the regulations which more clearly and accurately reflect our existing statutory authority to terminate a contract. The existing enumerated list of determinations that are the basis to terminate a contract are not all inclusive. Initially it was our belief that continuing to add to the existing list may fail to stress to sponsoring organizations that failure to comply with all of our regulations and contract and performance requirements may be used to support a termination decision. After receiving numerous comments concerning this provision we have decided, however, not to remove the enumerated list and instead to add language to provide additional examples of determinations that could support a decision to terminate a contract. Also, we have revised the proposed regulatory language to clarify that the failure to comply with the regulatory requirements contained in parts 422 and 423 or failure to meet our performance requirements, may constitute a basis for CMS to determine that the MA Organization or Part D sponsor meets the requirements for contract termination in accordance with the statutory standard.

2. Changing the Standards of Review, Clarifying the Standard of Proof and Burden of Proof for Appeals, and Modifying the Conduct of Hearing for Contract Decisions (Including Denials of Initial Applications to Contract, Service Area Expansions for Existing Contracts, Contract Non-Renewals and Terminations, and Intermediate Sanctions)

We are finalizing our change to the standards of review and clarification of the standard of proof when an appeal of a contract determination or intermediate sanction is requested and an evidentiary hearing is conducted. The existing standards of review require the Hearing Officer to determine whether the sponsoring organization can demonstrate "substantial compliance" with Part C and/or Part D requirements on the "earliest of" the following three dates: the date the organization received written notice of contract determination or intermediate sanction, the date of the most recent onsite audit, or the date of the alleged breach of current contract or past substantial noncompliance. In practice, these standards of review ("substantial compliance" and "earliest of test") have led to confusion among parties to the hearing and have been difficult for the hearing officer to apply. Additionally, though the existing regulations explicitly state that the sponsoring organization bears the burden of proof, it does not provide the standard of proof that is to be applied by the Hearing Officer. Therefore, we have deleted the "substantial compliance" and "earliest of" test and revise the regulations to explicitly state the standard of proof and provide clear standards of review for each type of contract determination or intermediate sanction.

First, we have explicitly stated that the hearing officer must apply the "preponderance of the evidence" standard of proof when weighing the evidence at all hearings for contract determinations or intermediate sanctions. Second, we have clarified the standards of review, which vary according to the type of contract determination or intermediate sanction. In particular, the change makes the distinction between how the evidentiary standard of review is to be applied to appeals of CMS determinations involving Part C or D contract qualification applications, those involving the termination or non-renewal of a Part C or D sponsor contract, and those involving the imposition of intermediate sanctions. Finally, we have clarified that because the sponsoring organization bears the burden of proof, under any briefing schedule determined by the hearing officer, it must first present evidence and argument to the hearing officer before we present our evidence and argument. We considered leaving the existing regulations unchanged, but ultimately rejected that option.

3. Clarify That CMS May Require a "Test Period" During an Enrollment/Marketing Sanction

We are finalizing our proposal that in instances where an enrollment and/or marketing suspension has been imposed, we may determine that it is appropriate to subject the MA organization or Part D sponsor to a "test period" whereby the organization or sponsor will, for a limited time, engage in marketing activities and/or accept enrollments in order to assist us in making a determination as to whether the bases for the sanctions have been corrected and are not likely to recur.

We considered leaving the existing regulations unchanged. However, we believe the requirements in this final rule will strengthen our ability to adequately assess compliance with our requirements. Also, it will help us avoid situations where we may lift a sanction based on inadequate testing of an organization's systems/processes, only to find that the deficiencies have not been corrected, thereby requiring us to reinstate the sanction.

4. Right for CMS To Require an Independent Audit of Sponsoring Organizations Under Intermediate Sanction

We are finalizing language in the October 2009 proposed rule which states that CMS may require sponsoring organizations that are under intermediate sanctions to hire an independent auditor to evaluate whether the bases for a sanction have been corrected and are not likely to recur in order to assist CMS in its determination whether to lift the sanction. The purpose of this provision is to provide us with additional assurances, through a neutral third party evaluation, whether the sponsoring organization is in compliance with CMS requirements and the bases for the sanction have been corrected and are not likely to recur.

Another option we considered was to not require sanctioned sponsoring organizations to hire an independent auditor but rather to allow sponsoring organizations the discretion to hire an independent auditor. We believe that this alternative proposal is not necessary to promulgate in regulation as sanctioned sponsoring organizations

already have the discretion to hire an independent auditor.

We also considered leaving the regulations unchanged. However, given our experience with the nature and extent of some compliance deficiencies (for example, those caused by information technology issues or lack of adequate internal controls) and the need to obtain the level of skill and experience necessary to conduct an exhaustive evaluation of the correction of these deficiencies, we believe this additional assurance and access to expertise (such as a qualified independent auditor) is appropriate and will benefit both plan sponsors and CMS.

5. The Ability for CMS To Require Sponsors To Disclose to Current and Potential Enrollees Compliance and Performance Deficiencies

We are finalizing our proposal that we may require certain sponsoring organizations to disclose their current compliance and/or performance deficiencies to existing and potential enrollees. Our intent is to invoke this disclosure authority when we become aware that an MA organization has serious compliance and/or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. An additional purpose is to provide appropriate incentives for sponsoring organizations to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices.

We considered not adding this disclosure authority to the existing regulations. However, we believe this change is necessary to provide us with another tool to strengthen our compliance and oversight authority and provide appropriate transparency concerning compliance and/or performance deficiencies to beneficiaries and the public.

6. Reducing Duplicative and Low Enrollment Plans (Parts C and D)

We are implementing regulations to reduce duplicative benefit packages based upon our authority to add such additional terms to our contracts with Medicare Advantage organizations or Part D plan sponsors as we "may find necessary and appropriate" as specified in section 1857(e)(1) of the Act (see also section 1860D–12(b)(3)(D) of the Act (incorporating section 1857(e)(1) of the Act by reference for Part D.)) In addition, we are using our authority under section 1860D–11(d)(2)(B) of the Act as further support to propose regulations imposing "reasonable minimum standards" on Part D sponsors.

One alternative would be to make no changes to our current regulations regarding bid submission and review and to continue our current efforts to eliminate duplicative or low enrollment plan options. However, since our current regulations do not explicitly address the issue of eliminating duplicative or low enrollment plans, we believe that codifying our authority to do so will provide us with more leverage over plans during the bid submission, review, negotiation, and approval processes.

Another alternative would be to provide more detail in regulation text regarding the specific criteria we would use to eliminate duplicative or low enrollment plan options. We believe by addressing the issue generally in regulations text, we maintain our flexibility to adjust our review processes and criteria consistent with current market trends.

7. Validation of Part C and Part D Reporting Requirements and CAHPS Survey Administration

Several of the required changes involve costs to MAOs and Part D sponsors. One such regulatory change was the audit requirement of Part C and Part D measures. We considered not requiring an audit. However, because we believe that an audit is necessary to ensure that the Part C and Part D measures are consistent with our specifications, are reliable, valid, and comparable, and are credible to stakeholders, this alternative was rejected. A second such regulatory change was requiring MAOs and Part C sponsors to assume a portion of the cost of the annual CAHPs survey as a result of hiring contractors to conduct the data collection. We considered not requiring MAOs and Part C sponsors to hire contractors to perform the CAHPs data collection. However, we rejected this alternative because we believe that the benefits obtained through this regulatory change outweigh the costs incurred by the MAOs and Part C sponsors. We believe these changes actually benefit the plans by informing them of the issues that, from the beneficiaries' perspectives, needs attention.

*G. Accounting Statement*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf)*, in Table 11, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. The accounting statement is based on estimates in Table 10 (our best estimate of the costs and savings as a result of the changes) discounted at the 7 percent and 3 percent for the time period of CY 2010 through CY 2015.

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015

[$ in millions]

| Category | TRANSFERS (MIPPA 176) | | | |
|---|---|---|---|---|
| | Year dollar | Units discount rate | | Period covered |
| | | 7% | 3% | |
| Annualized Monetized Transfers | 2009 | −$318.64 | −$331.65 | CYs 2010–2015 |
| From Whom To Whom? | Federal Government to MAO and Part D Sponsors | | | |

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015

[$ in millions]

| | COSTS (All other provisions) | | | |
|---|---|---|---|---|
| | Year dollar | Units discount rate | | Period covered |
| | | 7% | 3% | |
| Annualized Costs to MAOs and Part D Sponsors | 2009 | $283.86 | $284.35 | CYs 2010–2015 |

Compared to the proposed rule, the annualized costs to MAOs and Part D sponsors have decreased from $319.51 million and $319.46 million, at the 7 and 3 percent annualized discount rates, to $283.86 million and $2284.35 million at the 7 and 3 percent discount rates for the final rule.

*H. Conclusion*

We estimate that the cost of implementing these provisions will be $260.3 million in CY 2010. This is $61.4 million less than the estimated cost in the proposed rule ($321.7 million). Sponsors will experience additional costs which they are likely to pass on to CMS through direct subsidy payments and to beneficiaries through increases in premiums as reflected in their bids. Beginning in CY 2012, we expect that these provisions will generate a net savings to the Medicare program on an annual basis. For the entire estimated time period, CYs 2010 through 2015, we estimate the overall impact to be a savings of $341.70 million (undiscounted).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

**List of Subjects**

*42 CFR Part 417*

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

*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 480*

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, and Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

## PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

**Authority:** Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

### Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract

■ 2. Section 417.428 is revised to read as follows:

**§ 417.428 Marketing activities.**

(a) With the exception of § 422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

### Subpart L—Medicare Contract Requirements

■ 3. Section 417.472 is amended by adding paragraphs (i) and (j) to read as follows:

**§ 417.472 Basic contract requirements.**

* * * * *

(i) The HMO or CMP must comply with the requirements at § 422.152(b)(5).

(j) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS

specifications and submit the survey data to CMS.

■ 4. Section 417.492 is amended by revising paragraph (b)(2) to read as follows:

**§ 417.492 Nonrenewal of contract.**

* * * * *

(b) * * *

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in § 417.494(b).

■ 5. Section 417.494 is amended by revising paragraph (b)(2) to read as follows:

**§ 417.494 Modification or termination of contract.**

* * * * *

(b) * * *

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

* * * * *

■ 6. Section 417.500 is revised to read as follows:

**§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.**

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422 of this chapter.

## Subpart O—Medicare Payment: Cost Basis

■ 7. Section 417.564 is amended by adding new paragraphs (b)(2)(iii) and (c) to read as follows:

**§ 417.564 Apportionment and allocation of administrative and general costs.**

* * * * *

(b) * * *

(2) * * *

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

(1) Donations.

(2) Fines and penalties.

(3) Political and lobbying activities.

(4) Charity or courtesy allowances.

(5) Spousal education.

(6) Entertainment.

(7) Return on equity.

## Subpart R—Medicare Contract Appeals

■ 8. Section § 417.640 is revised to read as follows:

**§ 417.640 Applicability.**

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

**§ 417.642 through § 417.694 [Removed]**

■ 9. Remove § 417.642 through § 417.694.

## Subpart U–Health Care Prepayment Plans

■ 10. Section 417.840 is revised to read as follows:

**§ 417.840 Administrative review procedures.**

The HCPP must apply § 422.568 through § 422.626 of this chapter to—

(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and

(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

## PART 422—MEDICARE ADVANTAGE PROGRAM

■ 11. 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).

## Subpart A—General Provisions

■ 12. Section 422.2 is amended by—

■ A. Adding the definitions of "Attestation process," "Hierarchical condition categories," and "Initial Validation Contractor."

■ B. Revising the definition of "Point of service."

■ C. Adding the definitions of "RADV payment error calculation appeal process" and "Risk adjustment data validation (RADV) audit.

■ D. Revising the introductory text of the definition of "Service area".

■ E. Adding the definition of "The one best medical record".

The additions and revisions read as follows:

**§ 422.2 Definitions.**

* * * * *

*Attestation process* means a CMS-developed RADV audit-related dispute process that enables MA organizations undergoing RADV audit to submit CMS-generated and physician practitioner signed attestations for medical records with missing or illegible signatures or credentials. Physicians/practitioners who documented health care services in the specific medical record under RADV review will be allowed to attest that they provided and documented the health care services evidenced in the specific medical record.

* * * * *

*Hierarchical condition categories (HCC)* means disease groupings consisting of disease codes (currently ICD–9–CM codes) that predict average healthcare spending. HCCs represent the disease component of the enrollee risk score that are applied to MA payments.

* * * * *

*Initial Validation Contractor (IVC)* means the first level of medical record review under the RADV audit process.

* * * * *

*Point of service (POS)* means a benefit option that an MA HMO plan can offer to its Medicare enrollees as a mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services

received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

* * * * *

*RADV payment error calculation appeal process* means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.

*Risk adjustment data validation (RADV) audit* means a CMS-administered payment audit of a Medicare Advantage (MA) organization that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

*Service area* means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

* * * * *

*The one best medical record* for the purposes of Medicare Advantage Risk Adjustment Validation (RADV) means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

■ 13. Amend § 422.4 by—

■ A. Revising paragraphs (a)(1)(v)and (a)(2)(i)(A).

■ B. Redesignating paragraph (a)(2)(i)(B) as paragraph (a)(2)(i)(C).

■ C. Adding new paragraphs (a)(2)(i)(B) and (a)(3)(iv).

The revisions and additions read as follows:

**§ 422.4 Types of MA plans.**

(a) * * *

(1) * * *

(v) A PPO plan is a plan that—

(A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;

(C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and

(D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan's standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.

(2) * * *

(i) * * *

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);

(B) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and

* * * * *

(3) * * *

(iv) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

* * * * *

## Subpart B—Eligibility, Election, and Enrollment

■ 14. Section 422.74 is amended by revising paragraphs (d)(1)(i)(B) and (d)(4)(iii) to read as follows:

**§ 422.74 Disenrollment by the MA organization.**

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period must—

(*1*) Be at least 2 months; and

(*2*) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

* * * * *

(4) * * *

(iii) *Exception.* If the MA plan offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (d)(4)(iii)(D) of this section consistent with Medicare access and availability requirements at § 422.112 of this part.

* * * * *

## Subpart C—Benefits and Beneficiary Protections

■ 15. Section 422.100 is amended by—

■ A. Revising the introductory text for paragraph (f).

■ B. In paragraphs (f)(1) and (f)(2) removing the ";" and adding a "." in its place.

■ C. Adding new paragraphs (f)(4) through (f)(6).

The revisions and additions read as follows:

**§ 422.100 General requirements.**

* * * * *

(f) *CMS review and approval of MA benefits and associated cost sharing.*

CMS reviews and approves MA benefits and associated cost sharing using written policy guidelines and requirements in this part and other CMS instructions to ensure all of the following:

* * * * *

(4) Except as provided in paragraph (f)(5), MA local plans (as defined in § 422.2) must have an out-of pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS.

(5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) applies only to use of network providers. Such local PPO plans must include a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is—

(i) Consistent with the requirements applicable to MA regional plans at § 422.101(d)(3) of this part; and

(ii) Not greater than the annual limit set by CMS.

(6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services.

* * * * *

■ 16. Section 422.103 is amended by adding a new paragraph (d)(3) to read as follows:

**§ 422.103 Benefits under an MA MSA plan.**

* * * * *

(d) * * *

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part or during any other enrollments occurring after January 1.

* * * * *

■ 17. Section 422.105 is amended by revising paragraphs (b), (c), and (f) to read as follows:

**§ 422.105 Special rules for self-referral and point of service option.**

* * * * *

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an HMO plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

* * * * *

(f) *POS-related data.* An MA organization that offers a POS benefit through an HMO plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

■ 18. Section 422.108 is amended by revising paragraph (b)(3) to read as follows:

**§ 422.108 Medicare secondary payer (MSP) procedures.**

* * * * *

(b) * * *

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

* * * * *

■ 19. Section 422.111 is amended by adding a new paragraph (g) to read as follows:

**§ 422.111 Disclosure requirements.**

* * * * *

(g) CMS may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

■ 20. Section 422.112 is amended by adding a new paragraph (a)(10) to read as follows:

**§ 422.112 Access to services.**

(a) * * *

(10) *Prevailing patterns of community health care delivery.* Coordinated care and PFFS MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

* * * * *

## Subpart D—Quality Improvement

■ 21. Section 422.152 is amended by—

■ A. Revising paragraphs (a)(1) and (a)(2).

■ B. Redesignating paragraph (b)(3)(ii) as paragraph (b)(3)(iii).

■ C. Adding new paragraph (b)(3)(ii).

■ D. Adding new paragraph (b)(5).

■ F. Redesignating paragraphs (e)(2)(ii) and (e)(2)(iii) as paragraphs (e)(2)(iii) and (e)(2)(iv), respectively.

■ H. Adding a new paragraph (e)(2)(ii).

The revisions and additions read as follows:

**§ 422.152 Quality improvement program.**

(a) * * *

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meet the requirements of paragraph (d) of this section, and address areas identified by CMS; and

* * * * *

(b) * * *

(3) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

* * * * *

(5) All coordinated care contracts (including local and regional PPOs,

contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

* * * * *

(e) * * *

(2) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

* * * * *

■ 22. Section 422.153 is added to reads as follows:

**§ 422.153 Use of quality improvement organization review information.**

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter only data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following limited functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

■ 23. Section 422.156 is amended by revising paragraphs (b)(7) and (f) to read as follows:

**§ 422.156 Compliance deemed on the basis of accreditation.**

* * * * *

(b) * * *

(7) The requirements listed in § 423.165 (b)(1) through (3) of this chapter for MA organizations that offer prescription drug benefit programs.

* * * * *

(f) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

## Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

■ 24. Section 422.254 is amended by adding new paragraphs (a)(4) and (b)(5) to read as follows:

**§ 422.254 Submission of bids.**

(a) * * *

(4) *Substantial differences between bids.* An MA organization's bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions.

(b) * * *

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

* * * * *

■ 25. Section 422.256 is amended by adding a new paragraph (b)(4) to read as follows:

**§ 422.256 Review, negotiation, and approval of bids.**

* * * * *

(b) * * *

(4) *Substantial differences between bids*—(i) *General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different from the MA organization's other bid submissions. In order to be considered "substantially different," as provided under § 422.254(a)(4) of this subpart, each bid must be significantly different from other plans of its plan type with respect to premiums, benefits, or cost-sharing structure.

(ii) Transition period for MA organizations with new acquisitions. After a 2-year transition period, CMS approves a bid offered by an MA organization (or by a parent organization to that MA organization) that recently purchased (or otherwise acquired or merged with) another MA organization only if it finds that the benefit package or plan costs represented by that bid are substantially different, as provided under paragraph (b)(4)(i) of this section, from any benefit package and plan costs represented by another bid submitted by the same MA organization (or parent organization to that MA organization).

* * * * *

## Subpart G—Payments to Medicare Advantage Organizations

■ 26. Section 422.306 is amended by revising paragraph (a) to read as follows:

**§ 422.306 Annual MA capitation rates.**

* * * * *

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

* * * * *

■ 27. A new section 422.311 is added to read as follows:

**§ 422.311 RADV audit dispute and appeal processes.**

(a) *Risk adjustment data validation (RADV) audits.* In accordance with § 422.2 and § 422.310(e), CMS annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.

(b) *RADV audit results.* (1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors.

(3) *Medical record review appeal.* MA organizations that do not agree with the medical record review determinations for audited HCCs may appeal the medical record review determinations of the initial validation contractor to CMS in accordance with paragraph (c)(2) of this section.

(c) *RADV audit dispute and appeal processes*—(1) *Attestation process*—(i) *Submission requirements for attestations.* MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature-related or credential-related RADV errors in accordance with the attestations provisions of this section.

(B) Are not obligated to submit attestations to CMS.

(ii) *RADV audit-related errors eligible for attestation process.* CMS will only accept an attestation to support a physician or outpatient medical record with a missing signature or missing credential or both.

(iii) *RADV audit-related errors and documentation ineligible for attestation process.*

(A) Attestations from providers for anything other than signature-related and credential-related errors will not be permitted.

(B) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation.* (A) CMS will provide MA organizations selected for RADV audits with attestations and accompanying instructions at the time the organization receives its audit instructions.

(B) If an organization decides to submit attestations completed by physicians or other practitioners, the MA organization must submit the attestations to CMS at the same time that the MA organization is required to submit related medical records for RADV audit.

(v) *Attestation content.* An attestation must accompany and correspond to the medical record submitted for RADV audit and must meet the following requirements:

(A) Contain only CMS-generated attestations.

(B) The CMS attestation form may not be altered unless otherwise instructed and agreed-upon in writing by CMS.

(C) Attestations must be completed and be signed and dated by the eligible risk adjustment physician/practitioner whose medical record accompanies the attestation.

(D) Attestations must be based upon medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners.

(vi) *Attestation review and determination procedures.* CMS—(A) Reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review; and

(B) Provides written notice of its determination(s) regarding submitted attestations to the MA organization at the time CMS issues its RADV audit report.

(vii) *Effect of CMS's attestation determination.* (A) CMS' attestation determination is final.

(B) An MA organization may choose to appeal its medical record review determinations for audited HCCs following initial validation contractor review using a CMS-administered medical record review determination appeal process.

(2) *RADV-related medical record review errors and documentation eligible for medical record review determination appeal process:* (i) *General rules.* (A) In order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow CMS rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization's request for appeal invalid.

(B) The medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV initial validation contractor (IVC).

(C) MA organizations that choose to appeal the IVC's medical record review determination(s) may only submit the IVC-audited one best medical record and IVC-reviewed attestation, previously submitted in accordance with paragraph (c)(1) of this section, to CMS for re-review.

(D) MA organizations' request for medical record review determination appeal may not include additional documentary evidence beyond the IVC-audited one best medical record and IVC-reviewed attestation.

(ii) *RADV-related audit errors and documentation ineligible for medical record review appeal process.* (A) MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS.

(B) Any other documentation submitted to CMS beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by CMS under the medical record review determination appeal process.

(C) The MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that CMS identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal.

(iii) *Manner and timing of a request for medical record review determination appeal.* (A) At the time CMS issues its IVC RADV audit report to audited MA organizations, CMS notifies these MA organizations of any RADV HCC errors that are eligible for medical record review determination appeal.

(B) MA organizations have 30 calendar days from date of issuance of the RADV audit report to file a written request with CMS for medical record review determination appeal.

(C) A request for medical record review determination appeal must specify the determinations with which the MA organization disagrees and the reasons for the request for appeal.

(iv) *Medical record review determination appeal review and notification procedures.* (A) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the medical record review determination appeal. The hearing officer need not be an ALJ.

(B) *Disqualification of hearing officer.* (*1*) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(*2*) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(*3*) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(*i*) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(*ii*) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

(v) *Hearing officer's review.* The hearing officer reviews the IVC-audited one best medical record and the IVC-reviewed attestation submitted by the MA organization to determine whether it supports overturning medical record review determination errors listed in the MA organization's IVC-level RADV audit report.

(vi) *Hearing procedures.* (A) CMS provides written notice of the time and

place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS hearing officer is limited to the review of the record that was before the IVC.

(vii) *Hearing officer's decision.* As soon as practical after the hearing, the hearing officer issues a decision which provides written notice of the hearing officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS.

(viii) *Computations based on hearing decision.* In accordance with the hearing officer's decision, CMS recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization.

(ix) *Effect of hearing decision.* The hearing officer's decision is final and binding, unless the MA organization requests review of the hearings officer appeal determination by the CMS Administrator.

(x) *Review by the CMS Administrator.* (A) A MA organization that has received a hearing officer decision may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's determination. A request for CMS Administrator review must be made in writing and filed with CMS.

(B) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing decision.

(C) If the CMS Administrator elects to review the hearing decision, the CMS Administrator—

(*1*) Acknowledges the decision to review the hearing decision in writing; and

(*2*) Reviews the decision and determine based upon all of the following whether the determination should be upheld, reversed, or modified:

(*i*) The hearing record.

(*ii*) Written arguments submitted by the MA organization or CMS.

(xi) *Notification of Administrator determination.* (A) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of acknowledging his or her decision to review the hearing decision.

(B) The decision of the hearing officer is final if the Administrator—

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

(3) *RADV payment error calculation appeal process.* (i) MA organizations may appeal CMS' RADV payment error calculation.

(ii) *RADV payment error-related issues ineligible for appeal.* MA organizations may not—

(A) Appeal RADV medical record review-related errors as part of the RADV payment error calculation appeal process. In accordance with paragraph (c)(2) of this section, MA organizations that wish to appeal medical record review determinations may do so following issuance of the IVC RADV audit report of findings.

(B) Introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(C) Appeal RADV errors that result from an MA organization's failure to submit a medical record.

(D) Appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.* (A) MA organizations may not appeal their RADV error calculation until any appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(B) At the time CMS issues either its IVC or post-medical record review appeal RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(C) MA organizations have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation.

(iv) *Burden of proof.* The MA organization bears the burden of proof in demonstrating that CMS failed to follow its stated RADV payment error calculation methodology.

(v) *Content of request.* The written request for reconsideration must specify the issues with which the MA organization disagrees and the reasons for the disagreements.

(A) The written request for reconsideration may include additional documentary evidence the MA organization wishes CMS to consider.

(B) CMS does not accept reconsiderations for issues with the methodology applied in any part of the RADV audit.

(vi) *Conduct of written reconsideration.* (A) In conducting the written reconsideration, CMS reviews all of the following information:

(*1*) The RADV payment error calculation.

(*2*) The evidence and findings upon which they were based.

(*3*) Any other written evidence submitted by the MA organization.

(B) CMS ensures that a third party—either within CMS or a CMS contractor—not otherwise involved in the initial RADV payment error calculation reviews the written request for reconsideration.

(C) The third party recalculates the payment error in accordance with CMS RADV payment calculation procedures described in CMS' RADV payment error calculation standard operating procedures.

(D) The third party described in paragraph (c)(3)(vi)(B) of this section provides his or her determination to a CMS reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vi) *Decision of the CMS reconsideration official.* The CMS reconsideration official informs the MA organization and CMS in writing of the decision of the CMS reconsideration official.

(vii) *Effect of the CMS reconsideration official.* The written reconsideration decision is final and binding unless a request for a hearing is filed by CMS or the appellant MA organization in accordance with paragraph (c) (4) of this section.

(4) *Right to a hearing.* CMS or a MA organization dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section.

(i) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 30 calendar days of the date CMS and the MA organization receives the CMS reconsideration officer's written reconsideration decision.

(ii) *Content of request.* The written request for hearing must include a copy of the written decision of the CMS reconsideration official and must specify the findings or issues in the reconsideration decision with which either CMS or the MA organization disagrees and the reasons for the disagreement.

(iii) *Hearing procedures.* (A) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may schedule a live

or telephonic hearing on his/her own motion.

(C) The hearing is conducted by the CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made either its initial RADV payment error calculation determination or its post-medical record review appeal payment error calculation determination and when the CMS reconsideration official issued the written reconsideration decision.

(C) The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers include the authority to dismiss the appeal with prejudice or take any other action which the hearing officer considers appropriate for failure to comply with such rules and procedures.

(iv) *Decision of the CMS Hearing Officer.* The CMS hearing officer decides whether the reconsideration official's decision was correct, and sends a written decision to CMS and the MA organization, explaining the basis for the decision.

(v) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c)(5) of this section.

(vi) *Review by the CMS Administrator.* (A) CMS or a MA organization that has received a hearing officer's decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's decision.

(B) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(C) If the CMS Administrator chooses to review the case, the CMS Administrator—

(*1*) Acknowledges his or her decision to review the hearing officer's decision in writing; and

(*2*) Determines whether to uphold, reverse, or modify the Hearing Officer's decision based on his or her review of the following:

(*i*) The Hearing Officer's decision.

(*ii*) Written documents submitted by CMS or the MA organization to the Hearing Officer.

(*iii*) Any other any other information included in the record of the Hearing Officer's decision.

(D) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review.

(E) If the Administrator chooses to review, the Administrator's determination is final and binding.

(F) The decision of the hearing officer is final if the Administrator—

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

## Subpart K—Contracts With Medicare Advantage Organizations

■ 28. Section 422.501 is amended by—
■ A. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively.
■ B. Adding a new paragraph (b).
■ C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions read as follows:

### § 422.501 Application requirements.

* * * * *

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

* * * * *

■ 29. Section 422.502 is amended by—
■ A. Revising paragraphs (a)(1), (a)(2), and (b).
■ B. Adding a new paragraph (c)(2)(iii).
■ C. Revising paragraph (c)(3)(iii).
■ D. Removing paragraph (d).

The revisions and addition read as follows:

### § 422.502 Evaluation and determination procedures.

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

■ 30. Section 422.503 is amended by—
■ A. Revising paragraphs (b)(4)(vi).
■ B. Adding new paragraph (b)(7).

The revisions and addition read as follows:

### § 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must

include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the organization; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(*2*) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution,

(*2*) Identify noncompliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(*3*) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

* * * * *

(*7*) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

* * * * *

■ 31. Section 422.504 is amended by—

■ A. Redesignating paragraph (e)(1(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

■ B. Adding a new paragraph (e)(1)(ii).

■ C. Revising newly redesignated paragraph (e)(1)(iii).

■ D. Revising paragraph (i)(2)(i).

■ E. Add a new paragraph (m).

The additions and revisions read as follows:

**§ 422.504 Contract provisions.**

* * * * *

(e) * * *

(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

* * * * *

(i) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

* * * * *

(m)(1) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

■ 32. Section 422.506 is amended by—
■ A. Revising paragraph (a)(2)(ii).
■ B. Removing paragraph (a)(2)(iii).
■ C. Revising paragraph (a)(3)(i).
■ D. Adding a new paragraph (b)(1)(iv).
■ E. Revising paragraph (b)(2)(ii).
■ F. Removing paragraph (b)(2)(iii).
■ G. Revising paragraph (b)(3).

The revisions and addition read as follows:

**§ 422.506 Nonrenewal of contract.**

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) * * *

(i) The MA organization notifies its Medicare enrollees in accordance with paragraph (a)(2)(ii) of this section; and

* * * * *

(b) * * *

(1) * * *

(iv) The contract must be nonrenewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the MA organization's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(b) * * *

(3) *Opportunity to develop and implement a corrective action plan.*

(i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

■ 33. Section 422.508 is amended by adding paragraph (c) to read as follows:

**§ 422.508 Modification or termination of contract by mutual consent.**

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration.

■ 34. Section 422.510 is amended by—
■ A. Revising paragraphs (a), (b) introductory text, and (b)(2)(i).
■ B. Redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as (b)(2)(iii) and (b)(2)(iv), respectively.
■ C. Adding a new paragraph (b)(2)(ii).
■ D. Revising paragraph (c).

The revisions and addition read as follows:

**§ 422.510 Termination of contract by CMS.**

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care programs, including submission of false or fraudulent data.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid data as required under § 422.310.

(7) Fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(8) Substantially fails to comply with the prompt payment requirements in § 422.520.

(9) Substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(10) Fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(11) Substantially fails to comply with the marketing requirements in subpart V of this part.

(12) Fails to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(13) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization; or

(B) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

* * * * *

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable

opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization;

(ii) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

* * * * *

■ 35. Section 422.516 is amended by—
■ A. Revising the section heading.
■ B. Adding a new paragraph (g).

The revision and addition to read as follows:

**§ 422.516 Validation of Part C reporting requirements.**

* * * * *

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

## Subpart M—Grievances, Organization Determinations, and Appeals

■ 36. Section 422.561 is amended by revising the definition of "Representative" to read as follows:

**§ 422.561 Definitions.**

* * * * *

*Representative* means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

**§ 422.566 [Amended]**

■ 37. Section 422.566 is amended by—
■ A. Republishing paragraph (b) introductory text.
■ B. Revising paragraph (b)(4).
■ C. Redesignating paragraph (b)(5) as (b)(6).
■ D. Adding a new paragraph (b)(5).
■ E. In paragraphs (c)(1)(i), and (c)(2)(i) removing the parenthetical phrase "(including his or her authorized representative)" is removed and "(including his or her representative)" is added in its place.

The revision and addition to read as follows:

**§ 422.566 Organization determinations.**

* * * * *

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

* * * * *

(4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(5) Reduction of a previously authorized course of treatment if the enrollee believes that continuation of the course of treatment is medically necessary.

* * * * *

■ 38. Section 422.568 is amended by —
■ A. Redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.
■ B. Adding a new paragraph (a).
■ C. Revising newly designated paragraph (d).

The addition and revision read as follows:

**§ 422.568 Standard timeframes and notice requirements for organization determinations.**

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny service or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item or service, in whole or in part.

* * * * *

■ 39. Section 422.574 is amended by revising paragraph (a) to read as follows:

**§ 422.574 Parties to the organization determination.**

* * * * *

(a) The enrollee (including his or her representative);

* * * * *

■ 40. Section 422.622 is amended by revising paragraph (f)(3) to read as follows:

**§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.**

* * * * *

(f) * * *

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

* * * * *

■ 41. Section 422.624 is amended by revising paragraph (c)(1) to read as follows:

**§ 422.624 Notifying enrollees of termination of provider services.**

* * * * *

(c) * * *

(1) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

* * * * *

■ 42. Section 422.626 is amended by—
■ A. Redesignating paragraph (f) as paragraph (g).
■ B. Redesignating paragraph (e)(5) as paragraph (f) and revising the newly redesignated paragraph (f).

The revisions read as follows:

**§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).**

* * * * *

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with § 422.624(b) of this subpart.

* * * * *

## Subpart N—Medicare Contract Determinations and Appeals

■ 43. Section 422.644 is amended by revising paragraph (c) to read as follows:

**§ 422.644 Notice of contract determination.**

* * * * *

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

* * * * *

■ 44. Section § 422.660 is revised to read as follows:

**§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.**

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with § 422.501 and § 422.502.

(2) An MA organization whose contract has been terminated under § 422.510 of this part.

(3) An MA organization whose contract has not been renewed under § 422.506 of this part.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.* (1) During a hearing to review a contract determination as described at § 422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.501 and § 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750 of this part, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752 of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

■ 45. Section 422.662 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 422.662 Request for hearing.**

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

■ 46. Section 422.664 is amended by revising paragraph (b)(2) to read as follows:

**§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.**

* * * * *

(b) * * *

(2) A contract terminated in accordance with § 422.510(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 47. Section 422.670 is revised to read as follows:

**§ 422.670 Time and place of hearing.**

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

■ 48. Section 422.676 is amended by revising paragraph (d) to read as follows:

**§ 422.676 Conduct of hearing.**

* * * * *

(d) The MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

■ 49. Section 422.682 is revised to read as follows:

**§ 422.682 Witness lists and documents.**

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

■ 50. Section 422.692 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 422.692 Review by the Administrator.**

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review.

If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

■ 51. Section 422.696 is amended by revising the section heading and paragraph heading for paragraph (a) to read as follows:

**§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.**

(a) *Contract determination.** * *

* * * * *

## Subpart O—Intermediate Sanctions

■ 52. Section 422.750 is amended by revising paragraph (a) to read as follows:

**§ 422.750 Types of intermediate sanctions and civil money penalties.**

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization.

* * * * *

■ 53. Section 422.752 is amended by revising paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4) to read as follows:

**§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.**

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

■ 54. Section 422.756 amended by—

■ A. Revising paragraph (b).

■ B. Removing paragraph (c).

■ C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

■ D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

**§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.**

* * * * *

(b) *Hearing.* (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at § 422.660 through § 422.684.

(c) *Effective date and duration of sanction*—(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

## Subpart V—Medicare Advantage Marketing Requirements

■ 55. Section 422.2260 is amended by revising paragraph (5)(vii) of the definition of "marketing materials" and adding a new paragraph (6) to read as follows:

**§ 422.2260 Definitions concerning marketing materials.**

* * * * *

*Marketing materials.** * *

(5) * * *

(vii) *Membership activities* (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim specific notification information).—

(6) *Marketing materials exclude ad hoc enrollee communications materials, meaning* informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover claims processing or other operational issues.

■ 56. Section 422.2262 is amended by—

■ A. Revising the section heading.

■ B. Revising paragraphs (a)(1) and (b).

■ C. Adding new paragraphs (c) and (d).

The revisions and additions read as follows:

**§ 422.2262 Review and distribution of marketing materials.**

(a) * * *

(1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this subpart), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

* * * * *

(b) *File and use.* The MA organization may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

## PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 57. The authority citation for part 423 continues to read as follows:

**Authority:** Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

### Subpart B—Eligibility and Enrollment

■ 58. Section 423.34 is revised to read as follows:

#### § 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions—Full-benefit dual-eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) Medical assistance under section 1902(a)(10(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

*Low-income subsidy-eligible individual.* For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals as set forth in this section) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low-income subsidy-eligible individuals.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low-income subsidy-eligible individuals in another PDP if CMS determines that the further enrollment is warranted.

(d) *Enrollment rules*—(1) *General rule.* Except for low-income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low-income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.* (i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

■ 59. Section 423.38 is amended by revising paragraph (c)(4) to read as follows:

**§ 423.38 Enrollment periods.**

* * * * *

(c) * * *

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772 of this part.

* * * * *

■ 60. Section 423.44 is amended by—

■ A. Redesignating paragraphs (d)(1)(iii) and (d)(1)(iv) as paragraphs (d)(1)(iv) and (d)(1)(v), respectively.

■ B. Adding a new paragraph (d)(1)(iii).

■ C. Redesignating the introductory text of paragraph (d)(5) as paragraph (d)(5)(i).

■ D. Adding new paragraph (d)(5)(ii).

The revisions and additions read as follows:

**§ 423.44 Involuntary disenrollment by the PDP.**

* * * * *

(d) * * *

(1) * * *

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 months; and

(B) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

* * * * *

(5) * * *

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan effective on the first day of the 13th month after the individual left the service area.

* * * * *

## Subpart C—Benefits and Beneficiary Protections

■ 61. Section 423.100 is amended by adding the definitions of "Drug category or class," "Major or life threatening clinical consequences," "Multiple drugs," "Restricted access," and "Significant need for access to multiple drugs" to read as follows:

**§ 423.100 Definitions.**

* * * * *

*Drug category or class* means, for the purpose of § 423.120(b)(2)(v) of the subpart, the identification of a drug grouping that is reasonable to identify the applicable drug products.

* * * * *

*Major or life threatening clinical consequences* means consequences in which serious clinical events may arise as a result of not taking a drug that can lead to patient hospitalization, or a persistent or significant disability or incapacity, or that can result in death.

*Multiple drugs* mean two or more Part D drugs.

* * * * *

*Restricted access* means, for the purposes of § 423.120(b)(2)(v)(A) of this subpart, an enrollee who but for § 423.120(b0(2)(v) of this subpart urgently requires a Part D drug but is waiting for an expedited redetermination by a Part D plan or an CMS independent review entity with respect to coverage of that drug.

* * * * *

*Significant need for access to multiple drugs* means instances in which —

(1) There is a need for simultaneous use of drugs within a drug grouping because such drugs work in combination with each other; or

(2) There is a strong likelihood of sequential use of drugs within a class or category within a short period of time due to the unique effects the drugs have on various individuals.

* * * * *

■ 62. Section 423.104 by—

■ A. Revising paragraph (b).

■ B. Adding a new paragraph (d)(2)(iii).

The revision and addition read as follows:

**§ 423.104 Requirements related to qualified prescription drug coverage.**

* * * * *

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan's service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area.

* * * * *

(d) * * *

(2) * * *

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this paragraph may not exceed levels annually determined by CMS to be discriminatory.

* * * * *

■ 63. Section 423.112 is amended by revising paragraph (a) to read as follows:

**§ 423.112 Establishment of prescription drug plan sponsor service areas.**

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

* * * * *

■ 64. Section 423.120 is amended by—

■ A. Revising paragraph (a).

■ B. Redesignating paragraphs (b)(1)(ix) as paragraph (b)(1)(x).

■ C. Adding a new paragraph (b)(1)(ix).

■ E. Revising paragraph (b)(3).

■ F. Redesignating paragraph (c) as paragraph (c)(1).

■ G. Adding new paragraphs (c)(2) through (c)(4).

The revisions and additions read as follows:

**§ 423.120 Access to covered Part D drugs.**

(a) *Assuring pharmacy access*—(1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor's service area (as defined in § 423.112(a) of this part), each State in a regional MA-organization's service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count I/T/U pharmacies and pharmacies operated

by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) * * *

(1) * * *

(ix) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

* * * * *

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i) Be applicable to all of the following:

(A) New enrollees into Part D plans following the annual coordinated election period.

(B) Newly eligible Medicare enrollees from other coverage.

(C) Individuals who switch from one plan to another after the start of the contract year.

(D) Current enrollees remaining in the plan affected by formulary changes.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules).

(A) In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days and requires the Part D sponsor to allow multiple fills to provide up to a total of 30 days of medication.

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 93 days in 31 day supply increments, with refills provided, if needed, unless a

lesser amount is actually prescribed by the prescriber.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(c) * * *

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) Beginning January 1, 2012, a part D sponsor must assign and exclusively use a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

■ 65. Section 423.128 is amended by adding a new paragraph (f) to read as follows:

**§ 423.128 Dissemination of Part D plan information.**

* * * * *

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

■ 66. Section 423.132 is amended by—

■ A. Revising the introductory text of paragraph c.

■ B. In paragraphs (c)(2) and (c)(3), removing the ";" and adding a "." in its place.

■ C. In paragraph (c)(4), removing "; and" and adding a "." in its place.

■ D. Redesignating paragraph (c)(5) as (c)(6).

■ E. Adding a new paragraph (c)(5).

■ F. Revising paragraph (d).

The revisions and additions read as follows:

**§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.**

* * * * *

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in any of the following cases:

* * * * *

(5) A long-term care network pharmacy.

* * * * *

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

## Subpart D—Cost Control and Quality Improvement Requirements

■ 67. Section 423.153 is amended by—

■ A. Adding paragraphs (d)(1)(v) through (vii).

■ B. Revising paragraph (d)(2).

The additions and revisions read as follows:

**§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).**

* * * * *

(d) * * *

(1) * * *

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) Annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet all of the following:

(i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment.

(ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment.

(iii) Are likely to incur the following annual Part D drug costs:

(A) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(B) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in § 423.104(d)(5)(iv) of this part.

* * * * *

■ 68. Section 423.156 is revised to read as follows:

**§ 423.156 Consumer satisfaction surveys.**

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

■ 69. Section 423.165 is amended by—

■ A. Removing paragraph (b)(4).

■ B. Revising paragraph (f).

The revision reads as follows:

**§ 423.165 Compliance deemed on the basis of accreditation.**

* * * * *

(f) *Authority.* Nothing in this section limits CMS' authority under subparts K and O of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

## Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval

■ 70. Section 423.265 is amended by revising paragraph (b) to read as follows:

**§ 423.265 Submission of bids and related information.**

* * * * *

(b) *Bid submission*—(1) *General.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be

considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

* * * * *

■ 71. Section 423.272 is amended by adding a new paragraph (b)(3) to read as follows:

**§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.**

* * * * *

(b) * * *

(3) *Substantial differences between bids*—(i) *General.* CMS approves a bid only if it finds that the benefit package or plan costs represented by that bid are substantially different as provided under § 423.265(b)(2) of this subpart from the benefit package or plan costs represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package or plan costs represented by that bid are substantially different from any benefit package or plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor.

* * * * *

## Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

**§ 423.308 [Amended]**

■ 72. Section 423.308 is amended in paragraph (1) of the definition of "gross covered prescription drug costs" by removing the phrase "The share of negotiated prices" and adding in its place "The share of actual costs".

## Subpart J—Coordination Under Part D Plans With Other Prescription Drug Coverage

■ 73. Section 423.462 is amended by—

■ A. Redesignating the existing text as paragraph (a).

■ B. Adding a paragraph heading for paragraph (a) and new paragraph (b).

The additions read as follows:

**§ 423.462 Medicare secondary payer procedures.**

(a) *General rule.* * * *

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

■ 74. Section 423.464 is amended by adding new paragraphs (a)(3), (e)(1)(vi), (g), and (h) to read as follows:

**§ 423.464 Coordination of benefits with other providers of prescription drug coverage.**

(a) * * *

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

* * * * *

(e) * * *

(1) * * *

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

* * * * *

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made and for amounts being held for payment by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

(h) *Reporting requirements.* A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

■ 75. A new § 423.466 is added to subpart J to read as follows:

**§ 423.466 Timeframes for coordination of benefits.**

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

## Subpart K—Application Procedures and Contracts With PDP Sponsors

■ 76. Section 423.502 is amended by—

■ A. Redesignating paragraphs (b) through (d) as (c) through (e), respectively

■ B. Adding a new paragraph (b).

■ C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions reads as follows:

**§ 423.502 Application requirements.**

* * * * *

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting an Notice of Intent to Apply will not form the basis of any action taken against the organization by CMS.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must describe thoroughly how the entity is

qualified to meet the all requirements described in this part.

* * * * *

■ 77. Section 423.503 is amended by—

■ A. Revising paragraphs (a)(1), (a)(2), and (b).

■ B. Adding a new paragraph (c)(2)(iii).

■ C. Revising paragraph(c)(3)(iii).

■ D. Removing paragraph (d).

The revisions and addition read as follows:

**§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.**

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits.

(2) After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

■ 78. Section 423.504 is amended by—

■ A. Revising paragraph (b)(4)(vi)

■ B. Redesignating paragraph (b)(6) as paragraph (b)(7).

■ C. Adding a new paragraph (b)(6).

The revision and addition read as follows:

**§ 423.504 General provisions.**

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the Part D plan sponsor's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the Part D plan sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of the Part D plan sponsor's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the Part D plan sponsor on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the Part D plan sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each Part D plan sponsor must establish, implement and provide effective training and education for its employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(*2*) The training and education must occur at a least annually and be a part of the orientation for new employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(*3*) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and governing body, and the Part D plan sponsor's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution;

(*2*) Identify non-compliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of

compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(*3*) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

* * * * *

(6) Not have terminated a contract by mutual consent under which, as a condition of the consent, the Part D plan sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period up to 2 years per § 423.508(e) of this subpart.

* * * * *

■ 79. Section 423.505 is amended by—

■ A. Redesignating paragraph (e)(1)(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

■ B. Adding a new paragraph (e)(1)(ii).

■ C. Revising newly redesignated paragraph (e)(1)(iii).

■ D. Revising paragraph (f)(3) introductory text.

■ E. Revising paragraphs (i)(2)(i) and (m)(1)(iii)(C).

■ F. Add a new paragraph (n).

The additions and revisions read as follows:

**§ 423.505 Contract provisions.**

* * * * *

(e) * * *

(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the Part D sponsor to include computer and other electronic systems; and

* * * * *

(f) * * *

(3) All data elements included in all its drug claims for purposes deemed necessary and appropriate by the Secretary, including, but not limited to the following:

* * * * *

(i) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related entities related to CMS' contract with the Part D sponsor.

* * * * *

(m)(1) * * *

(iii) * * *

(C) Plan identifier elements on the claim are encrypted or unavailable for release to external entities with the exception of HHS grantees that CMS determines meet all of the following criteria:

(*1*) The plan identifier is essential to the study.

(*2*) The study is key to the mission of the sponsoring agency.

(*3*) The study provides significant benefit to the Medicare program.

(*4*) The requestor attests that any public findings or publications will not identify plans.

* * * * *

(n)(1) CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when the sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D sponsors.

■ 80. Section 423.507 is amended by—

■ A. Revising paragraph (a)(2)(ii)

■ B. Removing paragraph (a)(2)(iii).

■ C. Adding a new paragraph (b)(1)(iii).

■ D. Revising paragraph (b)(2)(ii).

■ E. Removing (b)(2)(iii).

■ F. Redesignating paragraph (b)(2)(iv) as (b)(2)(iii).

■ G. In newly redesignated paragraph (b)(2)(iii), removing the reference "paragraphs (b)(2)(ii) and (iii) of this section" and add the reference "paragraph (b)(2)(ii) of this section" in its place.

■ H. Revising paragraph (b)(3).

The revisions and addition read as follows:

**§ 423.507 Nonrenewal of a contract.**

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan and PDP options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

* * * * *

(b) * * *

(1) * * *

(iii) The contract must be nonrenewed as to an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

* * * * *

(3) *Opportunity to develop and implement a corrective action plan.* (i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D sponsor's deficiencies and reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

■ 81. Section 423.508 is amended by adding a new paragraph (e) to read as follows:

**§ 423.508 Modification or termination of contract by mutual consent.**

* * * * *

(e) *Agreement to limit new Part D applications.* As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions for a period up to 2 years, absent circumstances warranting special consideration.

■ 82. Amend § 423.509 by—

■ A. Revising paragraphs (a), paragraph (b) introductory text, and paragraph (b)(2)(i).

■ B. Redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as (b)(2)(iii) and (b)(2)(iv), respectively.

■ C. Adding a new paragraph (b)(2)(ii).

■ D. Revising paragraph (c).

The revisions and addition read as follows:

**§ 423.509 Termination of contract by CMS.**

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on credible evidence, has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(7) Substantially fails to comply with the service access requirements in § 423.120.

(8) Substantially fails to comply with either of the following:

(i) Marketing requirements in subpart V of this part.

(ii) Information dissemination requirements of § 423.128 of this part.

(9) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(10) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(11) Fails to comply with the regulatory requirements contained in this part.

(12) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) The procedures specified in (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(B) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the violation specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination in is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

* * * * *

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(ii) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

* * * * *

■ 83. Section 423.514 is amended by—

■ A. Revising the section heading.

■ B. Adding a new paragraph (g).

The revision and addition to read as follows:

**§ 423.514 Validation of Part D reporting requirements.**

* * * * *

(g) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

## Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

■ 84. Section 423.551 is amended by adding a new paragraph (g) to read as follows:

**§ 423.551 General provisions.**

* * * * *

(g) *Sale of beneficiaries not permitted.* (1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization which will be recognized and allowed by CMS.

(2) CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a pharmacy benefit package, or one contract if the sponsor holds more than one PDP contract.

## Subpart M—Grievances, Coverage Determinations, and Appeals

■ 85. Section 423.568 is revised to read as follows:

### § 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file.

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

■ 86. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

### § 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's or other prescriber's supporting statement.

* * * * *

■ 87. Section 423.572 is amended by revising paragraphs (b) and (c) to read as follows:

### § 423.572 Timeframes and notice requirements for expedited coverage determinations.

* * * * *

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee, the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

* * * * *

■ 88. Section 423.590 is amended by—

■ A. Redesignating paragraph (d)(2) as paragraph (d)(3).

■ B. Adding a new paragraph (d)(2).

■ C. Revising the introductory text of paragraph (g).

■ D. Adding a new paragraph (h).

The revisions and additions read as follows:

### § 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(d) * * *

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

* * * * *

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

## Subpart N—Medicare Contract Determinations and Appeals

■ 89. Section 423.642 is amended by revising paragraph (c) to read as follows:

### § 423.642 Notice of contract determination.

* * * * *

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the Part D plan sponsor 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 423.509(b)(2)(i) of this part, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

* * * * *

■ 90. Section 423.650 is revised to read as follows:

**§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.**

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated under § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) and (b) of this part.

(b) *Burden of proof, standard of proof, and standard of review at hearing.* (1) During a hearing to review a contract determination as described at § 423.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) *Timing of favorable decision.* Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

■ 91. Section 423.651 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 423.651 Request for hearing.**

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

■ 92. Section 423.652 is amended by revising paragraph (b)(2) to read as follows:

**§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.**

* * * * *

(b) * * *

(2) A contract terminated in accordance with § 423.509(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

* * * * *

■ 93. Section 423.655 is revised to read as follows:

**§ 423.655 Time and place of hearing.**

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

■ 94. Section 423.658 is amended by revising paragraph (d) to read as follows:

**§ 423.658 Conduct of hearing.**

* * * * *

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

■ 95. Section 423.661 is revised to read as follows:

**§ 423.661 Witnesses lists and documents.**

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing.

■ 96. Section 423.666 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 423.666 Review by the Administrator.**

(a) *Request for review by Administrator.* CMS or a Part D plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

■ 97. Section 423.668 is amended by revising the section heading and the paragraph heading for paragraph (a) to read as follows:

**§ 423.668 Reopening of a contract determination or decision of a hearing officer or the Administrator.**

(a) *Contract determination.* * * *

* * * * *

## Subpart O—Intermediate Sanctions

■ 98. Section 423.750 is amended by revising paragraph (a) to read as follows:

**§ 423.750 Types of intermediate sanctions and civil money penalties.**

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor.

* * * * *

■ 99. Section 423.752 is amended by revising the paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4) to read as follows:

**§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.**

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

■ 100. Section 423.756 is amended by—

■ A. Revising paragraph (b).

■ B. Removing paragraph (c).

■ C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

■ D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

**§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.**

* * * * *

(b) *Hearing.* (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662 of this part.

(c) * * *

(1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

## Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

■ 101. Section 423.773 by revising paragraph (c)(2) to read as follows:

**§ 423.773 Requirements for eligibility.**

* * * * *

(c) * * *

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

* * * * *

■ 102. Section 423.800 is amended by adding a new paragraph (e) to read as follows:

**§ 423.800 Administration of subsidy program.**

* * * * *

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing.* Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries in accordance with the timeframe specified in § 423.466(a) of this part.

## Subpart V—Part D Marketing Requirements

■ 103. Section 423.2260 is amended by revising paragraph (5)(vii) of the definition "marketing materials" and adding a new paragraph (6) to read as follows:

**§ 423.2260 Definitions concerning marketing materials.**

* * * * *

*Marketing materials.* * * *

(5) * * *

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

■ 104. Section 423.2262 is amended by—

■ A. Revising paragraph (a)(1)(i).

■ B. Adding new paragraphs (c) and (d) to read as follows:

**§ 423.2262 Review and distribution of marketing materials.**

(a) * * *

(1) * * *

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

* * * * *

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

## PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

■ 105. The authority citation for part 480 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 106. Section 480.140 is amended by adding a new paragraph (g) to read as follows:

**§ 480.140 Disclosure of quality review study information.**

* * * * *

(g) The QIO must disclose to CMS quality review study information collected as part of the Reporting Hospital Quality Data for Annual Payment Update program, under section 1886(b)(3)(B)(viii) of the Act following hospital review of the data. The quality review study information must include identifiers of MA plan beneficiaries, hospitals, practitioners, and services when CMS requests this information for the sole purpose of conducting activities related to MA organizations as described in § 422.153 of this chapter.

**Authority:**

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 11, 2010.

**Charlene Frizzera,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: April 2, 2010.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2010–7966 Filed 4–6–10; 4:15 pm]

BILLING CODE 4120–01–P

Federal Register

Thursday,
April 15, 2010

# Part III

# Department of the Interior

## 48 CFR Chapter 14

## Acquisition Regulation Rewrite; Interim Final Rule

**DEPARTMENT OF THE INTERIOR**

**Office of the Secretary**

**48 CFR Chapter 14**

**RIN 1093–AA11**

## Acquisition Regulation Rewrite

**AGENCY:** Office of the Secretary, Interior.

**ACTION:** Interim final rule.

**SUMMARY:** The Department of the Interior (DOI) is taking interim final action on administrative changes to the Department of the Interior Acquisition Regulation (DIAR). This action revises the DIAR, 48 CFR Chapter 14, but does not impose any new requirements on DOI contractors. The revisions in this interim final rule will make minor corrections to and streamline DOI acquisition processes to be consistent with and non-duplicative of the Federal Acquisition Regulation (FAR). Some DIAR coverage is being revised and obsolete material is being removed. FAR clauses are now available that provide coverage for the DIAR clauses that are removed by this rule.

**DATES:** This rule is effective on May 17, 2010. Submit comments by June 14, 2010.

**ADDRESSES:** You may submit comments on the rulemaking through the Federal eRulemaking Portal at *http://www.regulations.gov.* Please use the Regulation Identifier Number (RIN) 1093–AA11 in your message. Follow the instructions on the Web site for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Tiffany A. Schermerhorn, Senior Procurement Analyst, Office of Acquisition and Property Management, Office of the Secretary, telephone (202) 513–0747, fax (202) 219–4244, or e-mail *tiffany_schermerhorn@ios.doi.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

This rule revises the Department of the Interior Acquisition Regulation (DIAR) in order to update references to other federal and Departmental directives, remove obsolete material and references, and clarify and streamline internal policies and procedures.

This rule is a result of the DIAR Rewrite Project. DOI is undertaking this project to revise the DIAR to maintain consistency with the FAR and make other administrative changes. No DOI clauses are being changed, with the exception of the removal of obsolete clauses. We view this as a noncontroversial amendment and anticipate no adverse comment. This rule does not impose any new requirements on DOI contractors. All changes are minor and are consistent with the FAR. We are providing an opportunity for the public to comment on this interim rule and will carefully consider and respond to any comments that we receive. We have found good cause to publish this rule without prior proposal. We have determined that it would be impracticable, unnecessary, and contrary to the public interest to delay publication of this rule in final form pending an opportunity for public comment.

### II. Procedural Matters

*1. Public Availability of Comments*

Public availability of comments

Before including your address, phone number, e-mail 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.

*2. Regulatory Planning and Review (Executive Order 12866)*

This document is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This rule does not raise novel legal or policy issues.

*3. The Regulatory Flexibility Act*

The Department of the Interior certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements on small entities.

*4. Small Business Regulatory Enforcement Fairness Act (SBREFA)*

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

*5. Unfunded Mandates Reform Act*

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

*6. Takings (Executive Order 12630)*

Under the criteria in Executive Order 12630, this proposed rule does not have significant takings implications. This rule does not impose conditions or limitations on the use of any private property; consequently, a takings implication assessment is not required.

*7. Federalism (Executive Order 13132)*

Under the criteria in Executive Order 13132, this rule does not have Federalism implications. This rule does not substantially or directly affect the relationship between Federal and State governments or impose costs on States or localities. A Federalism Assessment is not required.

*8. Civil Justice Reform (Executive Order 12988)*

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) of the Order.

*9. Paperwork Reduction Act of 1995*

This rule does not contain an information collection, as defined by the Paperwork Reduction Act.

*10. National Environmental Policy Act*

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required.

*11. Data Quality Act*

In developing this rule we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

*12. Effects on the Energy Supply*

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

*13. Clarity of This Regulation*

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, which sections where you feel lists or tables would be useful, etc.

**List of Subjects in 48 CFR Chapter 14**

Government Procurement.

Dated: March 22, 2010.

**Pamela K. Haze,**

*Deputy Assistant Secretary, Budget, Finance, Performance and Acquisition.*

■ For the reasons set out in the preamble, we are revising Chapter 14 of Title 48 Code of Federal Regulations to read as follows:

Title 48—Federal Acquisition Regulations System
CHAPTER 14—DEPARTMENT OF THE INTERIOR
SUBCHAPTER A—GENERAL
PART 1401—DEPARTMENT OF THE INTERIOR ACQUISITION REGULATION SYSTEM
PART 1402—DEFINITIONS OF WORDS AND TERMS
PART 1403—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST
PART 1404—ADMINISTRATIVE MATTERS
SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING
PART 1405—PUBLICIZING CONTRACT ACTIONS
PART 1406—COMPETITION REQUIREMENTS
PART 1407—ACQUISITION PLANNING
PART 1408—REQUIRED SOURCES OF SUPPLIES AND SERVICES
PART 1409—CONTRACTOR QUALIFICATIONS
PARTS 1410—1412 [RESERVED]
SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES
PART 1413—SIMPLIFIED ACQUISITION PROCEDURES
PART 1414—SEALED BIDDING
PART 1415—CONTRACTING BY NEGOTIATION
PART 1416—TYPES OF CONTRACTS
PART 1417—SPECIAL CONTRACTING METHODS
PART 1418—[RESERVED]
SUBCHAPTER D—SOCIOECONOMIC PROGRAMS
PART 1419—SMALL BUSINESS PROGRAMS
PARTS 1420—1421 [RESERVED]
PART 1422—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS
PART 1423—[RESERVED]
PART 1424—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION
PART 1425—FOREIGN ACQUISITION
PART 1426—OTHER SOCIOECONOMIC PROGRAMS
SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS
PART 1427—PATENTS, DATA, AND COPYRIGHTS
PART 1428—BONDS AND INSURANCE
PART 1429—TAXES
PART 1430—COST ACCOUNTING STANDARDS ADMINISTRATION
PART 1431—CONTRACT COST PRINCIPLES AND PROCEDURES
PART 1432—CONTRACT FINANCING
PART 1433—PROTESTS, DISPUTES, AND APPEALS
SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING
PART 1434—[RESERVED]
PART 1435—RESEARCH AND DEVELOPMENT CONTRACTING
PART 1436—CONSTRUCTION AND ARCHITECT–ENGINEER CONTRACTS
PART 1437—SERVICE CONTRACTING
PARTS 1438—1441 —[RESERVED]
SUBCHAPTER G—CONTRACT MANAGEMENT
PART 1442—CONTRACT ADMINISTRATION AND AUDIT SERVICES
PART 1443—CONTRACT MODIFICATIONS
PART 1444—[RESERVED]
PART 1445—GOVERNMENT PROPERTY
PART 1446—QUALITY ASSURANCE
PART 1447—[RESERVED]
PART 1448—VALUE ENGINEERING
PART 1449—TERMINATION OF CONTRACTS
PART 1450—EXTRAORDINARY CONTRACTUAL ACTIONS AND THE SAFETY ACT
PART 1451—USES OF GOVERNMENT SOURCES BY CONTRACTORS
PART 1452—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

SUBCHAPTER A—GENERAL

## PART 1401—DEPARTMENT OF THE INTERIOR ACQUISITION REGULATION SYSTEM

### Subpart 1401.1—Purpose, Authority, Issuance

Sec.
1401.105–3 Copies.

### Subpart 1401.2—Administration

1401.201 Maintenance of the Federal Acquisition Regulation (FAR).
1401.201–1 The Civilian Agency Acquisition Council (CAAC).

### Subpart 1401.3—Agency Acquisition Regulations

1401.301 Policy.
1401.301–70 Definitions.
1401.303 Publication and codification.
1401.304 Agency control and compliance procedures.
1401.370 Acquisition Managers' Partnership.

### Subpart 1401.4—Deviations from the FAR and DIAR

1401.403 Individual deviations.
1401.404 Class deviations.
1401.405 Deviations pertaining to treaties and executive agreements.

### Subpart 1401.6—Career Development, Contracting Authority, and Responsibilities

1401.601 General.
1401.602 Contracting officers.
1401.602–1 Authority.
1401.602–3 Ratification of unauthorized commitments.
1401.603 Selection, appointment and termination of appointment.
1401.603–1 General.
1401.603–2 Selection.
1401.603–3 Appointment.
1401.670 Contracting officers' representatives.
1401.670–1 Contract clause.

### Subpart 1401.70—Acquisition Reviews

1401.7000 Scope of subpart.
1401.7001 Review and approval of contract actions.

1401.7001–1 Review and approval by Assistant Secretaries.
1401.7001–2 Legal review by the Office of the Solicitor.
1401.7001–3 Administrative review and approval by bureaus and offices.
1401.7001–4 Acquisition performance measurement systems.
1401.7001–5 Acquisition Management Reviews (AMRs).

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1401.1—Purpose, Authority, Issuance

### 1401.105–3 Copies.

Copies of the Department of the Interior Acquisition Regulation (DIAR) and Department-wide internal guidance may be obtained from the Office of Acquisition and Property Management, Office of the Secretary, U.S. Department of the Interior, 1849 C Street (MS 2607–MIB), NW., Washington, DC 20240. Additional information on DOI may be obtained on the Internet at *http://www.doi.gov/pam.*

## Subpart 1401.2—Administration

### 1401.201 Maintenance of the Federal Acquisition Regulation (FAR).

### 1401.201–1 The Civilian Agency Acquisition Council (CAAC).

The Department of the Interior is represented on the CAAC by a member of the Office of Acquisition and Property Management (PAM).

## Subpart 1401.3—Agency Acquisition Regulations

### 1401.301 Policy.

(a)(1) Subject to the authorities in paragraph (c) of this section, the Department issues acquisition regulations which implement or supplement the FAR under the DIAR System. The regulation, as part of the FAR system, is issued in accordance with the policy in FAR 1.301(a)(1).

(2) Subject to the authorities in paragraph (c) of this section, the Department also issues internal guidance and instructions under the DIAR System in accordance with the policy in FAR 1.301(a)(2).

(b) Public participation in promulgating acquisition regulations, which are published in the **Federal Register**, shall follow the Department's rulemaking procedures prescribed in Part 318, Chapter 5 of the Departmental Manual (318 DM 5) and the procedures in FAR Subpart 1.5.

(c) Regulations and internal guidance under the DIAR System are issued pursuant to the authority of the Secretary of the Interior under 5 U.S.C. 301 and 40 U.S.C. 486(c). This authority has been delegated to the Assistant Secretary—Policy, Management and Budget under Part 209, Chapter 4.1A of the Departmental Manual (209 DM 4.1A).

### 1401.301–70 Definitions.

(a) "Implement," as used in this subpart, means coverage that expands upon or specifically indicates the manner of compliance with related higher level coverage.

(b) "Supplement," as used in this subpart, means material for which there is no counterpart in higher-level coverage.

### 1401.303 Publication and codification.

(a)(1) Implementing and supplementing regulations issued under the DIAR System are codified under Chapter 14 in Title 48, Code of Federal Regulations and shall parallel the FAR in format, arrangement, and numbering system.

(2)(i) Department-wide regulations are assigned parts 1401 through 1479 under 48 CFR, Chapter 14.

(ii) Where material in the FAR requires no implementation, there will be no corresponding number in the DIAR. Thus, there are gaps in the DIAR sequence of numbers where the FAR, as written, is deemed adequate. Supplemental material shall be numbered as specified in FAR 1.303.

(3) Bureau-wide regulations are authorized for codification in Appendices to Chapter 14, as assigned by the Director, PAM, in accordance with 1401.304(a)(3).

(b) Regulations implementing the FAR or DIAR are numbered using Parts 1401 through 1479. Supplemental material is numbered using Parts 1480 through 1499. Numbers for implementing or supplementing regulations by bureaus/offices are preceded by a prefix to the number 14 (indicating Chapter 14–DIAR) for the organization indicated by lettered appendices as follows:

(1) Bureau of Indian Affairs—BIA
(2) Bureau of Reclamation—WBR
(3) National Business Center—NBC
(4) Bureau of Land Management—LLM
(5) U.S. Geological Survey—WGS
(6) Office of Surface Mining Reclamation & Enforcement—LSM
(7) Minerals Management Service—LMS
(8) National Park Service—FNP
(9) U.S. Fish and Wildlife Service—FWS

(c) *e.g.,* FAR 1.3 then DIAR 1401.3 [Department level] then in Appendix A, BIA 1401.3 [Bureau level].

### 1401.304 Agency control and compliance procedures.

(a)(1) The DIAR System is under the direct oversight and control of the Director, PAM, who is responsible for reviewing and preparing the issuance of all Department-wide and bureau-wide acquisition regulations published in the **Federal Register** to ensure compliance with FAR Part 1. Review procedures are contained in Part 401 of the Departmental Manual (401 DM) and paragraph (a)(3) of this section. One copy of all material issued shall be furnished to the Director, PAM, at the time of issuance.

(2) The Director, PAM, is also responsible for reviewing and issuing unpublished Department-wide internal guidance under the DIAR System.

(3) A bureau wishing to issue bureau-wide regulations shall submit a request to the Director, PAM, for authority to proceed with the regulation. The request shall include a justification for the regulation and a proposed outline of the regulation and the significant contents of the coverage to be included. The Director, PAM, shall review the request to determine whether the regulation should be considered for inclusion in the DIAR or FAR. If a determination is made that the regulation is appropriate for inclusion in the DIAR or FAR, PAM will process the regulation accordingly. If a determination is made that the regulation is appropriate for inclusion in bureau-wide regulations only, the Director, PAM, shall assign an appendix to 48 CFR Chapter 14 and authorization shall be granted for the bureau to proceed with the regulation in accordance with the procedures referenced in 1401.301(b). Rulemaking notices shall be submitted to the Director, PAM, for processing of AS/PMB approval under 401 DM 1.4C(3), before the appropriate program Assistant Secretary signs them.

(4) HCAs are responsible for establishing and implementing formal procedures for oversight and control of all unpublished bureau-wide internal guidance issued to implement FAR or DIAR requirements. The Director, PAM, shall review and approve these procedures and they shall include:

(i) Provisions for centralized issuance of all guidance and instructions using a directives system;

(ii) Methods for periodic review and updating of all issuances;

(iii) Distribution processes which ensure timely receipt by all affected contracting offices; and

(iv) Provisions for maintaining compliance with FAR 1.304.

(b) The Director, PAM, is responsible for evaluating coverage under the DIAR

System to determine applicability to other agencies and for recommending coverage to the FAR Secretariat for inclusion in the FAR.

**1401.370 Acquisition Managers' Partnership.**

(a) The Acquisition Managers' Partnership (AMP) is a forum for DOI's senior acquisition management community to work cooperatively and continuously to improve the management, efficiency and effectiveness of its procurement services in support of DOI's mission.

(b) The AMP consists of the BPCs and representatives from PAM and OSDBU.

(c) The AMP Charter provides that the Chairperson and Associate Chairperson are leadership roles that will rotate annually. The AMP Chairperson determines when the partnership will meet and develops meeting agendas. The Chairperson will distribute the meeting minutes to all members.

## Subpart 1401.4—Deviations from the FAR and DIAR

**1401.403 Individual deviations.**

(a) The Director, PAM, is authorized to approve deviations of FAR provisions (see FAR 1.4) or DIAR provisions which affect only one contracting action.

(b) Requests for deviations under paragraph (a) of this section shall be submitted by the BPC and include justification for the deviation.

(c) A copy of the approved deviation shall be included in the contract file.

**1401.404 Class deviations.**

(a) The Director, PAM, is authorized to approve class deviations of FAR or DIAR provisions which affect more than one contracting action.

(b) Requests for deviations under paragraph (a) of this section shall be submitted by the HCA and include justification for the deviation and the number of contracting actions which will be affected.

(c) For a FAR class deviation the Director, PAM, shall consult with the CAAC, as required in FAR 1.404(a)(1), before authorizing the deviation.

(d) A copy of each approved class deviation shall be referenced in the contract file.

(e) Recommended revisions to the FAR and a copy of each approved class FAR deviation shall be transmitted to the FAR Secretariat by the Director, PAM, as required in FAR 1.404.

**1401.405 Deviations pertaining to treaties and executive agreements.**

(a) The Director, PAM, is responsible for transmitting to the FAR Secretariat the information required in FAR 1.405(d).

(b) For deviations not authorized by FAR 1.405(b) or (c), the Director, PAM, shall process the request for deviation through the FAR Secretariat.

(c) Deviations authorized or requested under paragraph (d) or (e) of this section shall be submitted by the HCA to the Director, PAM for further action.

## Subpart 1401.6—Career Development, Contracting Authority, and Responsibilities

**1401.601 General.**

(a) The authority and responsibility vested in the Secretary to contract for authorized supplies and services is delegated to Assistant Secretaries.

(b) The contracting authority and responsibility delegated to Assistant Secretaries may be redelegated to heads of bureaus and offices under their supervision in accordance with 200 DM 3. Such redelegations are published in bureau chapters of the Part 200 series of the Departmental Manual.

(c) Bureau heads and assistant or associate heads thereof (known as HCAs as defined in 1402.1) may redelegate contracting authority only as prescribed in 1401.603.

**1401.602 Contracting officers.**

**1401.602–1 Authority.**

Information on the limits of CO's authority shall be maintained by the HCA as required in FAR 1.602–1.

**1401.602–3 Ratification of unauthorized commitments.**

(a) The HCA may redelegate ratification authority to the CCO as defined in Subpart 1402.1 and implemented in bureau procedures.

(b) Legal concurrence is required prior to ratification of unauthorized actions for amounts greater than the micropurchase threshold.

(c) Nonratifiable commitments shall be coordinated with the SOL.

**1401.603 Selection, appointment and termination of appointment.**

**1401.603–1 General.**

BPCs are authorized to select and appoint COs and terminate their appointment as prescribed in the Department's Certificate of Appointment (COA) Manual. Copies of the manual may be obtained at *http://www.doi.gov/pam/Acqworkfor.html.*

**1401.603–2 Selection.**

COs, regardless of series or organizational placement, must be certified at a level commensurate with their appointment level, as prescribed in the Department's Federal Acquisition Certification in Contracting (FAC–C) Program Manual. Director, PAM, is the approving authority for all new and reinstated FAC–C certifications. BPCs are authorized to approve renewal FAC–C certifications.

**1401.603–3 Appointment.**

Purchase card holders may be appointed in writing or in accordance with the bureau/office procedures within the constraints of DOI Integrated Charge Card Program Policy Manual located at *http://www.doi.gov/pam/chargecard.* Additional guidance is available in the GSA Smart Pay program at *http://www.gsa.gov/smartpay.*

**1401.670 Contracting officers' representatives.**

When a CO elects to appoint an individual to act as an authorized representative in the administration of a contract, such appointment must be made in accordance with the DOI Contracting Officers' Representative Manual available at *http://www.doi.gov/pam/Acqworkfor.html.*

**1401.670–1 Contract clause.**

Insert the clause at 1452.201–70 in solicitations and contracts under which a COR or COTR will be appointed. Complete the fill-in before award.

## Subpart 1401.70—Acquisition Reviews

**1401.7000 Scope of subpart.**

This subpart sets forth requirements for review and approval of contract actions and the conduct of acquisition management reviews.

**1401.7001 Review and approval of contract actions.**

**1401.7001–1 Review and approval by Assistant Secretaries.**

Contract actions shall be reviewed and approved by Assistant Secretaries as prescribed in 211–255 DM. Their approvals shall be obtained before requesting any other approvals prescribed in the DIAR.

**1401.7001–2 Legal review by the Office of the Solicitor.**

The Office of the Solicitor (SOL) will review for legal sufficiency selected types and portions of contract actions from Bureaus and offices as required by the FAR, DIAR, and Department-wide policy. COs may request SOL advice or guidance on acquisition-related matters at any time. Matters related to legal sufficiency reviews that cannot be resolved between the respective CO and SOL Attorney-Advisor must be submitted for resolution to the HCA and the Assistant Solicitor for Acquisitions

and Intellectual Property, Washington, DC.

**1401.7001–3 Administrative review and approval by bureaus and offices.**

(a) Administrative review and approval requirements for contract actions shall be established by the HCA and issued as internal bureau procedures. At a minimum, the review and approval requirements must address a representative percentage of the overall contract actions within a bureau/office. The procedures shall include:

(1) Identifying the type and dollar amounts of the actions to be reviewed based on the volume and nature of the contracting office workload;

(2) Designating the stage(s) in the acquisition process when the review(s) shall be performed;

(3) Establishing review and approval levels based on the type and dollar amount of the action and the capabilities of the reviewing office;

(4) Specifying what information is required to review the action, which includes creating a review and approval form and mechanism for following up on the correction of deficiencies noted in the review; and

(5) Providing for periodic review of procedures and revision as required, to assure necessary controls are maintained.

**1401.7001–4 Acquisition performance measurement systems.**

(a) The acquisition performance measurement system is a three-pronged approach that includes self assessment, statistical data for validation and flexible quality reviews and assessment techniques. This system is required to:

(1) Evaluate the effectiveness and efficiency of bureau and office acquisition systems;

(2) Assess the adequacy of policies, procedures and regulations governing the acquisition process; and

(3) Identify and implement changes necessary to improve the systems.

(b) HCA's are responsible for ensuring contracting activity compliance with law and regulations through the review and oversight process.

**1401.7001–5 Acquisition Management Reviews.**

Acquisition Management Reviews (AMRs) are to be conducted using the Government Accountability Office's (GAO) "Framework for Assessing the Acquisition Function at Federal Agencies" available at *http://www.gao.gov/new.items/d05218g.pdf.*

## PART 1402—DEFINITIONS OF WORDS AND TERMS

### Subpart 1402.1—Definitions

Sec.
1402.101 Definitions.
1402.170 Acronyms.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1402.1—Definitions

**1402.101 Definitions.**

As used in this part:

*Bureau procurement chief (BPC)* is defined as the senior GS–1102 official in a bureau or office. His/her authority may be delegated, unless specified otherwise, to the CCO. If the BPC is also the CO for an action requiring approval of the BPC, then approval shall be at the HCA level.

*Chief of the contracting office (CCO)* is defined as the senior GS–1102 within a contracting office unless otherwise specified by bureau/office regulation. If the CCO is also the Contracting Officer (CO) for an action requiring approval of the CCO, then approval shall be at a level above the CCO in accordance with bureau procedures.

*Contracting activity* is defined as an office with delegated procurement authority. Within the Office of the Secretary (OS), the Office of Inspector General (OIG) is a contracting activity. The *National Business Center (NBC)* contracts for the OS.

*Head of the agency* (also called "agency head") is defined as the Secretary of the Interior and the Assistant Secretary—*Policy, Management and Budget (AS/PMB).*

*Head of the contracting activity (HCA*) is defined as the assistant or associate administrative head of each bureau and office who has overall responsibility for managing contracting. In reference to the OS, the HCAs are the Assistant Inspector General for Management and Policy and the Director, NBC. The authority of the HCA may be redelegated to the BPC unless otherwise specified.

*Senior procurement executive* is defined as the Director, *Office of Acquisition and Property Management (PAM).*

**1402.170 Acronyms.**

A&E Architect & Engineering
ACMIS Acquisition Career Management Information System
AMP Acquisition Manager's Partnership
AMR Acquisition Management Review
AS/PMB Assistant Secretary—Policy, Management and Budget
BPA Blanket Purchase Agreement
BPC Bureau Procurement Chief
BUDS Business Utilization Development Specialist
CA Competition Advocate
CAAC Civilian Agency Acquisition Council
CAS Cost Accounting Standards
CASB Cost Accounting Standards Board
CBCA Civilian Board of Contract Appeals
CCO Chief of the Contracting Office
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CFR Code of Federal Regulations
CIO Chief Information Officer
CO Contracting Officer
COA Certificate of Appointment
COI Conflicts of Interest
COR Contracting Officer's Representative
COTR Contracting Officer's Technical Representative
DISP Defense Industrial Security Program
DM Departmental Manual
DOI Department of the Interior
DOL Department of Labor
EC Electronic Commerce
FAR Federal Acquisition Regulation
FBMS Financial Business Management System
FPDS—NG Federal Procurement Data System—Next Generation
GAO Government Accountability Office
GIDEP Government-Industry Data Exchange Program
GPE Government Point of Entry
GPO Government Printing Office
GSA General Services Administration
GSBCA General Services Board of Contract Appeals
HCA Head of the Contracting Activity
IT Information Technology
IPMD Interior Property Management Directives
MBDA Minority Business Development Agency
OCIO Office of Chief Information Officer
OIG/IG Office of Inspector General/ Inspector General
OFPP Office of Federal Procurement Policy
OHA Office of Hearings and Appeals
OMB Office of Management and Budget
OS Office of the Secretary
OSDBU Office of Small and Disadvantaged Business Utilization
PAM Office of Acquisition and Property Management
PMO Property Management Officer
PNM Procurement Negotiation Memorandum
SAT Simplified Acquisition Threshold
SBA Small Business Administration

SOL Office of the Solicitor
TFM Treasury Financial Manual
U.S.C. United States Code
VECP Value Engineering Change Proposal

## PART 1403—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

### Subpart 1403.1—Safeguards

Sec.
1403.101 Standards of conduct.
1403.101–3 Agency regulations.
1403.101–70 Technical evaluators and advisors.
1403.104 Procurement integrity.
1403.104–2 Applicability.
1403.104–4 Disclosure, protection and marking of contractor bid or proposal information and source selection information.
1403.104–7 Violations or possible violations.

### Subpart 1403.2—Contractor Gratuities to Government Personnel

1403.203 Reporting suspected violations of the Gratuities clause.
1403.204 Treatment of violations.

### Subpart 1403.3—Reports of Suspected Antitrust Violations

1403.303 Reporting suspected antitrust violations.

### Subpart 1403.4—Contingent Fees

1403.405 Misrepresentations or violations of the Covenant Against Contingent Fees.

### Subpart 1403.5—Other Improper Business Practices

1403.570 Restrictions on contractor advertising.
1403.570–1 Policy.
1403.570–2 Procedures.
1403.570–3 Contract clause.

### Subpart 1403.6—Contracts With Government Employees or Organizations Owned or Controlled by Them

1403.602 Exceptions.
1403.603 Responsibilities of the contracting officer.

### Subpart 1403.7—Voiding and Rescinding Contracts

1403.704 Policy.
1403.705 Procedures.

### Subpart 1403.8—Limitation on the Payment of Funds to Influence Federal Transactions

1403.804 Policy.
1403.806 Processing suspected violations.

### Subpart 1403.10—Contractor Code of Business Ethics and Conduct

1403.1004 Contract clause.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1403.1—Safeguards

### 1403.101 Standards of conduct.

#### 1403.101–3 Agency regulations.

(a) Policy. DOI regulations governing the conduct and responsibilities of regular and special employees are contained in 43 CFR Part 20. Additional guidance is contained in the DOI publication "Ethics Guide for Department of the Interior Employees." Copies of the Guide can be obtained from the Bureau/Office Ethics Office or on the Internet at *http://www.doi.gov/ethics/*. With regard to the provisions of 43 CFR Part 20, officials who participate personally and substantially in DOI procurements (as defined in FAR 3.104–3), may not solicit or accept any gift, gratuity, favor, entertainment, loan or anything of monetary value from a competing contractor during the conduct of a procurement.

(b)(1) Officials may not accept or solicit from any competing contractor any services that involve the development of specifications, statements of work, evaluation criteria, or formal cost estimates to be used in a procurement unless such services are formally contracted for pursuant to the FAR and DIAR, and until the organizational COI provisions in FAR Subpart 9.5 have been fully addressed. This does not preclude COs from issuing formal Requests for Comment (RFC) or draft RFPs.

(2) IT resources shall not be accepted, installed or utilized by the Department on a no cost, free of charge basis (this includes donated equipment but not public domain software), except as permitted by law.

#### 1403.101–70 Technical evaluators and advisors.

(a) Technical evaluators and advisors, including members of proposal evaluation committees, must render impartial, technically sound, and objective assistance and advice.

(b) With the exception of contracting personnel, proposal evaluators and advisors are not required to file a Confidential Financial Disclosure Report (SF450) unless they occupy positions identified in 43 CFR 20.735.30(b). Therefore, when an individual is appointed as an evaluator or advisor, he/she must sign and return to the CO a Conflict of Interest Certificate in a format approved by the HCA. If a potential COI exists, the appointee must not be allowed to evaluate or advise on an offeror's proposal until the conflict has been resolved with the servicing Ethics Counselor.

(c) During the evaluation process, each evaluator and advisor is responsible for ensuring that there are no financial or employment interests that conflict or give the appearance of conflicting with his or her duty to evaluate proposals impartially and objectively. Examples of situations that may be prohibited or represent a potential COI include:

(1) Financial interest, including stocks and bonds, in a firm that submits, or is expected to submit, an offer in response to the solicitation;

(2) Outstanding financial commitments to any actual or potential offeror;

(3) Employment in any capacity, even if otherwise permissible, by any actual or potential offeror;

(4) Employment within the last 12 months by an actual or potential offeror;

(5) Any non-vested pension or re-employment rights, or interest in profit sharing or stock bonus plans arising out of past employment by an actual or potential offeror; or

(6) Employment of any member of the immediate family by an actual or potential offeror.

(d) Bureaus shall include a notice similar to the following in all correspondence notifying employees of appointments to serve as technical evaluators or advisors, formally called Technical Evaluation Panels (TEP) and/or Source Evaluation Boards (SEB):

> You shall not solicit or accept any gift, gratuity, favor, entertainment, loan, or anything of monetary value from a competing contractor involved in any action for which you participate personally and substantially under this delegation of authority. You are also reminded of other conduct prohibitions in FAR 3.104–3, including negotiating with competing contractors for future employment, disclosure of contractor bid or proposal information or source selection information, and post-Government employment restrictions.
>
> Such notice shall include an acknowledgement of receipt signed and returned by the employee.

### 1403.104 Procurement integrity.

#### 1403.104–2 Applicability.

Construction contracts (or subcontracts in such cases where the tribal contractor has subcontracted the activity) awarded under the authority of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, as amended, are subject to the provisions promulgated under that Act.

#### 1403.104–4 Disclosure, protection, and marking of contractor bid or proposal information and source selection information.

(a) The following classes of persons may be authorized access to contractor

bid or proposal information and source selection information to the extent necessary to accomplish their requisite duties and responsibilities with respect to a particular procurement:

(1) Individuals who generate contract requirements, including program and technical experts involved in the development of statements of work, specifications or similar documents;

(2) Contracting personnel acting in support of the CO;

(3) Secretarial, clerical and administrative personnel of the contracting activity directly involved in the procurement;

(4) Supervisors in the CO's chain of command;

(5) Attorneys in the SOL;

(6) OIG contract auditors, and auditors of other agencies such as the Defense Contract Audit Agency (DCAA) and DHHS when requested to perform contract audits by the OIG;

(7) Engineers and other technical support personnel who provide support to the CO;

(8) Small Business Technical Advisors and BUDS;

(9) SBA personnel responsible for reviewing determinations related to set-aside acquisitions, determining the small business status of offerors, processing applications for Certificates of Competency, reviewing subcontracting plans, or awarding contracts under the 8(a) program;

(10) Personnel in DOL responsible for making eligibility determinations or for processing preaward EEO clearances;

(11) Personnel who review bid protests in the GAO and the CBCA;

(12) Personnel serving on technical evaluation boards or source selection evaluation boards;

(13) Contract clearance personnel;

(14) Departmental and bureau/office Competition Advocates;

(15) Personnel in the Congressional liaison offices;

(16) Agency ethics official and servicing Ethics Counselors;

(17) Members of Congress and members of their staff. (See also DIAR 1405.403.); and

(18) Anyone specifically authorized by the CO.

#### 1403.104–7 Violations or possible violations.

(a)(1) The CO's determination that there is no impact on the procurement due to a possible violation of the Procurement Integrity Act and decision to proceed with contract award shall receive concurrence from an individual one level above the CO.

(2) In case of nonconcurrence with the CO's determination, the HCA shall provide a copy of the reported violation and recommended action to the OIG in accordance with Part 111 DM 3. The CO, in consultation with the SOL and the OIG, must justify the compelling circumstances for immediate award and obtain approval to proceed from the BPC without the power of redelegation. Copies of the determination to proceed with the award will be sent to the Director, PAM, for submission to the AS/PMB.

### Subpart 1403.2—Contractor Gratuities to Government Personnel

#### 1403.203 Reporting suspected violations of the Gratuities clause.

When suspected violations of the clause at FAR 52.203–3, Gratuities, become known to a Federal Government employee, the matter shall be reported, in writing, to the cognizant CO or the CO's supervisor, as appropriate. The report shall clearly state the alleged circumstances surrounding the incident or incidents in which the contractor offered or gave a gratuity to a Federal Government employee and intended to obtain a contract or favorable treatment under a contract because of the gratuity. The date(s), location(s) and name(s) of all parties involved in the incident shall be included in the report.

#### 1403.204 Treatment of violations.

(a) The CO will provide the contractor with a formal notice that summarizes the events involving the suspected violation and affords the contractor the opportunity to take the action(s) listed under FAR 3.204(b). The notice shall contain a time limit for reply and shall be sent by certified mail return receipt requested. The CO will submit the report, additional documentary evidence and other pertinent information to the HCA for disposition with a recommended course of action. A copy of this submission must also be sent to the Deputy Assistant Inspector General for Investigations. In consultation with the SOL and the OIG, and based on the results of any further discussion with the contractor, its counsel or witnesses, the HCA may make a recommendation to the Director, PAM, pursuant to FAR 3.204(c) and shall provide formal notice to the contractor of such recommendation.

(b) If the decision involves the termination of a contract (see FAR 3.204(c)(1)), the CO will be responsible for implementing the decision.

### Subpart 1403.3—Reports of Suspected Antitrust Violations

#### 1403.303 Reporting suspected antitrust violations.

(a) Reports on suspected violations of antitrust laws as required by FAR 3.303 shall be prepared by the CO, reviewed by the SOL, and submitted by the HCA directly to the Attorney General, Department of Justice. A copy of this submission must also be sent to the Deputy Assistant Inspector General for Investigations.

(b) Depending on the nature of the suspected violation or the disposition of the matter, the HCA may recommend debarment or suspension in accordance with FAR 9.406–2(a)(2) or 9.407–2(a)(2) and Subpart 1409.4.

### Subpart 1403.4—Contingent Fees

#### 1403.405 Misrepresentation or violations of the Covenant Against Contingent Fees.

(a) In addition to notifying the CO, the matter must also be reported to the Deputy Assistant Inspector General for Investigations and the HCA.

(b) The HCA may recommend debarment and suspension in accordance with Subpart 1409.4.

(c) The CCO shall consult with the SOL and OIG prior to forwarding a report of suspected fraudulent or criminal violations to the Department of Justice for action.

### Subpart 1403.5—Other Improper Business Practices

#### 1403.570 Restrictions on contractor advertising.

#### 1403.570–1 Policy.

Award of a contract does not signify endorsement of the supplies or services purchased, nor does it signify agreement with any views espoused by officials of the awardee. It is vital to the integrity of the procurement system to avoid even the appearance of an improper preference toward a particular vendor. Therefore, contractors shall not be permitted to publicize, or otherwise circulate, promotional materials that state or imply Governmental endorsement of a product, service or position which the contractor represents.

#### 1403.570–2 Procedures.

If a contractor requests a determination as to the propriety of such promotional material, the response shall be coordinated with the cognizant Public Affairs Office and Ethics Officer.

#### 1403.570–3 Contract clause.

CO's shall include the clause at 1452.203–70, Restriction on

Endorsements, in all solicitations, contracts and agreements which are not executed in accordance with FAR Parts 12 or 13.

## Subpart 1403.6—Contracts With Government Employees or Organizations Owned or Controlled by Them

### 1403.602 Exceptions.

The HCA, without the power of redelegation, is authorized to except a contract from the policy in FAR 3.601. However, no exceptions may be granted where the proposed contractor is owned or controlled by a Government employee or one or more members of the employee's immediate family and the employee or any subordinate is serving as a procurement official on the proposed contract.

### 1403.603 Responsibilities of the contracting officer.

The CO shall prepare a written determination and findings for the signature of the HCA when requesting authorization to allow a contract award to a Government employee or business concern or other organization owned or substantially owned or controlled by one or more Government employees.

## Subpart 1403.7—Voiding and Rescinding Contracts

### 1403.704 Policy.

The HCA is authorized to declare void and rescind contracts in accordance with the procedures in FAR 3.705.

### 1403.705 Procedures.

(a) *Reporting.* The facts concerning any final conviction for any violation of 18 U.S.C. 201–224 involving or relating to any contract awarded by a bureau or office shall be set forth in a report and submitted by the HCA to the Civil Division of the Department of the Justice. The report shall also contain a recommendation to initiate a debarment action. If debarment is recommended, the procedures in 1409.406–3(a) shall be followed. Copies of the report shall be provided to Director, PAM, and the Deputy Assistant Inspector General for Investigations for informational purposes.

(b) *Notice of Proposed Action.* Based upon review of the report in paragraph (a) of this section and after consultation with the SOL and the OIG, as appropriate, the HCA shall give notice of the proposed action to the contractor in accordance with the requirements of FAR 3.704(c).

(c) *Final Agency Decision.* The HCA shall make the final decision on voiding and rescinding contracts in accordance with the requirements of FAR 3.705(e).

## Subpart 1403.8—Limitation on the Payment of Funds to Influence Federal Transactions

### 1403.804 Policy.

The BPC shall receive copies of contractor disclosures and forward them to the Director, PAM, for submission to Congress.

### 1403.806 Processing suspected violations.

Suspected violations shall be referred to the HCA. The HCA, in consultation with the SOL and OIG, shall act in accordance with FAR 3.807.

## Subpart 1403.10—Contractor Code of Business Ethics and Conduct

### 1403.1004 Contract clause.

(a) In all awards expected to exceed $3,000,000, including options, for which performance is expected to exceed 120 days, except purchases conducted in accordance with FAR Part 12 and contracts to be performed entirely outside the United States, replace "$5,000,000" with "$3,000,000" in paragraph (d) of FAR 52.203–14.

(b) Insert the following into paragraph (b)(3) of the same clause: "Downloadable hotline posters as well as instructions for obtaining a hard copy poster are available at *http://www.doioig.gov/hotline*."

# PART 1404—ADMINISTRATIVE MATTERS

## Subpart 1404.4—Safeguarding Classified Information within Industry

Sec.
1404.402 General.
1404.403 Responsibilities of contracting officers.

## Subpart 1404.7—Contractor Records Retention

1404.702 Applicability.

## Subpart 1404.8—Contract Files

1404.802 Contract files.
1404.804 Closeout of contract files.
1404.804–70 Release of claims.
1404.805 Disposal of contract files.

## Subpart 1404.70—Deposit of Contract Publications

1404.7001 General.
1404.7002 Policy.
1404.7003 Exceptions.
1404.7004 Procedures.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1404.4—Safeguarding Classified Information Within Industry

### 1404.402 General.

(a) The DOI has entered into an agreement with the DOD to be covered by the National Industrial Security Program (NISP). The agreement is contained in 443 DM 1, Appendix 1.

(b) Classified acquisitions or contracts (see FAR 4.401) shall be subject to the instructions contained in the DOD publications listed in FAR 4.402(b).

### 1404.403 Responsibilities of contracting officers.

(a) For proposed solicitations that may require access to Departmental classified information, the CO shall consult with the Office of Managing Risk and Public Safety for guidance on NISP in accordance with 443 DM 1.

(b) For proposed contracts where the contractor provides service for the handling and transmission of registered or certified mail at activities that customarily receive and transmit classified information (see FAR 4.401), the contractor shall be cleared to the degree of SECRET. This clearance shall be obtained through the Office of Managing Risk and Public Safety in accordance with 442 DM 8.

(c) For proposed contracts where guard services are assigned to safeguard Department activities in possession of classified information (see FAR 4.401), review and approval shall be obtained from the Office of Managing Risk and Public Safety in accordance with 442 DM 8.

## Subpart 1404.7—Contractor Records Retention

### 1404.702 Applicability.

In addition to the clauses listed at FAR 4.702, the policies and procedures at FAR 4.7 shall also apply to records generated under contracts containing the clause at 1452.215–70, Examination of Records by the Department of the Interior.

## Subpart 1404.8—Contract Files

### 1404.802 Contract files.

In addition to the requirements in FAR 4.802, files shall also be maintained in accordance with the provisions of 380 DM 3.

### 1404.804 Closeout of contract files.

### 1404.804–70 Release of claims.

(a) The CO shall insert the clause at 1452.204–70, Release of Claims, in all construction, architect and engineering, and cost-reimbursement contracts that exceed the SAT. The Release of Claims

clause may be inserted in other types of contracts when the CO determines that the release is necessary to protect the interests of the Government.

(b) Form DI–137, Release of Claims, shall be used to obtain a release of claims.

#### 1404.805 Disposal of contract files.

Disposition of files shall be accomplished in accordance with 384 DM.

### Subpart 1404.70—Deposit of Contract Publications

#### 1404.7001 General.

The DOI Departmental Library is responsible for maintaining a complete collection of Departmental publications. As used in this Subpart, the term "Departmental publication" means any publication or report produced under a DOI contract or Interagency agreement.

#### 1404.7002 Policy.

The CO shall direct the contractor, in the technical instructions, to acknowledge Federal sponsorship in the final report or publication by placing the following statement on the title page:

"This publication was funded by U.S. Department of the Interior, (Name of Bureau/Office), Washington, DC, under contract number_____."

#### 1404.7003 Exceptions.

The following types of publications are excluded from the requirements of this Subpart:

(a) Internal documents required for administrative or operational purposes that have no public interest, educational, scientific, or research value;

(b) Classified publications and material otherwise marked prohibiting unauthorized disclosure;

(c) Tentative drafts such as preliminary planning reports that will appear later in revised or final form;

(d) Journal and magazine articles; or

(e) Disclosure materials containing any description, specification, data, plan, or drawing of any unpatented invention upon which a patent application is likely to be filed, unless an opinion by the SOL, or his/her duly authorized designee, has been rendered which finds that the interests of the Government will not be prejudiced by disclosure of such materials.

#### 1404.7004 Procedures.

(a) The CO shall direct the contractor, in the technical instructions, to provide two copies of each publication or report produced under a contract to: U.S. Department of the Interior, Departmental Library, 1849 C Street, NW., MS–2258, Main Interior Bldg., Washington, DC 20240.

(b) A transmittal letter shall accompany the copies and identify the sender and the publication(s). The bibliographic information required by 481 DM 1.3B(4) shall be also included with the submission of all translations.

## SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

## PART 1405—PUBLICIZING CONTRACT ACTIONS

### Subpart 1405.2—Synopses of Proposed Contract Actions

Sec.

1405.202 Exceptions.
1405.207 Preparation and transmittal of synopses.

### Subpart 1405.3—Synopses of Contract Awards

1405.303 Announcement of contract awards.

### Subpart 1405.4—Release of Information

1405.403 Requests from members of Congress.
1405.404 Release of long-range acquisition estimates.
1405.404–1 Release procedures.

### Subpart 1405.5—Paid Advertisements

1405.502 Authority.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1405.2—Synopses of Proposed Contract Actions

#### 1405.202 Exceptions.

The AS/PMB is authorized to approve the written determination documenting the reasons why a synopsis is not appropriate or reasonable. The CO shall prepare the determination, submit it to the HCA and then to the Director, PAM, for AS/PMB approval.

#### 1405.207 Preparation and transmittal of synopses.

In addition to the synopsis information generally required under FAR 5.207, as a best business practice, it is recommended each synopsis of a proposed contract action under other than full and open competition include the location where the offeror may obtain:

(a) A description of specific qualifications the Government requires of the product or service to meet the Government's minimum needs; and

(b) The factors the Government will use to evaluate the product or service information prospective contractors provide under the proposed contract action.

### Subpart 1405.3—Synopses of Contract Awards

#### 1405.303 Announcement of contract awards.

(a) The CO shall report the following information to the cognizant bureau congressional affairs officer for notification to Congress 24 hours prior to the award of a contract expecting to exceed $500,000:

(1) Proposed award date;

(2) Contractor name and address;

(3) Geographical location of contract performance;

(4) Description of the contracted work;

(5) Dollar amount of contract; and

(6) Contractor business size and whether the firm is minority-owned or is a disadvantaged business concern.

(b) With the concurrence of the Office of Congressional and Legislative Affairs, the HCA may waive the announcement of sensitive awards.

### Subpart 1405.4—Release of Information

#### 1405.403 Requests from Members of Congress.

For purposes of this subpart, the agency head is the HCA with the power of redelegation to the BPC.

#### 1405.404 Release of long-range acquisition estimates.

#### 1405.404–1 Release procedures.

(a) The authority to release acquisition requirements anticipated in the coming year is delegated to the OSDBU and the HCA with redelegation limited to the BPC. The Government cost estimate shall not be revealed. The expected dollar values shall be advertised as falling within dollar ranges rather than specific dollar amounts.

(b) Classified information shall only be released in accordance with the procedures in 442 DM.

### Subpart 1405.5—Paid Advertisements

#### 1405.502 Authority.

(a) The CO shall obtain written authorization of the HCA before placing an advertisement in a newspaper to advertise a contracting opportunity.

(b) Advertisements placed in media other than newspapers do not require advance authorization.

## PART 1406—COMPETITION REQUIREMENTS

### Subpart 1406.2—Full and Open Competition After Exclusion of Sources

Sec.

1406.202 Establishing or maintaining alternate sources.

**Subpart 1406.3—Other Than Full and Open Competition**

1406.302 Circumstances permitting other than full and open competition.
1406.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.
1406.302–7 Public interest.
1406.303 Justifications.
1406.303–70 Additional requirements.
1406.304 Approval of the justification.

**Subpart 1406.5—Competition Advocates**

1406.501 Requirement.
1406.502 Duties and responsibilities.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1406.2—Full and Open Competition After Exclusion of Sources

### 1406.202 Establishing or maintaining alternative sources.

HCAs are authorized to approve the determinations and findings (D&Fs) to establish or maintain an alternative source or sources for supplies or services.

## Subpart 1406.3—Other Than Full and Open Competition

### 1406.302 Circumstances permitting other than full and open competition.

### 1406.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.

For contracts that will be awarded using this authority, the notices required by FAR 5.201 shall have been published and any bids, proposals, quotations, or capability statements must have been considered.

### 1406.302–7 Public interest.

The CO shall prepare the D&F and complete the justification to support use of public interest authority for other than full and open competition and submit it through the HCA to the Director, PAM, for further action.

### 1406.303 Justifications.

### 1406.303–70 Additional requirements.

(a) If other than full and open competition is recommended by the office initiating an acquisition requirement, the recommendation shall:

(1) Be in writing;

(2) Accompany the requisition;

(3) Contain the information required by FAR 6.303–2; and

(4) Request the CO to conduct a market survey by issuing a synopsis of the proposed contract action (see 1405.207). The initiating office shall evaluate and document all responses to the notice. The CO shall prepare the D&F that only one source can meet the Government's needs based on the evaluation results. The evaluation results shall be included in the justification as required by FAR 6.303–2(a)(8) if it is determined that only one source can meet the Government's needs.

(b) The procedure in paragraph (a) of this section is not required for proposed contract actions to be awarded under the authority in FAR 6.302–2 when the CO determines that preparation and approval of the justification would unreasonably delay the acquisition. Under these circumstances, a justification may be prepared and approved after award in accordance with FAR 6.303–1(d).

### 1406.304 Approval of the justification.

A class justification shall be approved in accordance with bureau procedures. Copies of approved class justifications shall be promptly transmitted to PAM.

## Subpart 1406.5—Competition Advocates

### 1406.501 Requirement.

(a) The competition advocate for DOI is located within PAM's staff. Applicable correspondence should be addressed to PAM, Attention: Competition Advocate.

(b) Competition Advocates for each bureau and office shall be as designated by the CAO–AS/PMB.

### 1406.502 Duties and responsibilities.

PAM is responsible for preparing and submitting the annual report required by FAR 6.502(b)(2). Bureau Competition Advocates shall furnish certain information, as may be required, to assist PAM in preparing the report.

# PART 1407—ACQUISITION PLANNING

**Subpart 1407.1—Acquisition Plans**

1407.102 Policy.

**Subpart 1407.3—Contractor Versus Government Performance**

1407.301 Policy.
1407.307 Appeals.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1407.1—Acquisition Plans

### 1407.102 Policy.

DOI has implemented its acquisition planning system in 404 DM. This system meets the criteria prescribed in FAR Subpart 7.1, 375 DM, OCIO Program Management, and 376 DM, Automated Data Processing. Each of these addresses strategic planning for OCIO and planning for acquisition of federal information processing resources.

## Subpart 1407.3—Contractor Versus Government Performance

### 1407.301 Policy.

404 DM, Procurement Planning, addresses the requirements of OMB Circular A–76.

### 1407.307 Appeals.

Department appeal procedures required by OMB Circular A–76 are codified in 43 CFR Part 4, Subpart M.

# PART 1408—REQUIRED SOURCES OF SUPPLIES AND SERVICES

**Subpart 1408.1—Excess Personal Property**

Sec.
1408.102 Policy.

**Subpart 1408.8—Acquisition of Printing and Related Supplies**

1408.802 Policy.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1408.1—Excess Personal Property

### 1408.102 Policy.

Inquiries on available excess or surplus personal property should be directed to the PMO or the designee in each Bureau or Office.

## Subpart 1408.8—Acquisition of Printing and Related Supplies

### 1408.802 Policy.

(a) *Duplicating* is the mass reproduction of materials beyond the capabilities of typical office copiers. Volumes are of sufficient mass quantities up to 5,000 single-page and 25,000 production units in the aggregate of multiple pages. Such duplicating units shall require Departmental approval to be processed through the Department of the Interior Publishing Council (DOIPC).

(b) *Copying* is distinguished from "duplicating" in that such work is administrative in nature, produced on office copying equipment and produced as necessary, in limited quantities. Volumes typically range from 1 to 500 single-pages to 2,500 production units in the aggregate of multiple pages. This volume standard is referred to as the "500/2500" rule. Reproduction work exceeding the "500/2500" rule is duplicating, and requires a waiver from the nearest servicing GPO office. Employees should consult with their bureau printing officer or the DOIPC representative to secure such a waiver.

(c) The DOIPC has been designated as the Department's liaison with the Joint Committee on Printing and GPO. Requirements for printing and related supplies shall be coordinated with the

DOIPC or the designated bureau publications liaison officer in accordance with 314 DM 1.

## PART 1409—CONTRACTOR QUALIFICATIONS

### Subpart 1409.2—Qualifications Requirements

Sec.
1409.202 Policy.
1409.206 Acquisitions subject to qualifications requirements.
1409.206–1 General.

### Subpart 1409.4—Debarment, Suspension and Ineligibility

1409.403 Definitions.
1409.404 Excluded Parties List System (EPLS).
1409.405 Effect of listing.
1409.405–1 Continuation of current contracts.
1409.406 Debarment.
1409.406–1 General.
1409.406–3 Procedures.
1409.407 Suspension.
1409.407–1 General.
1409.407–3 Procedures.

### Subpart 1409.5—Organizational and Consultant Conflicts of Interest

1409.503 Waiver.
1409.506 Procedures.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1409.2—Qualifications Requirements

### 1409.202 Policy.

(a) The HCA is the official responsible for establishing the qualification requirement in FAR 9.202(a)(1). This authority is not redelegable.

(b) The HCA is the approval official referenced in FAR 9.202(e).

### 1409.206 Acquisitions subject to qualification requirements.

### 1409.206–1 General.

The HCA is the approval official referenced in FAR 9.206–1(b).

## Subpart 1409.4—Debarment, Suspension, and Ineligibility

### 1409.403 Definitions.

As used in this subpart:

*Case Representative* refers to the individual who prepares and forwards the action referral memorandum to the Debarring and Suspending Official and provides additional assistance in the course of action resolution. Debarment and Suspension actions may be referred to the Debarring and Suspending Official for consideration from different sources, as appropriate. The HCA, or designee, may refer matters. The Office of Inspector General (OIG) may also refer actions.

*Conviction,* for the purposes of this subpart, means:

(a) A judgment or any other determination of guilt of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or plea, including a plea of nolo contendere; or,

(b) Any other resolution that is the functional equivalent of a judgment, including probation before judgment and deferred prosecution. A disposition without the participation of the court is the functional equivalent of a judgment only if it includes an admission of guilt.

*Debarring Official* refers to the Director, PAM. The Debarring Official is the official authorized to impose debarment or suspension. The Debarring Official also may settle a debarment or suspension action at any time if it is in the best interest of the Government.

*Suspending Official* refers to the Director, PAM.

### 1409.404 Excluded Parties List System (EPLS).

(a) PAM is responsible for accomplishing the actions required in FAR 9.404(c).

(b) COs should access the EPLS online at *http://www.epls.gov.*

### 1409.405 Effect of listing.

When a CO finds that a compelling reason exists to conduct business with a contractor listed on the EPLS, the HCA shall submit the determination and findings to the Director, PAM, for approval.

### 1409.405–1 Continuation of current contracts.

The HCA, without authority to redelegate, is authorized to take the actions listed in FAR 9.405–1.

### 1409.406 Debarment.

### 1409.406–1 General.

The Director, PAM, is authorized to make the statement regarding debarment by another agency's debarring official under the conditions in FAR 9.406–1(c).

### 1409.406–3 Procedures.

(a) *Investigation and referral.* Whenever a cause for debarment, as listed in FAR 9.406–2. becomes known to a DOI employee, the matter shall be referred by the case representative to the Debarring Official, in consultation, as appropriate, with the HCA involved, the SOL, and OIG. The case representative will review the matter and, as warranted, prepare and submit to the Debarring Official for consideration an Action Referral Memorandum (ARM) with supporting documentation.

(b) *Notice of Proposed Debarment.* Based upon review of the ARM, as appropriate, the Debarring Official shall initiate proposed debarment by taking the actions listed in FAR 9.406–3(c) and advising the contractor of DOI's process for contesting the action.

(c) *Decision-making process.*

(1) For debarment actions based upon a conviction, civil judgment, or in which there is no genuine dispute over material facts, consistent with FAR 9.406–3(d)(1), the Debarring Official shall make a decision on the basis of the information in the administrative record, including any contractor submissions. Where the proceeding includes an oral presentation of matters in opposition (PMIO) to the Debarring Official, the PMIO will be conducted in an informal business meeting format and tape recorded for the administrative record.

(2) For actions listed under FAR 9.406–3(b)(2), upon concluding from a contractor's information in response to the action notice that facts material to the existence of cause for debarment are genuinely in dispute, the Debarring Official may refer the disputed material facts to another official for fact-finding. The hearing shall be conducted in accordance with Debarment Program fact-finding procedures.

(i) The fact-finding proceeding will be transcribed. The fact-finding official will file the original copy of the transcript with the case record. The reporter's fees and other direct costs associated with the hearing shall be borne by the bureau or office initiating the debarment action, except in the case of actions initiated by the OIG. For actions initiated by the OIG, the costs will be borne by the bureau(s) and/or office(s) out of which the matter arose. A transcript of the proceedings shall be made available to the contractor as provided under FAR 9.406–3(b)(2)(ii).

(ii) Subject to the provisions of 43 CFR Part 1, the contractor, and any specifically named affiliate, may be represented by counsel or any duly authorized representative. Witnesses may be called by either party. The proceedings shall be conducted expeditiously and in such a manner that each party will have a full opportunity to present all information considered pertinent to the proposed debarment. A transcript of the proceedings shall be made available to the contractor under the condition in FAR 9.406–3(b)(2)(ii).

(iii) The fact-finding official will prepare findings of fact, certify the entire hearing record and provide said findings and record to the Debarring Official. The fact-finding official shall not make any recommendations unless the Debarring Official has expressly requested such recommendations in

writing. Following receipt of the findings of fact, the Debarring Official shall complete debarment proceedings and issue a written debarment decision.

(d) *Administrative Agreements.* Matters may be resolved through administrative agreement at any stage of proceedings of a debarment action where a contractor agrees to appropriate terms. The specific effect of administrative agreements that incorporate terms regarding eligibility for DOI contracting will vary with the terms of the agreements. In general, such agreements resolve debarment concerns and thereby terminate any imposed or pending award ineligibility. In the event of an agreement, PAM will notify COs of the agreement and its terms.

(e) *Administrative Appeal.* Administrative review of the Debarring Official's decision under FAR 9.406–3(e) may be sought as follows:

(1) The contractor may within thirty (30) days of receipt of the decision, request the Debarring Official to reconsider the decision for clear material errors of fact or law which would change the outcome of the matter.

(2) The Debarring Official may exercise his/her discretion and stay the debarment pending reconsideration review. The Debarring Official will notify the contractor in writing of the decision on reconsideration.

(3) A review request under this section must be in writing, clearly state the specific findings believed to be in error and include the reasons or legal bases for the position.

#### 1409.407 Suspension.

#### 1409.407–1 General.

The Director, PAM, is authorized to make the determination in FAR 9.407–1(d).

#### 1409.407–3 Procedures.

(a) *Investigation and referral.* Whenever a cause for suspension, as listed in FAR 9.407–2, becomes known to a DOI employee, the matter shall be referred by the case representative to the Suspending Official, in consultation, as appropriate, with the HCA involved, the SOL, and the OIG. The case representative will review the matter and, if warranted, prepare and submit to the Debarring Official for consideration an Action Referral Memorandum (ARM) with supporting documentation.

(b) *Notice of Suspension.* After review of the ARM, if appropriate, the Debarring Official shall initiate a suspension by taking the actions listed in FAR 9.407–3(c), and advising the contractor of the Department's process for contesting the action.

(c) *Decision making process.*

(1) For suspension actions based upon an indictment or equivalent charging document, or where there is no genuine dispute over material facts, consistent with FAR 9.407–3(d), or in which additional proceedings to determine disputed material facts have been denied on the basis of DOJ advice, the Suspending Official shall make a decision on the basis of the information in the administrative record, including any submission by the contractor. Where the proceeding includes an oral PMIO to the Suspending Official, the PMIO will be conducted in an informal business meeting format and tape recorded for the administrative record.

(2) For actions listed under FAR 9.407–3(b)(2), when the Debarring Official concludes from information in a contractor's response to the proposed action notice that facts material to the existence of a cause for debarment are genuinely in dispute, the Suspending Official may refer the disputed material facts to another official for hearing and findings of fact.

(i) The hearing shall be conducted in accordance with Suspension Program fact-finding procedures.

(ii) The fact-finding proceeding will be transcribed. The reporter's fees and other direct costs associated with the hearing shall be borne by the bureau or office initiating the suspension referral, except in the case of actions initiated by the OIG. For actions initiated by the OIG, costs will be borne by Bureaus and/or offices out of which the matter arose. A transcript of the proceedings shall be made available to the contractor under the condition in FAR 9.407–3(b)(2)(ii).

(iii) Subject to the provisions of 43 CFR Part 1, the contractor, and any specifically named affiliates, may be represented by counsel or any duly authorized representative. Witnesses may be called by either party. The proceedings shall be conducted expeditiously and in such a manner that each party will have a full opportunity to present all information considered pertinent to the suspension.

(iv) The fact-finding official will prepare findings of fact, certify the entire hearing record and provide said findings and record to the Suspending Official. The fact-finding official shall not make any recommendations unless the Suspending Official has expressly requested such recommendations in writing. Following receipt of the findings of fact, the Suspending Official shall complete suspension proceedings and issue a written decision. Matters may be resolved through an administrative agreement at any stage of the proceedings.

(d) *Administrative Agreements.* Matters may be resolved through an administrative agreement at any stage of proceedings in resolution of a suspension action where a contractor agrees to appropriate terms. The specific effect of administrative agreements that incorporate terms regarding eligibility for DOI contracting will vary with the terms of the agreements. In general, such agreements resolve suspension concerns and thereby terminate award ineligibility. An administrative agreement resolving a suspension action may by its terms be an interim agreement. In the event of an agreement, PAM will notify COs of the agreement and its terms.

(e) *Administrative Appeal.* Administrative review of the Suspending Official's decision under FAR 9.407–3(d) may be sought as follows:

(1) The contractor may within thirty (30) days of receipt of the decision, ask the Suspending Official to reconsider the decision for clear material errors of fact or law which would change the outcome of the matter.

(2) The Suspending Official may in the exercise of discretion stay the debarment pending reconsideration review. The Suspending Official will notify the contractor in writing of the decision on reconsideration.

(3) A review request under this section must be submitted in writing; clearly state the specific findings believed to be in error, and include the reasons or legal bases for the position.

### Subpart 1409.5—Organizational and Consultant Conflicts of Interest

#### 1409.503 Waiver.

(a) The Director, PAM, is authorized to waive any general rule or procedure in FAR Subpart 9.5, when such action is in the Government's interest.

(b) Request for waivers shall be made by the HCA, through the appropriate SOL, to the Director, PAM. Each request shall include:

(1) An analysis of the facts involving the potential or actual conflict, including benefits and detriments to the Government and prospective contractor(s);

(2) A discussion of the factors which preclude avoiding, neutralizing or mitigating the conflict; and

(3) Identification of the provision(s) in FAR Subpart 9.5 to be waived.

#### 1409.506 Procedures.

If the CO determines that contractor performance of the contemplated work

is likely to create an organizational conflict of interest, then the contracting officer shall refer the documentation of the potential conflict and proposed resolution prepared in accordance with 7.105(b)(18) to the HCA for approval. Referrals to the HCA shall be initiated by the CO and reviewed by the SOL.

## PARTS 1410–1412—[RESERVED]

### SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

## PART 1413—SIMPLIFIED ACQUISITION PROCEDURES

### Subpart 1413.2—Micro-Purchase

Sec.
1413.201 General.
1413.202–70 Policy.

### Subpart 1413.3—Simplified Acquisition Methods

1413.305 Imprest Fund.
1413.305–2 Agency responsibilities.
1413.305–4 Procedures.
1413.306 Standard Form 44, Purchase order—invoice—voucher.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1413.2—Micro-Purchase

#### 1413.201 General.

The procedures set forth in the Federal Supply Schedule for Government-wide Commercial Credit Card Services, Treasury Financial Manual, TFM 4–4500, and "U.S. Department of Interior Handbook for Utilization of Government Wide Commercial Credit Card" issued by PAM contain guidance on using Government-wide purchase card services.

#### 1413.202–70 Policy.

(a) The purchase card shall be used in preference to other methods of procurement for purchases up to $3,000. Other small purchase methods (BPAs, imprest funds, third-party drafts, SF–44 forms, and purchase orders) may be used in lieu of the Government purchase card when it is more cost-effective or practicable.

(b) The purchase card shall be issued primarily to personnel outside of procurement offices to purchase products and services up to the micro-purchase threshold ($2,000 for construction).

(c) The purchase card may be used in procurement offices for purchases up to the simplified acquisition threshold ($50,000 if not interim FACNET certified) not to exceed individual warrant limitations.

(d) Each contracting activity shall develop more specific procedures for use of purchase cards.

### Subpart 1413.3—Simplified Acquisition Methods

#### 1413.305 Imprest fund.

#### 1413.305–2 Agency responsibilities.

Policy governing the use and administration of imprest funds within the Department are contained in 330 DM, in addition to the policies and regulations outlined in FAR 13.305–1. HCAs shall establish written procedures for designation, by name, of personnel authorized to approve requisitions and make purchases using imprest funds. The procedures shall include a periodic review of imprest fund transactions by acquisition personnel.

#### 1413.305–4 Procedures.

The individual authorized to make purchases using imprest funds shall be responsible for compliance with the procedures and documentation requirements of FAR 13.305–4.

#### 1413.306 Standard Form 44, Purchase order-invoice-voucher.

HCAs are responsible for establishing bureau procedures to control the use of the SF 44 and accounting for all purchases made using the form. Bureau procedures shall include instructions covering:

(a) Maintenance of a list of designated individuals authorized to make purchases using the form;

(b) Controls for issuing the form to authorized individuals; and

(c) Review of purchase transactions using the form to assure compliance with authorized procedures.

## PART 1414—SEALED BIDDING

Sec.

### Subpart 1414.2—Solicitation of Bids

1414.201 Preparation of invitations for bids.
1414.201–70 Alternate bids.

### Subpart 1414.4—Opening of Bids and Award of Contract

1414.404 Rejection of bids.
1414.404–1 Cancellation of invitations after opening.
1414.407 Mistakes in bids.
1414.407–3 Other mistakes disclosed before award.
1414.407–4 Mistakes after award.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1414.2—Solicitation of Bids

#### 1414.201 Preparation of invitation for bids.

#### 1414.201–70 Alternate bids.

(a) Solicitations for supplies or services (other than construction) shall specify whether alternate bids are permitted, provide instructions for submitting alternate bids and clearly indicate how alternate bids will be evaluated.

(b) The clause set forth in 1452.236–71 may be used in non-construction contracts where additive and deductive alternate bids will be permitted.

### Subpart 1414.4—Opening of Bids and Award of Contract

#### 1414.404 Rejection of bids.

#### 1414.404–1 Cancellation of invitations after opening.

The CCO is authorized to make the written determination to cancel the IFB before award but after bid opening.

#### 1414.407 Mistakes in bids.

#### 1414.407–3 Other mistakes disclosed before award.

(a) The HCA is authorized to make the administrative determinations under FAR 14.407–3, except as set forth in paragraph (b) of this section. This authority is not redelegable.

(b) The CCO has the authority outlined in FAR 14.407–3(c) to make the written determination permitting a bidder to withdraw a bid, after review by the SOL.

(c) The CO shall submit a report on suspected or alleged mistakes in bids together with the supporting data to the BPC, who will forward it to the HCA. The CO may also include a report on bids where evidence of the intended bid is clear and convincing but the bidder has not requested permission to correct the bid. Incomplete reports may result in a delay in obtaining a determination.

(d) The BPC is responsible for maintaining records of administrative determinations.

#### 1414.407–4 Mistakes after award.

The CO is authorized to make the administrative determinations outlined in 14.407–4 after receiving concurrence from the SOL.

## PART 1415—CONTRACTING BY NEGOTIATION

### Subpart 1415.2—Solicitation and Receipt of Proposals and Information

Sec.
1415.201 Exchanges with industry before receipt of proposals.
1415.207 Handling proposals and information.

1415.207–70 Department of the Interior proposal and information handling procedures.
1415.207–71 Confidentiality of proposal evaluation.
1415.209 Solicitation provisions and contract clauses.
1415.209–70 Examination of records by the Department of the Interior.

**Subpart 1415.3—Source Selection**

1415.303 Responsibilities.
1415.305 Proposal evaluation.

**Subpart 1415.4—Contract Pricing**

1415.404 Proposal analysis.
1415.404–2 Information to support proposal analysis.
1415.404–4 Profit.
1415.406 Documentation.
1415.406–70 Department of the Interior price negotiation memorandum (PNM).

**Subpart 1415.6—Unsolicited Proposals**

1415.606 Agency procedures.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1415.2—Solicitation and Receipt of Proposals and Information

### 1415.201 Exchanges with industry before receipt of proposals.

(a) Use of a presolicitation conference shall be approved at one level above the CO.

(b) A CO may issue a solicitation for information or planning purposes without a written justification and without obtaining a higher level of approval.

### 1415.207 Handling proposals and information.

### 1415.207–70 Department of the Interior proposal and information handling procedures.

(a) *General.* This section establishes procedures that must be used in addition to those prescribed in FAR 15.207, for the use and disclosure of trade secret information and confidential commercial and financial information contained in solicited proposals.

(b) *Marking of solicited proposals.* A solicited proposal may contain trade secrets or confidential commercial or financial information which the offeror, or its subcontractors, prefers not to be disclosed to the public or used by the Government for any purpose other than evaluation of the proposal. To notify the Government of trade secrets and confidential commercial or financial information contained in a proposal, offerors must mark the cover page of the proposal and each affected page of the proposal with the legends specified in the solicitation provision at 1452.215–71, Use and Disclosure of Proposal Information—Department of the Interior. COs and other government personnel evaluating a proposal shall not refuse to consider the proposal because it contains information identified as trade secret information or confidential commercial or financial information.

(c) *Failure to mark.* The Government assumes no liability for the disclosure or use of information contained in a proposal if not marked in accordance with 1452.215–71. If a request under the Freedom of Information Act is made for information in a proposal not marked in accordance with 1452.215–71, the offeror concerned shall be notified promptly of the request and given an opportunity to provide its position to the Government. However, failure of an offeror to mark information contained in a proposal as trade secret information or confidential commercial and financial information will be treated by the Government as evidence that the information is not exempt from disclosure under the Freedom of Information Act, absent a showing that the failure to mark was due to unusual or extenuating circumstances, such as a showing that the offeror had intended to mark, but that markings were omitted from the offeror's proposal due to clerical error.

(d) *Solicitation provision.* The provision at 1452.215–71, Use and Disclosure of Proposal Information—Department of the Interior, shall be inserted in all requests for proposals and requests for quotations.

### 1415.207–71 Confidentiality of proposal evaluation.

(a) The safeguarding of evaluation data and information, including proposals, is essential in order to preserve the integrity of the proposal evaluation process. During the selection process, no member or advisor of any committee appointed to evaluate proposals shall discuss or disclose any information on the number, identity or content of proposals received to any other party (including supervisors) without the written approval of the CO. 18 U.S.C. 1905 prohibits the unauthorized disclosure of business, confidential or trade secret information unless authorized by law.

(b) At the initial meeting of the committee, the CO shall brief all members and advisors on the sensitivity of the evaluation process and the prohibition against unauthorized disclosure of information. At this meeting each member and advisor shall sign a Confidentiality Certificate. During the proposal evaluation process, all proposals, evaluation notes, scoring sheets, and other materials shall be locked in file cabinets or drawers when not in use by committee members and advisors.

(c) The CO shall be the single point of contact regarding communications received from outside parties relating to the acquisition and the evaluation and selection process. Any committee member or advisor who receives a communication from any outside party shall, without discussion, immediately refer the party to the CO. The CO will then determine what further action shall be taken, if any, in responding to the communication. Requests for information made pursuant to the Freedom of Information Act shall be referred to the CO for reply. Proposal evaluation committee members and advisors shall not contact any offeror whose proposal is under evaluation. All communications with offerors shall be handled by the CO.

(d) Bureaus and offices may only release proposals outside the Government for evaluation or advice in accordance with the following requirements:

(1) Decisions to release proposals outside the Government for evaluation or advice shall be approved in writing by the HCA;

(2) Outside evaluators and advisors shall sign a Conflict of Interest Certificate and a Confidentiality Certificate in a format approved by the HCA;

(3) Any authorized restrictive legends placed on the proposal by the prospective contractor or subcontractor, or by the Government shall be applied to any reproduction or abstracted information made by the outside evaluator or advisor;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government shall take into consideration requirements for avoiding individual conflicts of interest (see 1403.101) and organizational conflicts of interest (see 1409.5 and FAR Subpart 9.5), and the competitive relationship, if any, between the prospective contractor or subcontractor and the prospective outside evaluator.

(e) If outside individuals will be voting members of the evaluation committee or otherwise participate in other than an advisory capacity, then the committee must be constituted as a Federal Advisory Committee in accordance with the Federal Advisory Committee Act (PL 92–463) and 308 DM 2. Since the Secretary must appoint such committees in consultation with

the Office of Management and Budget, there should be very few occasions when use of outside individuals as voting members is justified.

(f) Outside evaluators will usually serve as advisors to the proposal evaluation committee and as such, are consultants. Consultants may be appointed as special employees in accordance with 5 U.S.C. 3109 or contracted for in accordance with 1437.1.

(g) Additional restrictions on the disclosure of acquisition evaluation information are listed in FAR Subpart 5.4.

#### 1415.209 Solicitation provisions and contract clauses.

#### 1414.209–70 Examination of records by the Department of the Interior.

The CO shall insert the clause at 1452.215–70, Examination of Records by the Department of the Interior, in all contracts requiring the clause at FAR 52.215–2 Audit and Records, Negotiation, as prescribed in FAR 15.209(b).

### Subpart 1415.3—Source Selection

#### 1415.303 Responsibilities.

(a) The HCA shall determine when a formal source selection process will be used and shall establish implementing procedures.

(b) The formal source selection procedures shall include designating the CO as the individual responsible for the proper control and appropriate release of proprietary and source selection information after source selection.

#### 1415.305 Proposal evaluation.

The CCO is authorized to make the determination to reject all proposals.

### Subpart 1415.4—Contract Pricing

#### 1415.404 Proposal analysis.

#### 1415.404–2 Information to support proposal analysis.

The CO shall initiate an audit by sending a completed form DI–1902, Request for Audit, to the Assistant Inspector General for Auditing, OIG (see 1453.215–70).

(a) The CO shall allow at least 30 working days in assigning a realistic deadline for receipt of the audit report. In exceptional circumstances 20 working days may be allowed but the circumstances shall be documented in the contract file.

(b) Upon receipt of a DI–1902, the OIG will conduct the audit or arrange for its conduct by the cognizant audit agency in accordance with 360 DM 3.7.

(c) Upon receipt of the audit report, the CO and the price analyst (if assigned), shall discuss any questions regarding the report's contents with the cognizant auditor. If a question cannot be resolved or agreement cannot be reached on a recommendation in the report, the CO shall prepare a written statement for the contract file documenting the decision on the matter. A copy of the statement shall be promptly forwarded to the Assistant Inspector General for Auditing for information.

#### 1415.404–4 Profit.

(a) DOI's policy is to use a structured approach for determining the profit or fee prenegotiation objective in acquisition actions that require cost analysis based on the profit analysis factors in FAR 15.905, as implemented and supplemented in this section.

(b) In addition to the factors listed in FAR 15.404–4(d), one additional factor, "Other Costs," will be used in evaluating and determining a weighted profit or fee. For further guidance also refer to the Armed Services Pricing Manual (ASPM No. 1). The "Other Costs" factor shall include the contribution of all other direct costs including travel, direct support and hiring of consultants for contract performance.

(c) Form DI–1920, Structured Approach for Profit/Fee Objective—Department of the Interior shall be used to calculate the profit or fee objective.

#### 1415.406 Documentation.

#### 1415.406–70 Department of the Interior price negotiation memorandum (PNM).

(a) *Policy.* In addition to the information required in FAR 15.406–3, the PNM prepared by the CO shall include the information in paragraph (c) of this section to the extent such information is applicable to the negotiation.

(b) *Applicability.* (1) The CO shall prepare a PNM documenting the negotiation of the initial contract award and any subsequent modifications affecting price, cost or fee, including revisions to the prices of contracts awarded through sealed bidding procedures. A PNM is not required for unilateral modifications such as exercising fixed price options or issuing change orders. The memorandum is required for concluding changes and settlements of claims and for issuing orders under Blanket Ordering Agreements, task orders and delivery orders that involve the negotiation of prices, estimated quantities or amounts.

(2) For simplified acquisitions conducted pursuant to FAR Part 13, the documentation requirements of 1413.106 and FAR 13.106 shall be followed.

(c) *Procedures.* When the CO prepares the memorandum prescribed in FAR 15.406–3, the following additional information shall be included to the extent it applies to the contract action. Information already contained in the contract file or in a previous PNM shall be referenced by location:

(1) A discussion of the reason(s) why sealed bidding is not appropriate as required by FAR 6.401 (or cross-reference the file location of the existing explanation);

(2) A memorandum identifying the type of contract used and why it was selected as required by FAR 16.103(d). The file location of any required determination and findings authorizing use of this type of contract (see Part 1416);

(3) A history of the contract action including: Whether the action was synopsized or the basis for exemption under FAR 5.202, and file location of the synopsis; consideration given to the use of set-asides and file location of DI–1886 (see Subpart 1419.2); solicitation issuance date, closing date for receipt of proposals and extensions; (iv) sources solicited (reference file location); late proposal or proposal modification information required by FAR 15.208; and the file location of "Justification for Other Than Full and Open Competition," if applicable.

(4) Evaluation of proposal(s), including: Evaluation factors used and weights (FAR 15.304); results of initial proposal evaluation (FAR 15.305); determination of competitive range (FAR 15.306); results of written or oral discussions conducted (FAR 15.306); discussion of final proposal revisions received (FAR 15.307) and results of final proposal evaluation; and basis for source selection. For formal source selection procedures (see 1415.303), information on the source selection plan, and the source selection decision including supporting documentation required by FAR 15.308.

(5) If cost or pricing data were not required, the cost or price analysis performed in accordance with FAR 15.404–1.

(6) If cost or pricing data were required, the cost analysis (FAR 15.404–1(c)) performed; and cost realism analysis (FAR 15.404–1(d)) and technical analysis (FAR 15.404–1(e)) performed, as applicable to the procurement.

(7) If an audit report was required (FAR 15.404–2), COs shall specifically describe actions taken in response to significant audit findings, including the monetary value and decisions made

with regard to any of the audit's questioned costs; i.e., COs shall identify the value of the questioned costs, indicate whether they will allow or disallow them, and provide an explanation for their decisions. For purposes of this section, "significant audit finding" and "questioned cost" are defined as those findings and/or costs cited or questioned in an external audit because of their relationship to unallowable costs claimed, a failure to comply with regulations or the terms of the contract, mathematical errors, and/or the duplication of costs. Questions and/or disagreements between the CO, price analyst (if assigned) and cognizant auditor as to an audit report's interpretation or recommendations regarding "significant audit finding" and/or "questioned costs" shall be clarified or resolved and appropriately documented. If a disagreement cannot be resolved or agreement cannot be reached, the CO shall prepare a written statement in the PNM that discusses the issue(s) in question and supports a final decision on the matter.

(8) The basis for determining profit or fee as prescribed in FAR Subpart 15.404–4 and form DI–1920 (or file location).

(d) *Approval.* The PNM shall be signed and dated by the contract specialist or contract negotiator who conducted the negotiation and approved by the CO.

(e) *Distribution.* Whenever field pricing support has been obtained, copies of related PNMs shall be forwarded to the Assistant Inspector General for Auditing, OIG, not later than 15 days after the execution of the resulting contract, modification or close-out action.

## Subpart 1415.6—Unsolicited Proposals

### 1415.606 Agency procedures.

The contact point for the receipt and coordination of unsolicited proposals is the contracting office, which will acknowledge and review the proposal contents and determine the proper activity within the bureau/office to evaluate and process the proposal. The policy or contracting office shall acknowledge unsolicited proposals and forward each one to the processing activity in an expeditious manner. Each bureau/office shall establish procedures for receipt, reproduction and disposition of unsolicited proposals consistent with the requirements of FAR 15.6.

# PART 1416—TYPES OF CONTRACTS


**Subpart 1416.2—Fixed-Price Contracts**

Sec.
1416.203 Fixed-price contracts with economic price adjustment.
1416.203–4 Contract clauses.

**Subpart 1416.4—Incentive Contracts**

1416.405 Contract clauses.


**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1416.2—Fixed-Price Contracts

### 1416.203 Fixed-price contracts with economic price adjustment.

### 1416.203–4 Contract clauses.

An economic price adjustment clause based on actual cost of labor or material may be used after approval by the BPC, without the power of redelegation.

## Subpart 1416.4—Incentive Contracts

### 1416.405 Contract clauses.

The BPC, without the power of redelegation, is authorized to approve an award fee clause to use in a solicitation when a cost-plus-award-fee contract is contemplated.

# PART 1417—SPECIAL CONTRACTING METHODS


**Subpart 1417.2—Options**

Sec.
1417.203 Solicitations.
1417.206 Evaluation.

**Subpart 1417.4—Leader Company Contracting**

1417.402 Limitations.

**Subpart 1417.5—Interagency Acquisitions Under the Economy Act**

1417.502 General.

**Subpart 1417.6—Management and Operating Contracts**

1417.602 Policy.
1417.605 Award, renewal and extension.


**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1417.2—Options

### 1417.203 Solicitations.

Option quantities in excess of the 50 percent limit may, in unusual circumstances, be approved by the CCO.

### 1417.206 Evaluation.

The determination in FAR 17.206(b) shall be approved by the CCO prior to soliciting offers.

## Subpart 1417.4—Leader Company Contracting

### 1417.402 Limitations.

Use of leader company contracting for a product, subject to the limitations in FAR 17.402, shall require advance discussion with the Director, PAM, prior to approval by the HCA. This authority may not be redelegated. Documentation shall include the circumstances requiring such action.

## Subpart 1417.5—Interagency Acquisitions Under the Economy Act

### 1417.502 General.

(a) The HCA, with authority to redelegate to the BPC, is authorized to make the determination prescribed in FAR 17.503 in accordance with the requirements in FAR 17.502. The CO shall prepare the determination, and for actions exceeding $100,000, obtain legal review from the SOL before submitting it to the HCA for signature. Class determinations may be utilized where appropriate.

(b) Bureaus and offices shall develop procedures governing the use of interagency acquisitions under the Economy Act that are consistent with the FAR and this subpart 1417.5, and which adequately protect the Department's interests.

## Subpart 1417.6—Management and Operating Contracts

### 1417.602 Policy.

(a) The AS/PMB is authorized to approve the CO's determination to enter into, extend or renew any management and operating contract.

(b) The CO shall prepared requests for authorization to enter into, extend or renew any management and operating contract shall be prepared by the CO and submitted by the HCA through the Director, PAM for approval by the AS/PMB. The request shall be submitted prior to solicitation for the requirement and shall:

(1) Reference the statutory authority for the requirement;

(2) Discuss the relationship between the requirement and the limitations in FAR 17.603;

(3) Include a copy of the proposed contract schedule and evaluation factors for; and

(4) If a noncompetitive procurement is proposed, include a copy of the Justification for Other than Full and Open Competition.

(c) The HCA shall be responsible for conducting the reviews required by FAR 17.602(c) and taking required actions within the time limit prescribed.

(d) The CO shall request authorization under paragraph (a) of this section for solicitation of offers for cost comparison purposes under OMB Circular A–76 (see FAR 7.3) for:

(1) Operation, maintenance, or support of a Government-owned or

controlled special production or testing facility; or

(2) Any other commercial or industrial service activity which, if performed by a contractor, would result in a management and operating contract as defined under FAR Subpart 17.6.

#### 1417.605 Award, renewal and extension.

The CO shall review each management and operating contract prior to any extension or exercise of a renewal option. Any extension or renewal of a management and operating contract shall first be authorized as required in 1417.602.

## PART 1418—[RESERVED]

## SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

## PART 1419—SMALL BUSINESS PROGRAMS

### Subpart 1419.2—Policies

Sec.
1419.201 General policy.
1419.202 Specific policies.
1419.202–70 Acquisition screening and BUDS recommendations.

### Subpart 1419.5—Set-Asides for Small Business

1419.503 Setting aside a class of acquisitions for small business.
1419.503–70 Class set-aside for construction acquisitions.
1419.505 Rejecting Small Business Administration recommendations.
1419.506 Withdrawing or modifying small business set-asides.

### Subpart 1419.6—Certificates of Competency and Determinations of Responsibility

1419.602 Procedures.
1419.602–1 Referral.

### Subpart 1419.7—The Small Business Subcontracting Program

1419.705 Responsibilities of the contracting officer under the subcontracting assistance program.
1419.705–2 Determining the need for a subcontracting plan.
1419.705–3 Preparing the solicitation.
1419.705–6 Postaward responsibilities of the contracting officer.

### Subpart 1419.8—Contracting with the Small Business Administration (the 8(A) program)

1419.803 Selecting acquisitions for the 8(a) program.
1419.810 SBA Appeals.

### Subpart 1419.9—Contracting Opportunities for Women-Owned Small Businesses

1419.901 Policy.

### Subpart 1419.10—Small Business Competitiveness Demonstration Program

1419.1003 Purpose.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1419.2—Policies

#### 1419.201 General policy.

HCAs, without the power of redelegation, shall be responsible for the establishment of annual goals. The purpose of these goals is to increase participation of small business and small disadvantaged businesses in contract and subcontract opportunities. Goals for contract awards to minority business enterprises and women-owned businesses shall also be developed.

(a) All program goals must comply with the criteria established by OSDBU and shall reflect improvement in participation of small businesses and small disadvantaged businesses. The goal setting process shall be conducted as follows:

(1) Proposed goals are to be submitted by contracting activities to OSDBU by August 15th for the next fiscal year. To the greatest extent possible, the goals shall be based on advance acquisition plans (see Subpart 1407.1), budget justifications, and past performance.

(2) OSDBU shall be responsible for consolidating bureau and office goals, performing trend analysis, and submitting proposed Departmental goals to SBA, and the Minority Business Development Agency (MBDA), Department of Commerce.

(3) Bureau and office goals shall be negotiated and finalized with the OSDBU based on current plans and budget projections. OSDBU shall negotiate final Departmental goals with SBA, and MBDA.

(4) Since goals are expressed as a percentage of planned acquisition dollars, final budget approvals may change specific dollar goals.

(b) HCAs may request revision of goals from OSDBU when final budget approvals result in a change of plus or minus 15% in planned acquisition dollars or in instances when a disproportionate change in the mix of products or services is required. The goal setting process with the Bureau/Offices shall be completed by December 31st of each year.

(c) In accordance with 111 DM 8, OSDBU is responsible for performing all functions and duties prescribed in FAR 19.201(d) and for:

(1) Developing and maintaining policies, procedures, regulations, and guidelines for the effective administration of the Department's small business and small disadvantaged business programs; and,

(2) Providing functional direction and policy guidance to personnel in the implementation of the programs under paragraph (c)(1) of this section.

(d) HCAs without authority to redelegate shall:

(1) Appoint a full-time BUDS (*e.g.,* procurement analyst or other non-operational contract person), for each contracting office where:

(i) Annual contract obligations regularly exceed $20 million or represent a substantial part of the bureau's total contracting program; and,

(ii) The number, type, and size of contract transactions provide sufficient opportunities for small business and small disadvantaged business participation.

(2) Appoint a part-time BUDS (*e.g.,* procurement analyst or other non-operational contract person), for each contracting office where the nature of the contracting program requires such action to ensure accomplishment of annual program goals;

(e) Each BUDS shall perform the duties listed at FAR 19.201(d)(5)(6), and (10), 405 DM 1, and in the BUDS Standard Operating Procedures Handbook (405 DM 2).

#### 1419.202 Specific policies.

#### 1419.202–70 Acquisition screening and BUDS recommendations.

(a) For open market acquisitions estimated to exceed the SAT, the DI Form 1886, "Acquisition Screening and Review Form," shall be completed by the CO and signed as indicated in Block 20 of the form. The completed form shall be placed in the solicitation/contract file prior to requesting quotations, publication of a FedBizOpps solicitation notice, or publication of a notice of intent to award a sole source contract.

(b) For open market acquisitions estimated to be greater than the micro-purchase threshold and less than the SAT that are not reserved for small business or proceeding under the 8(a) program, the DI Form 1886 shall be completed as specified in paragraph (a) of this section.

(c) Open market acquisitions, including charge card transactions, estimated to be less than the micro-purchase threshold are not routinely screened, but may be upon request by the purchaser.

(d) For Federal Supply Schedule competitions estimated to exceed the SAT and for which the source list contains less than three small businesses, the DI Form 1886 shall be completed as specified in paragraph (a) of this section.

(e) Federal Supply Schedule buys below the SAT are not routinely screened, but may be upon request by the CO.

(f) If the proposed method of acquisition is non-competitive, the Justification for Other than Full and Open Competition shall be attached to the DI Form 1886.

(g) Advance acquisition plans developed pursuant to FAR Part 7 shall be attached to the DI Form 1886.

(h) The CO shall document the rationale for not accepting a BUDS recommendation on DI Form 1886, under "Notes." (See FAR 19.202.) Disagreements between the CO and the BUDS concerning the decision to use a set aside or the 8(a) program shall be resolved by the BPC. The BPC shall annotate the resolution, with signature, in the "Notes" section of the form. The BPC may consult with the OSDBU to obtain assistance in resolving the disagreement.

## Subpart 1419.5—Set-Asides for Small Business

### 1419.503 Setting aside a class of acquisitions.

### 1419.503–70 Class set-aside for construction acquisitions.

(a) Acquisitions for construction (as defined in FAR 2.101) estimated to cost $2 million or less shall be set-aside on a class basis for exclusive participation by small business concerns. This class set-aside does not apply when:

(1) The acquisition is procured using simplified acquisition procedures;

(2) Use of a set-aside is precluded by the Small Business Competitiveness Demonstration Program (SBCDP) (See FAR 19.10);

(3) A non-competitive acquisition has been approved under the procedures of FAR 6.3;

(4) Work is to be performed outside the U.S.; or

(5) The BPC determines that adequate competition is not likely to be obtained if the acquisition is restricted to small business concerns, applying the requirements of FAR 19.202–2.

(b) The use of such set-asides is contingent upon current policy in effect under application of the SBCDP (See FAR 19.10).

### 1419.505 Rejecting Small Business Administration recommendations.

(a) A written justification in support of the CO's decision to reject the set-aside recommendation shall be approved by the HCA. It shall then be forwarded for sequential review through the Director, OSDBU and the Director, PAM, for action by the AS/PMB.

(b) As prescribed in FAR 19.505, the AS/PMB is authorized to reply to the Administrator of SBA on any SBA appeal of a contracting officer's set-aside recommendation.

### 1419.506 Withdrawing or modifying small business set-asides.

The HCA is authorized, without the power of redelegation, to resolve disagreements between the CO and the BUDS concerning withdrawals or modifications of individual or class set-asides as prescribed in FAR 19.506. OSDBU shall be provided timely notification of such disagreements and the recommendation of the BUDS in order to provide assistance in resolving the disagreement.

## Subpart 1419.6—Certificates of Competency and Determinations of Responsibility

### 1419.602 Procedures.

### 1419.602–1 Referral.

The CO shall obtain approval from the CCO for all determinations documenting a responsive small business' lack of responsibility prior to submission to the appropriate SBA office. A copy of the determination shall be sent to OSDBU.

## Subpart 1419.7—The Small Business Subcontracting Program

### 1419.705 Responsibilities of the contracting officer under the subcontracting assistance program.

### 1419.705–2 Determining the need for a subcontracting plan.

The CO's determination that no subcontract possibilities exist for a proposed contractual action shall be reviewed by the BUDS prior to the approval by a level above the CO, and a copy shall be forwarded to OSDBU within 5 working days of execution, but in no case later than the date of contract award. The BUDS may contact OSDBU and consider any comments or recommendations offered.

### 1419.705–3 Preparing the solicitation.

In solicitations containing subcontract plan requirements, COs should consider evaluating offered subcontract plans and the offerors' past subcontracting compliance and accomplishments in the evaluation and selection of proposals. This would be particularly appropriate for acquisitions known to offer significant subcontracting opportunities for small, small disadvantaged, and women-owned businesses or which include work previously performed by a small business. When used, this factor must be evaluated in such a way that the relative ranking or scoring of small business offerors is not adversely affected by the lack of a subcontract plan.

### 1419.705–6 Postaward responsibilities of the contracting officer.

In addition to the actions specified in FAR 19.705–6, the CO shall also be responsible for the following:

(a) Forwarding a copy of each approved subcontracting plan to OSDBU within 10 working days after approval of the plan.

(b) Ensuring that the contractor forwards the original copy of the Standard Form 295, Summary Contracting Report, to the Department of the Interior, Director, OSDBU, 18th & C Streets, NW., Washington, DC 20240, Rm. 2747.

(c) Forwarding a copy of the Standard Form 294, Subcontracting Report for Individual Contracts, received from individual contractors, within 10 working days, to OSDBU.

(d) Conducting on-site business and economic development program management reviews (see 405 DM 1) of a prime contractor's small and disadvantaged business subcontracting program. Reviews shall be conducted as required based on problems perceived such as insufficient progress in meeting subcontracting goals. The result of the review shall be documented in writing using the format shown at 1453.303–70. At the discretion of the CO, the BUDS may conduct the reviews. In addition to required bureau/office internal distribution, a copy of the review report shall be submitted to OSDBU within 60 calendar days after completion of the review.

## Subpart 1419.8—Contracting with the Small Business Administration (The 8(a) Program)

### 1419.803 Selecting acquisitions for the 8(a) Program.

The CO shall first screen the acquisition for suitability for award to SBA under the Section 8(a) program, before taking action under FAR 19.501, 19.502 or 1419.503–70. After selecting acquisitions suitable for the 8(a) program, the contracting office shall provide SBA appropriate advance acquisition planning information for all acquisitions found to be suitable for the 8(a) program (*See* also 1407.1).

### 1419.810 SBA appeals.

AS/PMB, without the power of redelegation, is authorized to issue the decision on an SBA appeal of a CO's Section 8(a) decision.

## Subpart 1419.9—Contracting Opportunities for Women-Owned Small Businesses

### 1419.901 Policy.

In support of the Department's policy to facilitate, preserve, and strengthen women's business enterprises:

(a) Annual goals for contract awards to women-owned businesses shall be established as prescribed in 1419.201(b); and

(b) Small women-owned businesses shall be considered for subcontracting opportunities under FAR 19.702, and subcontract awards shall be reported as prescribed in FAR 19.704.

(c) OSDBU, in accordance with 111 DM 8, is assigned the responsibility for carrying out the Department's women-owned business enterprise program.

## Subpart 1419.10—Small Business Competitiveness Demonstration Program

### 1419.1003 Purpose.

OSDBU is responsible for establishing the 10 targeted industry categories and monitoring DOI's participation.

## PARTS 1420–1421—[RESERVED]

## PART 1422—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

### Subpart 1422.1—Basic Labor Policies

Sec.
1422.101 Labor relations.
1422.101–1 General.
1422.101–3 Reporting labor disputes.
1422.101–4 Removal of items from contractors' facilities affected by work stoppages.
1422.103 Overtime.
1422.103–4 Approvals.

### Subpart 1422.3—Contract Work Hours and Safety Standards Act

1422.302 Liquidated damages and overtime pay.

### Subpart 1422.4—Labor Standards for Contracts Involving Construction

1422.404 Davis-Bacon Act wage determinations.
1422.404–6 Modifications of wage determinations.
1422.406–8 Investigations.
1422.406–9 Withholding from or suspension of contract payments.
1422.406–13 Semiannual enforcement reports.

### Subpart 1422.6—Walsh-Healey Public Contracts Act

1422.604 Exemptions.
1422.604–2 Regulatory exemptions.

### Subpart 1422.8—Equal Employment Opportunity

1422.803 Responsibilities.
1422.804 Affirmative action programs.
1422.804–2 Construction.
1422.805 Procedures.
1422.807 Exemptions.

### Subpart 1422.10—Service Contract Act of 1965, As Amended

1422.1003 Applicability.
1422.1003–4 Administrative limitations, variations, tolerances and exemptions.

### Subpart 1422.13—Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans

1422.1305 Waivers.

### Subpart 1422.14—Employment of Workers with Disabilities

1422.1403 Waivers.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1422.1—Basic Labor Policies

### 1422.101 Labor relations.

### 1422.101–1 General.

The HCA may designate programs or requirements for which notice of labor disputes is necessary.

### 1422.101–3 Reporting labor disputes.

Labor disputes that may interfere with contract performance shall be reported to the SOL and the HCA.

### 1422.101–4 Removal of items from contractors' facilities affected by work stoppages.

Prior to initiating any action for removal of items from contractors' facilities, the CO shall obtain advice from SOL.

### 1422.103 Overtime.

### 1422.103–4 Approvals.

The CO shall obtain approval for the use of overtime from the CCO after consultation with the cognizant program office.

## Subpart 1422.3—Contract Work Hours and Safety Standards Act

### 1422.302 Liquidated damages and overtime pay.

(a) HCAs are authorized to take the action in FAR 22.302(c)

(b) Funds withheld or collected for liquidated damages shall be disposed of in accordance with procedures under 1422.406–9.

## Subpart 1422.4—Labor Standards for Contracts Involving Construction

### 1422.404 Davis-Bacon Act wage determinations.

### 1422.404–6 Modifications of wage determinations.

The HCA is authorized to request an extension for awards not made within 90 days after bid opening.

### 1422.406–8 Investigations.

(a) Labor standards investigations required by FAR 22.406–8 shall be the responsibility of the CO.

(b) The CO's report of violations shall be submitted to the HCA, who is authorized to take the actions prescribed in FAR 22.406–8(d).

(c) The HCA shall forward all referrals through the OIG to the Attorney General.

### 1422.406–9 Withholding from or suspension of contract payments.

HCAs shall establish procedures for collection and disposition of funds withheld under FAR 22.406–9, including liquidated damages.

### 1422.406–13 Semiannual enforcement reports.

PAM is responsible for submitting the report required by FAR 22.406–13 to DOL. In accordance with DOL memoranda, PAM requires bureaus to submit the required reports by April 15 and October 15 for the reporting periods of October 1 through March 31 and April 1 through September 30, respectively.

## Subpart 1422.6—Walsh-Healey Public Contracts Act

### 1422.604 Exemptions.

### 1422.604–2 Regulatory exemptions.

The AS/PMB is authorized to request the Secretary of Labor to exempt contracts from the Walsh-Healey Public Contracts Act under FAR 22.604–2(b). A written finding justifying the exemption shall be prepared by the CO and submitted by the HCA to the Director, PAM for further action.

## Subpart 1422.8—Equal Employment Opportunity

### 1422.803 Responsibilities.

The CO shall forward matters involving the applicability of EO 11246 to the HCA for resolution. This authority is granted to the HCA without the power of redelegation.

### 1422.804 Affirmative action programs.

### 1422.804–2 Construction.

Bureau contracting offices are responsible for maintaining (including updates and revisions) lists of geographic areas subject to affirmative action requirements.

### 1422.805 Procedures.

Copies of the poster "Equal Employment Opportunity is the Law" (National Stock No. 7690–00–926–8988) may be ordered from the GSA supply depot.

#### 1422.807 Exemptions.

(a) The Director, PAM shall make the determination that a contract is essential to the national security and that the award of the contract without complying with one of the requirements of FAR 22.8 is necessary to national security.

(b) Requests for exemptions shall be submitted in writing by the CO, through the HCA, to the Director, PAM.

### Subpart 1422.10—Service Contract Act of 1965, as Amended

#### 1422.1003 Applicability.

#### 1422.1003–4 Administrative limitations, variations, tolerances and exemptions.

The CO shall submit requests for determination regarding application of the Service Contract Act and exemptions directly to DOL, Administrator of the Wage and Hour Division.

### Subpart 1422.13—Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans

#### 1422.1305 Waivers.

(a) The Director, PAM is authorized to:

(1) Waive any or all terms of the clause at FAR 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, under the conditions prescribed in FAR 22.1305(a), and

(2) Waive any requirement in FAR Subpart 22.13 as prescribed in FAR 22.1305(b).

(b) Requests for waivers, under paragraph (a) of this section, shall be made in writing by the CO through the HCA to the Director, PAM for further action.

### Subpart 1422.14—Employment of Workers with Disabilities

#### 1422.1403 Waivers.

The Director, PAM is authorized to waive any or all of the terms of the clause at FAR 52.222–36, Affirmative Action for Workers with Disabilities, under the conditions prescribed in FAR 22.1403(a), and waive any requirement in FAR Subpart 22.14 as prescribed in FAR 22.1403(b). Requests for waivers shall be made in writing by the CO through the HCA to the Director, PAM.

## PART 1423—[RESERVED]

## PART 1424—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

**Subpart 1424.1—Protection of Individual Privacy**

Sec.
1424.102 General.
1424.103 Procedures.
1424.104 Contract clauses.

**Subpart 1424.2—Freedom of Information Act.**

1424.203 Policy.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1424.1—Protection of Individual Privacy

#### 1424.102 General.

Procedures for implementing the Privacy Act of 1974 and Departmental regulations under 43 CFR Part 2, Subpart D, are contained in 383 DM.

#### 1424.103 Procedures.

When required by FAR 24.103(b)(2), the CO shall provide the contractor with a copy of the Department's Privacy Act regulations codified in 43 CFR Part 2, Subpart D.

#### 1424.104 Contract clauses.

The clause at FAR 52.224–1, Privacy Act Notification, as prescribed in FAR 24.104(a), shall be supplemented in accordance with 1452.224–1.

### Subpart 1424.2—Freedom of Information Act

#### 1424.203 Policy.

(a) The Department's implementation of the Freedom of Information Act is codified in regulations under 43 CFR Part 2, Subparts A and B.

(b) It is the policy of the Department to alert prospective contractors which place restrictions on the disclosure and use of proposal data that certain data may be subject to disclosure under a Freedom of Information Act request. (*See* 1415.207 and 1452.215–71.)

## PART 1425—FOREIGN ACQUISITION

Sec.
1425.003 Definitions.

**Subpart 1425.1—Buy American Act—Supplies**

1425.103 Exceptions.
1425.105 Determining reasonableness of cost.

**Subpart 1425.2—Buy American Act—Construction Materials**

1425.202 Exceptions.
1425.206 Noncompliance.

**Subpart 1425.7—Prohibited Sources**

1425.701 Restriction on acquisition of supplies or services from prohibited sources.

**Subpart 1425.10—Additional Foreign Acquisition Regulations**

1425.1001 Waiver of right to examination of records.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

#### 1425.003 Definitions.

*Impracticable,* as used in this subpart, includes reasons other than cost, and availability.

*Manufacture,* as used in this subpart, means completion of an end product in the form required to meet specifications. It includes only direct incorporation of components into the end products to alter the original material and establish the identity/character of the end product, and excludes other supplies, materials, and requirements such as testing, manuals, related equipment, etc.

### Subpart 1425.1—Buy American Act—Supplies

#### 1425.103 Exceptions.

(a) The AS/PMB is authorized to make the determination that a foreign end item will be acquired for Government use because preference for a U.S. item would be inconsistent with the public interest. Such determinations shall be prepared by the CO and submitted by the HCA to the Director, PAM for further action.

(b) The Director, PAM is authorized to make the determination that an article, material or supply not included in the list under FAR 25.104 is not mined, produced, or manufactured in the U.S. in sufficient and reasonably available commercial quantities of satisfactory quality. Determinations shall be prepared by the CO and submitted by the BPC for approval.

(c) Contracting activities which have information justifying the removal of an item from the list under FAR 25.104 shall submit such information to the Director, PAM for further disposition.

#### 1425.105 Determining reasonableness of cost.

(a) In unusual circumstances, the Director, PAM may authorize the use of evaluation differentials other than those prescribed in FAR 25.105 for a particular acquisition.

(b) Requests for use of other evaluation differentials shall be submitted by the HCA to the Director, PAM for further action.

## Subpart 1425.2—Buy American Act—Construction Materials

### 1425.202 Exceptions.

(a)(1) The CO may determine the reasonableness of cost as determined by the formula in 1425.203–70.

(2) The Director, PAM has the authority to make the determination that use of U.S. construction material would be impracticable. Failure of the Director, PAM to issue a determination within 30 days after receipt of a request will be deemed approval for use of the cited foreign material.

(3) For items not on the list at FAR 25.108(d), the CCO may make the non-availability determination if the items cost less than the SAT. The HCA may make the non-availability determination when the cost of the items exceeds the SAT.

(b) [Reserved]

### 1425.206 Noncompliance.

The CO will report, in writing, any use of non-excepted, foreign construction materials by contractors, subcontractors and suppliers through the HCA to the Director, PAM for debarment action in accordance with Subpart 1409.4.

## Subpart 1425.7—Prohibited Sources

### 1425.701 Restriction on acquisition of supplies or services from prohibited sources.

The AS/PMB is authorized to request permission from the Office of Foreign Assets Control (OFAC) for DOI use of supplies and services from the sources described in FAR 25.701. Requests shall be prepared by the CO and submitted through the HCA to the Director, PAM.

## Subpart 1425.10—Additional Foreign Acquisition Regulations

### 1425.1001 Waiver of right to examination of records.

The Director, PAM is authorized to make the determinations prescribed in FAR 25.1001(b). Determinations shall be prepared by the CO and submitted through the HCA to the Director, PAM.

# PART 1426—OTHER SOCIOECONOMIC PROGRAMS

## Subpart 1426.70—Indian Preference

Sec.

1426.7000 Scope of subpart.
1426.7001 Definitions.
1426.7002 Statutory requirements.
1426.7003 Applicability and contract clause.
1426.7004 Compliance enforcement.
1426.7005 Tribal preference requirements.

## Subpart 1426.71—Minority Business Reports

1426.7100 Scope of subpart.
1426.7101 Definitions.
1426.7102 Minority Business Development Agency (MBDA–91) Plan and Reports.
1426.7102–1 Statutory basis.
1426.7102–2 Requirements.
1426.7103 The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Superfund Minority Contractors Utilization Report).
1426.7103–1 Statutory basis.
1426.7103–2 Requirements.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1426.70—Indian Preference

### 1426.7000 Scope of subpart.

This subpart prescribes policies and procedures for implementation of Section 7(b) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638, 88 Stat. 2205, 25 U.S.C. 450e(b)).

### 1426.7001 Definitions.

For purposes of this subpart the following definitions shall apply:

*Indian* means a person who is a member of an Indian Tribe. If the contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual within thirty (30) days to provide evidence from the Tribe concerned that the person is a member of the Tribe.

*Indian organization* means that governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451).

*Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit provided that such Indian ownership shall constitute not less than 51 percent of the enterprise.

*Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act, (85 Stat. 688; 43 U.S.C. 1601 *et seq.*).

*Indian Tribe* means an Indian Tribe, band, nation, or other recognized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

*On or near an Indian reservation* means on a reservation or the distance within that area surrounding an Indian reservation(s) that a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

### 1426.7002 Statutory requirements.

Section 7(b) of the Indian Self-Determination and Education Assistance Act requires that any contract or subcontract entered into pursuant to that Act, the Act of April 16, 1934 (48 Stat. 596; 25 U.S.C. 452), as amended (the Johnson-O'Malley Act), or any other Act authorizing contracts with Indian organizations or for the benefit of Indians shall require that, to the greatest extent feasible:

(a) Preferences and opportunities for training and employment in connection with the administration of such contracts shall be given to Indians, and

(b) Preference in the award of subcontracts in connection with the administration of such contracts shall be given to Indian organizations and to Indian-owned economic enterprises as defined in Section 3 of the Indian Financing Act of 1974 (Sec. 3, Pub. L. 93–262; 88 Stat. 77; 25 U.S.C. 1452).

### 1426.7003 Applicability and contract clause.

(a) The CO shall insert the clause at 1452.226–70, Indian Preference—Department of the Interior, in solicitations issued and contracts awarded by:

(1) The Bureau of Indian Affairs;

(2) A contracting activity other than the Bureau of Indian Affairs when the contract is entered into pursuant to an act specifically authorizing contracts with Indian organizations; and,

(3) A contracting activity other than the Bureau of Indian Affairs where the work to be performed is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The CO shall insert the clause at 1452.226–71, Indian Preference Program—Department of the Interior, in all solicitations issued and contracts awarded by a contracting activity which may exceed $50,000, which contain the clause required by paragraph (a) of this section and where it is determined by the CO, prior to solicitation, that the work under the contract will be performed in whole or in part on or near an Indian reservation(s). The Indian Preference Program clause may also be included in solicitations issued and

contracts awarded by a contracting activity which may not exceed $50,000, but which contain the clause required by paragraph (a) of this section and which, in the opinion of the CO, offer substantial opportunities for Indian employment, training or subcontracting.

**1426.7004 Compliance enforcement.**

(a) The CO is responsible for conducting periodic reviews of the contractor to ensure compliance with the requirements of the clauses prescribed in 1426.7003. These reviews may be conducted with the assistance of the Indian Tribe(s) concerned.

(b) Complaints of noncompliance with the requirements of the clauses prescribed under 1426.7003 received in writing by the contracting activity shall be promptly investigated by the CO. A written disposition of the complaint shall be prepared by the CO.

**1426.7005 Tribal preference requirements.**

(a) Where the work under a contract is to be performed on an Indian reservation, the CO may supplement the clause at 1452.226–71, Indian Preference Program—Department of the Interior, by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the CO and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of Section 7(b) of Public Law 93–638 and must be approved by the SOL for legal sufficiency before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause at 1452.226–71 shall be included in the solicitation and clearly identified in order to ensure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this section shall be interpreted to preclude Tribes from independently developing and enforcing their own tribal preference requirements. Such independently developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart 1426.70 and must not hinder the Government's right to award contracts and to administer their provisions.

## Subpart 1426.71—Minority Business Reports

**1426.7100 Scope of subpart.**

This subpart sets forth reporting requirements established by Executive Order 12432 entitled "Minority Business Enterprise Development" and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), also known as "Superfund."

**1426.7101 Definitions.**

For purposes of this subpart the following definitions shall apply:

*Contract* means a contract or subcontract awarded pursuant to the FAR, as well as federal financial assistance, including a subcontract, cooperative agreement, grant, subagreement or subgrant.

*Minority business enterprise* means a business which is at least 51% owned by one or more minority individuals, or in the case of any publicly owned business, at least 51% of the voting stock is owned by one or more minority individuals. The daily business operations are likewise managed by the minority owner.

*Minority individual* means a U.S. citizen who has been subjected to racial or ethnic prejudice or cultural bias because of their identity as members of this group without regard to their individual qualities. Such groups include, but are not limited to: Black Americans; Hispanic Americans; Native Americans; Asian-Pacific Americans; and other groups whose members are U.S. citizens and are found to be disadvantaged by the Small Business Administration pursuant to Section 8(d) of the Small Business Act as amended (15 U.S.C. 637(d)), or the Secretary of Commerce.

(a) *Native Americans* are persons having origins in any of the original peoples of North America or the Hawaiian Islands; in particular, American Indians, Eskimos, Aleuts and Native Hawaiians.

(b) *Asian-Pacific Americans*—persons having origins from Japan, China, the Philippines, Vietnam, Korea, Samoa, Guam, the U.S. Trust Territories of the Pacific, Northern Marianas, Laos, Cambodia, Taiwan, Thailand, Malaysia, Indonesia, Singapore, Brunei, Republic of the Marshall Islands, or the Federated States of Micronesia.

**1426.7102 Minority Business Development Agency (MBDA–91) Plan and Reports.**

**1426.7102–1 Statutory basis.**

Executive Order 12432, dated July 14, 1983, established the requirement for the Department of Commerce (i.e., MBDA) to collect information on acquisition and financial assistance awards to minority businesses, as well as credit assistance to such firms.

**1426.7102–2 Requirements.**

(a) *MBDA–91 Plan.* The BPC is required to submit the Plan on form MBDA–91 to the OSDBU by no later than November 15 of each year. Section 1 of the form, "Procurement Program Activities," will be completed by OSDBU. Sections 2 through 5 must be completed by bureaus and offices.

(b) *MBDA–91 Reports.* The BPC must submit reports to the OSDBU within 30 days following the end of a fiscal quarter. Reports are cumulative from October 1 of the reporting fiscal year, and monetary figures should be rounded to whole dollars in each section of the report.

(c) "Negative report" means when the Bureau had no reportable activity during the quarter. Submit such a report using the MBDA–91 report form.

**1426.7103 The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Superfund Minority Contractors Utilization Report).**

**1426.7103–1 Statutory basis.**

Paragraph 105 of CERCLA requires the President of the United States to consider the availability of qualified minority business enterprises in awarding contracts under the Act and report annually to Congress on the extent of such awards, including the efforts made to encourage the participation of such firms in programs carried out under the act. The Environmental Protection Agency has delegated responsibility for preparing the report, which includes contracts for Superfund hazardous waste clean-up awarded by other agencies.

**1426.7103–2 Requirements.**

The contracting offices shall report designated projects funded with EPA monies, involving the actual award of contracts, subcontracts, financial assistance instruments, subagreements, etc. by DOI. Do not include Departmental projects covered by Superfund and funded solely with Departmental appropriations. The BPC must submit one of the following reports inclusive of all projects, as applicable, to the OSDBU by no later than November 8 of each year:

(a) EPA Forms 6005–3 and 6005–3A for applicable Superfund contract awards, including partial awards to minority businesses.

(b) EPA Form 6005–3A only, for applicable Superfund contract awards when no awards were made to minority firms, to report the efforts made to promote minority business participation in the designated projects.

(c) "Negative Report" when the reporting Bureau did not award contracts using Superfund monies.

## Subchapter E—General Contracting Requirements

## PART 1427—PATENTS, DATA, AND COPYRIGHTS

### Subpart 1427.2—Patents and Copyrights

Sec.
1427.201 Patent and copyright infringement liability.
1427.201–2 Contract clauses.
1427.202 Royalties.
1427.202–3 Adjustment of royalties.

### Subpart 1427.3—Patent Rights Under Government Contracts

1427.303 Contract clauses.
1427.304 Procedures.
1427.304–1 General.
1427.304–4 Appeals.
1427.306 Licensing background patent rights to third parties.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1427.2—Patents and Copyrights

### 1427.201 Patent and copyright infringement liability.

### 1427.201–2 Contract clauses.

Approval to exempt specific United States patents from the patent indemnity clause shall be obtained from the CCO with legal review and concurrence.

### 1427.202 Royalties.

### 1427.202–3 Adjustment of royalties.

The CO shall report to the Assistant Solicitor for Acquisitions and Intellectual Property the results of any action taken in compliance with FAR 27.202–3.

## Subpart 1427.3—Patent Rights Under Government Contracts.

### 1427.303 Contract clauses.

(a) The HCA is authorized to make the determination to sublicense foreign governments or international organizations, as prescribed in FAR 27.303(b)(3).

(b) If one of the exceptions in FAR 27.303(e)(1) is used, then insert clause 1452.227–70, Appeals of Use of Exceptions. The exception in FAR 27.303(e)(1)(ii) to use alternative provisions restricting or eliminating a contractor's right to retain title to any subject invention shall be made by the HCA, after consultation with the Assistant Solicitor for Acquisitions and Intellectual Property.

(c) Within 30 days after contract award the CO shall forward copies of determinations to use exceptions under FAR 27.303(e)(1) shall be forwarded to the Assistant Solicitor for Acquisitions and Intellectual Property for submission to the Secretary of Commerce and, if required, to the Chief Counsel for Advocacy of the Small Business Administration. The determinations shall include all supporting documentation.

### 1427.304 Procedures.

### 1427.304–1 General.

(a)(1) *Exceptions.* The Associate Solicitor for the General Law Division shall issue a decision on the appeal of a small business concern or nonprofit organization of the use of exceptions under FAR 27.303(e)(1).

(2) If the Associate Solicitor for the General Law Division determines that the appeal notice raises a genuine dispute over the material facts, a fact-finding hearing shall be conducted by OHA. The hearing shall be conducted at a location convenient to the parties concerned as determined by the Director, OHA, and on a date and time stated. The contractor may be represented by counsel or any duly authorized representative. Witnesses may be called by either party. The proceedings shall be conducted expeditiously and in such a manner that each party will have a full opportunity to present all information considered pertinent to the determination. A transcribed record of the proceedings shall be made and shall be made available at cost to the contractor upon request, unless the requirement for the transcribed record is waived by mutual agreement of the contractor and OHA.

(3) OHA shall prepare written findings of fact and transmit them to the Associate Solicitor for the General Law Division.

(4) OHA may hear oral arguments after fact-finding provided that the contractor, its counsel or other duly authorized representative, is present in order to have the opportunity to make arguments and rebuttal. The Associate Solicitor for the General Law Division shall issue a decision.

(b) *Greater rights determinations.* Determinations on requests for greater rights in subject inventions by contractors shall be made by the HCA after consultation with the Assistant Solicitor for Acquisitions and Intellectual Property. Appeals of such determinations shall be made to the CBCA.

(c) *Exercise of march-in-rights.* After notification to the contractor of information warranting the exercise of march-in rights, the CO shall prepare a written notice to the contractor after consultation with the Assistant Solicitor for Acquisitions and Intellectual Property. The notice shall be prepared and signed by the Associate Solicitor for the General Law Division. Within the time constraints, if the Associate Solicitor for the General Law Division determines any information submitted by the contractor (assignee or exclusive licensee) after notice of march-in is received raises a genuine dispute over material facts, a fact-finding hearing shall be conducted by OHA. The Associate Solicitor for the General Law Division shall issue a final determination, after consideration of any further written or oral arguments from the parties. An unfavorable determination to a contractor (assignee or exclusive licensee) shall be subject to appeal.

(d) *Licenses and assignments under contracts with nonprofit organizations.* COs may approve contractor requests for assignment of rights or exclusive licenses after obtaining the advice of the Assistant Solicitor for Acquisitions and Intellectual Property. Solicitations containing FAR clause 52.227–11 shall state that contractors should forward such requests to the CO.

### 1427.304–4 Appeals.

(a) The CO is authorized to make any of the determinations listed after consultation with the Assistant Solicitor for Acquisitions and Intellectual Property.

(b) Determinations made under paragraph (a) of this section shall be considered final decisions under the Contract Disputes Act and may be appealed to the CBCA in accordance with the procedures in DIAR Subpart 1433.2.

### 1427.306 Licensing background patent rights to third parties.

Any proposed determination to be made to require third party licensing shall be submitted by the HCA through the Assistant Solicitor for Acquisitions and Intellectual Property for signature of the AS/PMB. The contractor may request a public hearing on the record prior to the above determination. In such cases, the proposed determination and the contractor's request for a hearing shall be referred to OHA. OHA shall conduct public hearings as set forth in 1427.304–1(a)(4) and shall forward its findings and recommendations to the AS/PMB for a final determination. The final determination shall inform the contractor of the right to judicial review within sixty (60) days of the AS/PMB determination.

## PART 1428—BONDS AND INSURANCE

### Subpart 1428.3—Insurance

Sec.
1428.301 Policy.
1428.306 Insurance under fixed-price contracts.
1428.306–70 Insurance for aircraft services contracts.
1428.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.
1428.311–1 Contract clause.
1428.311–2 Agency solicitation provisions and contract clauses.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1428.3—Insurance

#### 1428.301 Policy.

It is the policy of DOI to insure its own risks only when such action is in the best interest of the Government. Circumstances where contractors are required to carry insurance are listed under FAR 28.301 and 28.306. In these circumstances, the CO shall insert the clause at 1452.228–70, Liability Insurance— Department of the Interior, in solicitations and contracts.

#### 1428.306 Insurance under fixed-price contracts.

#### 1428.306–70 Insurance for aircraft services contracts.

(a) Policy. The CO shall insert minimum insurance requirements in aircraft services contracts in order to protect the Government and its contractors.

(b) Applicability. The clauses prescribed in section 1428.311–2 are applicable to all fixed-price contracts involving use of aircraft with either a contractor-furnished or a Government-furnished pilot except for one-time charters when Government exposure is minimal and time limitations are present.

#### 1428.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.

#### 1428.311–1 Contract clause.

The CO shall modify the clause at FAR 52.228–7, Insurance—Liability to Third Persons, in accordance with 1452.228–7, and insert in solicitations and contracts as prescribed in FAR 28.311–1.

#### 1428.311–2 Agency solicitation provisions and contract clauses.

The following DOI clauses shall be used as prescribed:

(a) The CO shall insert the clause at 1452.228–71, Aircraft and General Public Liability Insurance—Department of the Interior, in solicitations and contracts when a fixed-price contract for operation of aircraft is anticipated and where the Government is using a contractor-furnished pilot.

(b) The CO shall insert the clause at 1452.228–72, Liability for Loss or Damage—Department of the Interior, in solicitations and contracts when a fixed-price contract for use of aircraft is anticipated and where the Government does not have a property interest and is using a Government-furnished pilot.

(c) The CO shall insert the clause at 1452.228–73, Liability for Loss or Damage (Property Interest)—Department of the Interior, in solicitations and contracts when a fixed-price contract for use of aircraft is anticipated and where the Government has a property interest in the aircraft and is using a Government-furnished pilot (*e.g.,* a lease with purchase option).

## PART 1429—TAXES

### Subpart 1429.3—State and Local Taxes

Sec.
1429.303 Application of State and local taxes to Government contractors and subcontractors.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1429.3—State and Local Taxes

#### 1429.303 Application of State and local taxes to Government contractors and subcontractors.

Contractors to be treated as agents of the Government for the purposes set forth in FAR 29.303(a) shall require the written review and approval of the AS/PMB. The HCA shall submit requests for approval through SOL, to the Director, PAM, for further action.

## PART 1430—COST ACCOUNTING STANDARDS ADMINISTRATION

### Subpart 1430.2—CAS Program Requirements

Sec.
1430.201 Contract requirements.
1430.201–5 Waiver.
1430.202 Disclosure requirements.
1430.202–2 Impracticality of submission.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1430.2—CAS Program Requirements

#### 1430.201 Contract requirements.

#### 1430.201–5 Waiver.

The CO shall prepare requests to waive contractor compliance with CAS prescribed in FAR 30.201–5 and 48 CFR 9903.201–5(e) (FAR Appendix). The CO shall submit the request for waiver to the Director, PAM, without the power of redelegation, for a determination. PAM must report any waivers granted on a fiscal year basis to the CASB in accordance with FAR 30.201–5(e).

#### 1430.202 Disclosure requirements.

#### 1430.202–2 Impracticality of submission.

The CO shall prepare any request to award a contract without the required contractor submission of the Form No. CASB–DS–1, Disclosure Statement, and submit it through the HCA, to the Director, PAM, and to the Secretary for approval. The Secretary, without the power of redelegation, must file a report to CASB within 30 days in accordance with 48 CFR 9903.202–2 (FAR Appendix).

## PART 1431—CONTRACT COST PRINCIPLES AND PROCEDURES

### Subpart 1431.1—Applicability

Sec.
1431.101 Objectives.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1431.1—Applicability

#### 1431.101 Objectives.

Individual deviations concerning cost principles and procedures shall require the approval of the cognizant Assistant Secretary, with further redelegation authorized. Redelegation is limited to the BPC.

## PART 1432—CONTRACT FINANCING

### Subpart 1432.1—Non-Commercial Item Purchase Financing

Sec.
1432.102 Description of contract financing methods.

### Subpart 1432.3—Loan Guarantees for Defense Production

1432.304 Procedures.
1432.304–2 Certificate of eligibility.

### Subpart 1432.4—Advance Payments for Non-Commercial Items

1432.402 General.
1432.407 Interest.

### Subpart 1432.5—Progress Payments Based on Costs

1432.501 General.
1432.501–2 Unusual progress payments.
1432.502–2 Contract finance office clearance.

### Subpart 1432.6—Contract Debts

1432.602 Responsibilities.
1432.610 Compromising debts.

### Subpart 1432.9—Prompt Payment

1432.903 Responsibilities.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1432.1—Non-Commercial Item Purchase Financing

### 1432.102 Description of contract financing methods.

Use of progress payments based on a percentage or stage of completion are authorized for construction contracts. Progress payments for other than construction, alteration, and repair contracts require the CO to write a determination that:

(a) Payments based on costs would be impracticable; and

(b) Adequate measures exist for determining quality standards and the percentage of work accomplished.

## Subpart 1432.3—Loan Guarantees for Defense Production

### 1432.304 Procedures.

### 1432.304–2 Certificate of eligibility.

Guaranteed loan applications shall be authorized and transmitted to the Federal Reserve Board by the AS/PMB, in accordance with FAR 32.304–2(h).

## Subpart 1432.4—Advance Payments for Non-Commercial Items

### 1432.402 General.

The HCA is authorized to approve determinations and findings, as well as contract terms, for advance payments. The CO shall submit a recommendation for approval or disapproval of the contractor's request to the HCA through the head of the bureau finance office.

### 1432.407 Interest.

The HCA may authorize advance payments without interest pursuant to FAR 32.407.

## Subpart 1432.5—Progress Payments Based on Costs

### 1432.501 General.

### 1432.501–2 Unusual progress payments.

The CO shall obtain the advance approval of the HCA, or designee, before providing a progress payment rate higher than the customary rates as defined in FAR 32.501–1. Advance approval to provide progress payment rates higher than the customary rates shall not be delegated lower than the CCO.

### 1432.502–2 Contract finance office clearance.

The CO shall obtain approval of the bureau finance office prior to taking actions listed in FAR 32.502–2.

## Subpart 1432.6—Contract Debts

### 1432.602 Responsibilities.

344 DM contains policy, standards, and guidelines for collection of debts within DOI. Each bureau and office is responsible for developing an internal debt collection system and prescribing internal procedures for collection of debts, including debts covered under FAR Subpart 32.6.

### 1432.610 Compromising debts.

The CO may recommend compromise of contractor actions pursuant to FAR 32.610, but shall consult 344 DM and SOL for further action.

## Subpart 1432.9—Prompt Payment

### 1432.903 Responsibilities.

The CO may modify the timing of payment specified in paragraph (a)(1)(i) and (ii) of the clause FAR 52.232–26, Prompt Payment for Fixed-Price Architect-Engineer Contracts, and/or paragraph (a)(1)(i) and (ii) of the clause at FAR 52.232–27, Prompt Payment for Construction Contracts, as appropriate, to provide for a period shorter than 30 days (but not less than 7 days) for making contract financing payments based on geographical site location, workload, contractor ability to submit a proper request for payment, or other factors. When considering a modification to these FAR standard(s), the CO should alert the finance and program officials involved in the payment process to ensure that such shorter contract payment terms to be specified in the solicitation and resulting contract will be met. A CO determination justifying a shorter payment period must be documented in writing, and incorporated into the solicitation/contract file.

# PART 1433—PROTESTS, DISPUTES, AND APPEALS

## Subpart 1433.1—Protests

Sec.

1433.102 General.
1433.103 Protests to the agency.
1433.104 Protests to GAO.
1433.106 Solicitation provisions and contract clauses.

## Subpart 1433.2—Disputes and Appeals

1433.203 Applicability.
1433.209 Suspected fraudulent claims.
1433.211 Contracting officer's decision.
1433.213 Obligation to continue performance.
1433.214 Alternative dispute resolution (ADR).
1433.215 Contract clauses.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1433.1—Protests

### 1433.102 General.

For protests filed with GAO, the SOL shall be responsible for handling all bid protest matters. Any communications to GAO shall be coordinated with the regional and/or field solicitor and the Assistant Solicitor, Acquisitions and Intellectual Property.

### 1433.103 Protests to the agency.

For protests filed with the agency, the CO shall coordinate with the regional and/or field solicitor and the Assistant Solicitor, Acquisitions and Intellectual Property, prior to making the protest decision and before suspending or terminating a contract award as a result of the protest. When a protest is denied by the CO, the decision issued shall advise the protester that the decision may be appealed to the GAO. All protest decisions must also contain a notice that appeals to GAO must include a copy of the CO's protest decision.

### 1433.104 Protests to GAO.

(a) *General procedure.* (1) A protester shall furnish a copy of its complete protest simultaneously to the CO and the Assistant Solicitor, Acquisitions and Intellectual Property. Upon being telephonically advised by the GAO of the receipt of a protest, the SOL shall inform the appropriate contracting activity which shall immediately notify the CO. For protests concerning Federal Information Processing (FIP) acquisitions, the SOL shall also inform the Director, Office of Information Resources Management (PIR), who, in turn, shall notify the appropriate bureau Information Resources Management contact and GSA official. The CO shall prepare the protest report as required by FAR 33.104(a)(3).

(2) The SOL will furnish promptly GAO's written notice of the protest to the cognizant contracting activity which, in turn, shall promptly transmit copies to the CO. The CO shall begin notification as prescribed in FAR 33.104(a)(2). The notification letters shall contain a specified period of time for submission of comments and include instructions that any comments submitted to the GAO should also be submitted simultaneously to the CO and the Assistant Solicitor, Acquisitions and Intellectual Property. Copies of the CO's notification letters shall be sent concurrently to the Assistant Solicitor, Acquisitions and Intellectual Property.

(3)(i) The contracting activity shall have no more than 15 working days from the date of telephonic notification by the SOL to deliver the protest report to the Assistant Solicitor, Acquisitions

and Intellectual Property. For reports involving use of the 10 working day express option, the SOL shall establish the report delivery date after consultation with the contracting activity.

(ii) If required, the SOL shall make the request for an extension in the report due date.

(iii) In addition to the requirements of FAR 33.104(a)(3), the report shall be appropriately titled and dated; shall cite the GAO file number; and shall be signed by the CO. Reports shall be prepared with the assistance of the local attorney-advisor of the SOL. A statement shall be included giving an estimate of the length of time an award may be delayed without significant expense or difficulty in performance. If appropriate, the report shall contain a statement regarding any urgency for the acquisition and the extent to which a delay in award may result in significant performance difficulties or additional expense to the Government. The contracting activity shall submit the CO's report to the Assistant Solicitor, Acquisitions and Intellectual Property, who will then submit it to GAO and provide a copy to each interested party who responded to the notification pursuant to FAR 33.104(a)(2).

(b) *Protests before award.* (1) The finding to award, notwithstanding protest, shall be written by the CO, reviewed by the SOL, and approved by the HCA. A copy of the approved written finding shall be placed in the contract file.

(2) The SOL shall be responsible for notifying GAO of the finding to award notwithstanding protest.

(c) *Protests after award.* (1) The CO shall notify the SOL prior to suspending or terminating the awarded contract.

(2) The written finding to authorize continued contract performance, notwithstanding protest, shall be written by the CO, reviewed by the SOL, and approved by the HCA.

(3) The SOL shall be responsible for notifying GAO of the finding to continue contract performance not withstanding protest.

(d) *Notice to GAO.* The CO shall prepare the report required by FAR 33.104(g), and coordinate it with the Assistant Solicitor, Acquisitions and Intellectual Property, and the Director, PAM, prior to HCA signature (signature level not redelegable). For protests regarding FIP acquisitions, the CO shall also coordinate the report with the Director, PIR. After signature, the report shall be forwarded to the Assistant Solicitor for Acquisitions and Intellectual Property for transmission to GAO.

#### 1433.106 Solicitation provisions and contract clauses.

The provision at FAR 52.233–2, Service of Protest, as prescribed in FAR 33.106, shall be modified in accordance with the instructions in DIAR 1452.233–2.

### Subpart 1433.2—Disputes and Appeals

#### 1433.203 Applicability.

(a) The CO shall prepare any determination that application of the Contract Disputes Act to contracts with a foreign or international organization would not be in the public interest and forward it to the HCA for review. The HCA shall be responsible for submitting the determination through the Director, PAM, to the AS/PMB for approval.

(b) The CBCA is authorized by the Contract Disputes Act or by the Secretary to consider and determine an appeal from a decision of a CO on a claim arising under or relating to a contract made by DOI.

#### 1433.209 Suspected fraudulent claims.

The CO shall refer all matters relating to suspected fraudulent claims by a contractor or individual to the OIG for further action or investigation.

#### 1433.211 Contracting officer's decision.

The CO's decision shall reference the Civilian Board of Contract Appeals, 6th Floor, 1800 M Street, NW., Washington, DC 20036, and its rules of procedure at *http://www.cbca.gsa.gov.*

#### 1433.213 Obligation to continue performance.

If the CO considers financing continued contractor performance to be in the best interest of the Government, the CO shall prepare and forward a determination to the HCA for approval.

#### 1433.214 Alternative dispute resolution (ADR).

DOI strongly encourages the use of ADR in the resolution of disputes in lieu of litigation or adjudication. Efforts shall be made to resolve disputes in an expeditious and financially responsible manner.

#### 1433.215 Contract clauses.

The Disputes clause contained in FAR 52.233–1 shall be used with its Alternate I in all solicitations and contracts.

## SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

## PART 1434—[RESERVED]

## PART 1435—RESEARCH AND DEVELOPMENT CONTRACTING

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

#### 1435.010 Scientific and technical reports.

If a Research and Development (R&D) contract results involve classified or national security information, the CO shall follow the agency procedures prescribed in DIAR 1404.403 prior to making the results available. Copies of publications and reports are also required to be sent to the DOI Departmental Library, 1849 C Street, NW., MS–2258, Main Interior Building, Washington, DC 20240.

## PART 1436—CONSTRUCTION AND ARCHITECT–ENGINEER CONTRACTS

### Subpart 1436.2—Special Aspects of Contracting for Construction

Sec.

1436.209 Construction contracts with architect-engineer firms.
1436.270 Preparation of solicitations and contracts for construction.
1436.270–1 Uniform contract format.
1436.270–2 Part I—The Schedule.
1436.270–3 Part II—Contract clauses.
1436.270–4 Part III—Documents, exhibits and other attachments.
1436.270–5 Part IV—Representations and instructions.

### Subpart 1436.5—Contract Clauses

1436.570 Prohibition against use of lead-based paint.
1436.571 Additive and deductive items.

### Subpart 1436.6—Architect-Engineer Services

#### 1436.602 Selection of firms for architect-engineer contracts.

1436.602–1 Selection criteria.
1436.602–2 Evaluation boards.
1436.602–3 Evaluation board functions.
1436.602–4 Selection authority.
1436.602–5 Short selection processes for contracts not to exceed the simplified acquisition threshold.
1436.603 Collecting data on and appraising firms' qualifications.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1436.2—Special Aspects of Contracting for Construction

#### 1436.209 Construction contracts with architect-engineer firms.

Approval to award a contract for construction to a firm or its subsidiaries that designed the project shall be made by the HCA only after discussion with Director, PAM, and with legal

concurrence. The request for approval prepared by the CO shall include the reason(s) why award to the design firm is required; an analysis of the facts involving potential or actual organizational conflicts of interest, including benefits and detriments to the Government and the prospective contractor; and the measures which are to be taken to avoid, neutralize or mitigate conflicts of interest. A copy of the documentation shall be forwarded to PAM at the time of consultation.

#### 1436.270 Preparation of solicitations and contracts for construction.

##### 1436.270–1 Uniform contract format.

(a) COs shall prepare solicitations and contracts for construction using the uniform contract format outlined in Table 1436–1.

(b) If any section of the uniform contract format does not apply, the CO should so mark that section in the solicitation. Upon award, the CO shall not physically include Part IV in the resulting contract, but shall retain it in the contract file.

TABLE 1436–1—UNIFORM CONTRACT FORMAT

| Section | Title |
|---|---|
| Part I—The Schedule | |
| A | Solicitation/contract form. |
| B | Bid schedule. |
| C | Specifications/Drawings. |
| D | Packaging and marking. |
| E | Inspection and acceptance. |
| F | Deliveries or performance. |
| G | Contract administration data. |
| H | Special contract requirements. |
| Part IV—Representations and Instructions | |
| K | Representations, certifications, and other statements of offerors. |
| L | Instructions, conditions, and notices to offerors. |
| M | Evaluation factors for award. |

##### 1436.270–2 Part I—The Schedule.

The CO shall prepare the Schedule as follows:

(a) *Section A, Solicitation/contract form.* Use SF 1442, Solicitation, Offer, and Award (Construction, Alteration or Repair), as prescribed in FAR 36.701(a).

(b) *Section B, Bid schedule.* Bid schedule.

(c) *Section C, Specifications/Drawings.* Include specifications and drawings (*See* FAR Part 11) or reference other location in the uniform contract format (*e.g.* Section J, attachment ___).

(d) *Section D, Packaging and Marking.* Not applicable.

(e) *Section E, Inspection and acceptance.* Include inspection, acceptance, quality assurance, and reliability requirements (*See* FAR Part 46).

(f) *Section F, Deliveries or performance.* Include Suspension of Work, Liquidated Damages, Commencement, Prosecution, and Completion of Work, Variation in Quantity clauses (*See* FAR Part 12).

(g) *Section G, Contract administration data.* Include Contracting Officer's Representative/Technical Representative identification, and any required administration information (*e.g.,* accounting and appropriation data).

(h) *Section H, Special contract requirements.* Include any special contract requirements which are not included in other sections of the uniform contract format.

##### 1436.270–3 Part II—Contract clauses.

For Section I, Contract clause, include any clauses required by law or by the FAR (including Subpart 36.5), the DIAR (including Subpart 1436.5), and any additional bureau-wide or local clauses expected to be included in any resulting contract which are not included in other sections of the uniform contract format.

##### 1436.270–4 Part III—Documents, exhibits and other attachments.

For Section J, List of documents, exhibits, and other attachments, include wage determinations (*See* FAR 22.404), SF–24—Bid Bond (*See* FAR 28.101), and other attachments by listing the title, date and number for each document.

##### 1436.270–5 Part IV—Representations and instructions.

The CO shall prepare the representations and instructions as follows:

(a) *Section K, Representations, certifications, and other statements of offerors.* Include provisions requiring representations, certifications, or submission of other information by an offeror.

(b) *Section L, Instructions, conditions, and notices to offerors.* Include other provisions or instructions to offerors which are not included in other sections of the uniform contract (*e.g.,* FAR 52.214–19 if using sealed bidding).

(c) *Section M, Evaluation factors for award.* Identify all factors that will be considered in awarding the contract (*See,* for example, FAR 14.201–8 for sealed bidding; FAR 15.304 for competitive proposals).

## Subpart 1436.5—Contract Clauses

#### 1436.570 Prohibition against use of lead-based paint.

(a) *Definitions.* As used in this section, "residential structure:" means any house, apartment, or structure intended for human habitation including any institutional structure where persons reside such as an orphanage, boarding school dormitory, day care center, or extended care facility.

(b) The CO shall insert the clause at 1452.236–70, Prohibition Against Use of Lead-Based Paint, in solicitations and contracts when construction of residential structures or rehabilitation (including dismantling, demolition, or removal) of residential structures is contemplated.

#### 1436.571 Additive and deductive items.

If it appears that funds available for a construction project may be insufficient for all the desired features, the CO may provide in the solicitation for a base bid item covering the work as specified and for one or more additive or deductive bid items which add or omit specified features of the work in a stated order of priority. Such solicitations shall include a provision substantially as set forth in 1452.236–71, and the low bidder and the bid items to be awarded shall be determined as provided in the provision.

## Subpart 1436.6—Architect-Engineer Services

#### 1436.602 Selection of firms for architect-engineer contracts.

##### 1436.602–1 Selection criteria.

(a) The CO may include specific evaluation criteria to be used in the evaluation of potential contractors, in accordance with the requirements of FAR 36.602–1.

(b) HCAs are authorized to approve the use of design competition.

##### 1436.602–2 Evaluation boards.

HCAs shall establish procedures for providing permanent or ad hoc architect-engineer evaluation boards. Bureau procedures shall provide for the appointment of private practitioners of architecture, engineering, or related professions when such action is determined by the HCA to be essential to meet the Government's minimum needs.

##### 1436.602–3 Evaluation board functions.

The selection report shall be prepared for HCA approval, in accordance with bureau/office procedures.

**1436.602–4 Selection authority.**

The HCA is authorized to serve as the designated selection authority.

**1436.602–5 Short selection processes for contracts not to exceed the simplified acquisition threshold.**

At each occurrence, CO approval shall be obtained prior to the utilization of either of the short selection processes used for architect-engineer contracts not expected to exceed the simplified acquisition threshold.

**1436.603 Collecting data on and appraising firms' qualifications.**

HCAs who require architect-engineer services shall use their established procedures to collect data on and appraising firms' qualifications.

## PART 1437—SERVICE CONTRACTING

### Subpart 1437.1—Service Contracts—General

Sec.
1437.102 Policy.
1437.103 Contracting officer responsibility.
1437.170 Special service contract requirements.

### Subpart 1437.70—Appraisal Services—(Real Property)

1437.7000 Scope of subpart.
1437.7001 Contractor qualification requirements.
1437.7002 Appraisal standards.

### Subpart 1437.71—Information Collection Services

1437.7100 Scope of subpart.
1437.7101 General.
1437.7102 Clauses.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1437.1—Service Contracts—General

1437.102 Policy.

The HCA is responsible for establishing internal review and approval procedures for service contracts in accordance with OFPP Policy Letter 93–1, Management Oversight of Service Contracting. Special attention shall be directed to avoidance of contracting for inherently governmental functions, as well as contract administration in the area of incurred cost monitoring to complement work progress monitoring.

**1437.103 Contracting officer responsibility.**

(a) While recognizing that program officials are responsible for accurately describing the need to be filled or the problem to be solved through the service contract, COs shall:

(1) Award and administer contracts in a manner that will provide the customer with quality services on time and within budget;

(2) Ensure that requirements are clearly defined and appropriate performance standards are included in the contract;

(3) Utilize the checklist in paragraph (b) of this section, or bureau substitute, to ensure compliance with general policies and the specific guidance in OFPP Policy Letters 92–1, Inherently Governmental Functions, 91–2, Service Contracting, and 89–1, Conflicts of Interest Policies Applicable to Consultants;

(4) Work in close collaboration with the beneficiaries of the services being purchased to ensure that contractor performance meets contract requirements and performance standards;.

(b) Following is a checklist to aid analysis and review of requirements for service contracts.

(1) *General.*

(i) Is the statement of work complete, with a clear-cut division of responsibility between the contracting parties?

(ii) Is it stated in terms the market can satisfy?

(iii) Does the statement of work encompass all commercially available services that can meet the actual functional need (eliminates any nonessential preferences that may thwart full and open competition)?

(iv) Is the statement of work performance-based to the maximum extent possible (i.e., is the acquisition structured around the purpose of the work to be performed, as opposed to either the manner by which the work is to be performed or a broad and imprecise statement of work? Does the statement of work follow OFPP Pamphlet IV, A Guide to Writing and Administering Performance Statements of Work for Service Contracts (Supplement 2 to OMB Circular A–76)?, as described in OFPP Pamphlet IV?)

(2) *Inherently Governmental Functions.* If the response to the first question below is affirmative, the contract requirement is for an inherently Governmental function that Government officials must perform. If the response to the second question below is affirmative, the contract may be for an inherently governmental function.

(i) Is the requirement for a function that is listed in Appendix A of OFPP Policy Letter 92–1?

(ii) If the function is not listed in Appendix A, do any of the factors in the totality of the circumstances analysis discussed in section 7(b) of the Policy Letter 92–1 indicate that the function may be inherently governmental?

(iii) Are Government employees currently performing the task to be contracted out? If so, has OMB Circular A–76 been consulted?

(3) *Cost Effectiveness.* If the response to any of the following questions is negative, the agency may not have a valid requirement or not be obtaining the requirement in the most cost effective manner.

(i) Is the statement of work written so that it supports the need for a specific service?

(ii) Is the statement of work written so that it permits adequate evaluation of contractor versus in-house cost and performance?

(iii) Are the choices of contract type, quality assurance plan, competition strategy, or other related acquisition strategies and procedures in the acquisition plan appropriate to ensure good contractor performance to meet the user's needs?

(iv) If a cost reimbursement contract is contemplated, is the acquisition plan adequate to ensure that the contractor will have the incentive to control costs under the contract?

(v) Is the acquisition plan adequate to address the cost effectiveness of using contractor support (either long-term or short-term) versus in-house performance?

(vi) Is the cost estimate, or other supporting cost information, adequate to enable the contracting office to effectively determine whether costs are reasonable?

(vii) Is the statement of work adequate to describe the requirement in terms of what is to be performed as opposed to how the work is to be accomplished?

(viii) Is the acquisition plan adequate to ensure that there is proper consideration given to quality and best value?

(4) *Control.* If the response to any of the following questions is negative, there may be a control problem.

(i) Are there sufficient resources to evaluate contractor performance when the statement of work requires the contractor to provide advice, analysis and evaluation, opinions, alternatives, or recommendations that could significantly influence agency policy development or decision-making?

(ii) Does the quality assurance plan provide for adequate monitoring of contractor performance?

(iii) Is the statement of work written so that it specifies a contract deliverable or requires progress reporting on contractor performance?

(iv) Is agency expertise adequate to independently evaluate the contractor's approach, methodology, results,

options, conclusions or recommendations?

(v) Is the requirement for a function or service absent from the list in Appendix B of OFPP Policy Letter 92–1? If it is similar to a function or service on that list, greater management scrutiny may be required.

(5) *Conflicts of Interest.* If the response to any of the following questions is affirmative, there may be a conflict of interest.

(i) Can the potential offeror perform under the contract in such a way as to devise solutions or make recommendations that would influence the award of future contracts to that contractor?

(ii) If the requirement is for support services (such as system engineering or technical direction), were any of the potential offerors involved in developing the system design specifications or in the production of the system?

(iii) Has a potential offeror participated in earlier work involving the same program or activity that is the subject of the present contract wherein the offeror had access to source selection or propriety information not available to other offerors competing for the contract?

(iv) Will the contractor be evaluating a competitor's work?

(v) Does the contract allow the contractor to accept its own products or activities on behalf of the Government?

(vi) Will the work under this contract put the contractor in a position to influence government decision-making, *e.g.,* developing regulations that will affect the contractor's current or future business?

(vii) Will the work under this contract effect the interests of the contractor's other clients?

(viii) Are any of the potential offerors, or their personnel who will perform the contract, former agency officials who—while employed by the agency—personally and substantially participated in the development of the requirement for, or the procurement of, these services within the past two years?

(6) *Competition.* If the response to any of the following questions is negative, completion may be unnecessarily limited.

(i) Is the statement of work defined so as to avoid overly restrictive specifications or performance standards?

(ii) Is the contract formulated in such a way as to avoid creating a continuous and dependent arrangement with the same contractor?

(iii) Is the use of an indefinite quantity or term contract arrangement appropriate to obtain the required services?

(iv) Will the requirement be obtained through the use of full and open competition?

#### 1437.170 Special service contract requirements.

The following types of services shall be acquired as specified in the following Departmental regulations:

(a) Aircraft-related services and maintenance shall be acquired as prescribed in 353 DM;

(b) Audiovisual services, including motion pictures, slide shows and videotape recordings, shall be acquired as prescribed in 471 DM 1;

(c) Information-technology services shall be acquired as prescribed in 376 DM 4;

(d) Guard services for safeguarding classified information shall be acquired as prescribed in 442 DM 8;

(e) Printing services shall be acquired as prescribed in 314 DM 1;

(f) Contracts which require collection of identical information from ten or more members of the public shall be cleared as prescribed in 381 DM 12.

### Subpart 1437.70—Appraisal Services (Real Property)

#### 1437.7000 Scope of subpart.

This subpart prescribes policies and procedures for acquiring real property appraisal services.

#### 1437.7001 Contractor qualification requirements.

(a) Prior to award of a contract for real property appraisal services when the services are required in support of court actions, the CO shall coordinate with the appropriate Solicitor's office and obtain written concurrence from the Assistant U.S. Attorney assigned to represent the Government in the matter that the source to be selected possesses the necessary qualifications for adequate contract performance. This requirement shall be treated as a special standard of responsibility (*See* FAR 9.104–2).

(b) The CO shall include the requirements of paragraph (a) of this section in all solicitations for real property appraisal services which may be subject to future court action.

#### 1437.7002 Appraisal standards.

(a) All real property appraisals for condemnation purposes shall be consistent with requirements of the Interagency Land Acquisition Conference publication "Uniform Appraisal Standards for Federal Land Acquisitions" published by the Government Printing Office and available at *http://www.gpoaccess.gov.*

(b) The standards in paragraph (a) of this section shall be made a part of all solicitations and resulting contracts for real property appraisal services procured for condemnation purposes.

### Subpart 1437.71—Information Collection Services

#### 1437.7100 Scope of subpart.

This subpart prescribes policies and procedures for acquiring information collection services which are subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.)

#### 1437.7101 General.

The Paperwork Reduction Act of 1980 requires that no federal agency shall conduct or sponsor the collection of information, upon identical items, from ten or more public respondents unless prior approval is obtained from OMB.

#### 1437.7102 Clauses.

The CO shall insert the clause at 1452.237–70, Information Collection—Department of the Interior, in all solicitations and contracts which are subject to the Paperwork Reduction Act of 1980.

## PARTS 1438–1441—[RESERVED]

## SUBCHAPTER G—CONTRACT MANAGEMENT

## PART 1442—CONTRACT ADMINISTRATION AND AUDIT SERVICES

### Subpart 1442.2—Contract Administration Services

Sec.

**1442.202 Assignment of contract administration.**

### Subpart 1442.6—Corporate Administrative Contracting Officer

1442.602 Assignment and location.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### Subpart 1442.2—Contract Administration Services

#### 1442.202 Assignment of contract administration.

(a) The decision to withhold normal individual contract administration functions is delegated to one level above the CO.

(b) The delegation of authority to issue orders under provisioning procedures in existing contracts and under basic ordering agreements for items and services identified in the schedule must be approved at one level above the CO.

## Subpart 1442.6—Corporate Administrative Contracting Officer

### 1442.602 Assignment and location.

The BPC has the authority to approve the appointment of a Corporate Administrative Contracting Officer.

## PART 1443—CONTRACT MODIFICATIONS

### Subpart 1443.2—Change Orders

Sec.
1443.205 Contract clauses.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1443.2—Change Orders

### 1443.205 Contract clauses.

BPCs may establish procedures, when appropriate, for authorizing the CO to vary the 30-day period for submission of requests for adjustment in the clauses prescribed by FAR 43.205.

## PART 1444—[RESERVED]

## PART 1445—GOVERNMENT PROPERTY

### Subpart 1445.3—Authorizing the Use and Rental of Government Property

Sec.
1445.302 Contracts with foreign governments or international organizations.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1445.3—Authorizing the Use and Rental of Government Property

### 1445.302 Contracts with foreign governments or international organizations.

The HCA, after coordinating with the cognizant PMO, shall establish procedures to recover use costs when foreign governments or international organizations request use of Government production and research property.

## PART 1446—QUALITY ASSURANCE

### Subpart 1446.1—General

Sec.
1446.170 Government-Industry Data Exchange Program (GIDEP).

### Subpart 1446.4—Government Contract Quality Assurance

1446.401 General.

### Subpart 1446.5—Acceptance

1446.501 General.

### Subpart 1446.6—Material Inspection and Receiving Reports

1446.670 Inspection, receiving and acceptance reports.
1446.671 Inspection, receiving and acceptance certification.

### Subpart 1446.7—Warranties

1446.704 Authority for use of warranties.
1446.708 Warranties of data.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1446.1—General

### 1446.170 Government-Industry Data Exchange Program (GIDEP).

(a) COs shall encourage contractors and subcontractors to participate in the GIDEP, a cooperative program managed and funded by the U.S. Government to exchange engineering, failure experience, metrology, product information, and reliability-maintain ability data on products, components (including construction materials), manufacturing processes, environmental issues associated with those manufacturing processes, recycling and waste prevention.

(b) The GIDEP is managed for the U.S. Government by the Department of the Navy. GIDEP participants are not subject to any fees or assessments other than the costs associated with dissemination of information by other than electronic means.

(c) An application to participate in the GIDEP may be obtained at *http://www.gidep.org*. COs shall include information on GIDEP in solicitation documents and during discussions at preaward and postaward conferences.

## Subpart 1446.4—Government Contract Quality Assurance

### 1446.401 General.

Inspection of supplies or services shall be documented as prescribed in DIAR Subpart 1446.6.

## Subpart 1446.5—Acceptance

### 1446.501 General.

Acceptance of supplies or services shall be documented as prescribed in DIAR Subpart 1446.6.

## Subpart 1446.6—Material Inspection and Receiving Reports

### 1446.670 Inspection, receiving and acceptance reports.

(a) Except for simplified acquisitions (*See* FAR 46.404) and unless otherwise prescribed by bureau procedures, the documentation in DIAR 1446.671 shall be inserted on each commercial shipping document or packing list, whether by manual or electronic means, for supplies or services and shall be signed by the authorized Government representative as required in FAR 46.401(f) and Subpart 46.5.

(b) The documentation required in paragraph (a) of this section shall be made at the place or places specified in the contract for performance of Government quality assurance (*See* FAR 46.401(b)) as prescribed in FAR 46.402 or FAR 46.403, as appropriate and for acceptance in accordance with FAR 46.503.

(c) If the CO elects to use a contractor's certificate of conformance (*See* FAR 46.315) under the conditions prescribed in FAR 46.504, the certificate may be used as the basis of Government acceptance.

### § 1446.671 Inspection, receiving and acceptance certification.

As prescribed in DIAR 1446.670, the following documentation shall be completed via manual or electronic means for each delivery of supplies or services in accordance with Bureau procedures:

**INSPECTION, RECEIVING AND ACCEPTANCE CERTIFICATION**

The listed items or services have been: ____ inspected, ____ received, and ____ accepted and they conform to the contract except as noted below or on attached documents.

_____ Signature and typed name of authorized Government representative.

Date ____

## Subpart 1446.7—Warranties

### 1446.704 Authority for use of warranties.

The CCO is authorized to make the written determination to use a warranty in an acquisition.

### 1446.708 Warranties of data.

Warranties of data shall only be used after consultation with the SOL.

## PART 1447—[RESERVED]

## PART 1448—VALUE ENGINEERING

### Subpart 1448.1—Policies and Procedures

Sec.
1448.102 Policies.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1448.1—Policies and Procedures

### 1448.102 Policies.

The HCA shall establish procedures for processing and evaluating VECP's as prescribed in FAR Subpart 48.1 and 369 DM, Value Engineering.

## PART 1449—TERMINATION OF CONTRACTS

### Subpart 1449.1—General Principles

Sec.
1449.106 Fraud or other criminal conduct.

1449.107 Audit of prime contract settlement proposals and subcontract settlements.
1449.111 Review of proposed settlements.

**Subpart 1449.4—Termination for Default**

1449.402 Termination of fixed-price contracts for default.
1449.402–3 Procedure for default.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1449.1—General Principles

### 1449.106 Fraud or other criminal conduct.

When fraud or other criminal conduct is suspected, the CO will submit a report documenting the incident to the BPC for transmittal to the OIG. Informational copies will be forwarded to the HCA and the Director, PAM.

### 1449.107 Audit of prime contract settlement proposals and subcontract settlements.

Requests for audits pursuant to FAR 49.107 shall be sent to the Assistant Inspector General for Auditing, in accordance with the procedures in 360 DM 2.3.

### 1449.111 Review of proposed settlements.

All proposed settlement agreements shall be reviewed by the SOL and approved at one level above the CO. Settlement agreements of $250,000 or more shall be approved by the BPC.

## Subpart 1449.4—Termination for Default

### 1449.402 Termination of fixed-price contracts for default.

### 1449.402–3 Procedure for default.

In addition to the requirements of FAR 49.402–3(g), the notice of termination shall contain instructions regarding the disposition of any Government property in the possession of the contractor, and, in the case of construction contracts, materials, appliances, and structures that may be on the construction site. The notice shall also contain a statement concerning the liability of the contractor or its surety for any liquidated damages (*See* FAR 49.402–7).

# PART 1450—EXTRAORDINARY CONTRACTUAL ACTIONS AND THE SAFETY ACT

**Subpart 1450.1—Extraordinary Contractual Actions**

Sec.p;
§ 1450.101 General.
§ 1450.101–2 Policy.
§ 1450.101–3 Records.
§ 1450.102 Delegation of and limitations on exercise of authority.
§ 1450.102–1 Delegation of authority.
§ 1450.103 Contract adjustments.
§ 1450.103–6 Disposition.
§ 1450.104 Residual powers.
§ 1450.104–2 General.
§ 1450.104–3 Special procedures for unusually hazardous or nuclear risks.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1450.1—Extraordinary Contractual Actions

### 1450.101 General.

### 1450.101–2 Policy.

Requests for extraordinary contractual actions shall be submitted by the HCA to the Director, PAM, for further action.

### 1450.101–3 Records.

The records of actions taken under FAR Part 50 shall be maintained by the Director, PAM.

### 1450.102 Delegation of and limitations on exercise of authority.

### 1450.102–1 Delegation of authority.

The AS/PMB shall approve all actions under FAR Part 50, except for actions in excess of $55,000, actions which increase the contract price without consideration, and indemnification actions, which shall be approved by the Secretary.

### 1450.103 Contract adjustments.

### 1450.103–6 Disposition.

The CO shall submit the Memorandum of Decision including the contractor's request, contractor information in support of the request required by FAR 50.103–4, the results of the CO's investigation required by FAR 50.103–5, and the information required by FAR 50.103–6 to the SOL for review. If the SOL concurs with the Memorandum of Decision, the Memorandum of Decision will be submitted through the HCA to the Director, PAM, for further action.

### 1450.104 Residual powers.

### 1450.104–2 General.

Proposals for the exercise of residual powers shall be processed using the procedures referred to in FAR 50.104–2.

### 1450.104–3 Special procedures for unusually hazardous or nuclear risks.

The CO shall submit the proposed Memorandum of Decision including the contractor's request for indemnification and the information required from the CO, to the SOL for review and approval. If the SOL approves the proposed Memorandum of Decision, it shall be submitted through the HCA, to the Director, PAM, for approval or disapproval by the Secretary.

# PART 1451—USES OF GOVERNMENT SOURCES BY CONTRACTORS

**Subpart 1451.1—Contractor Use of Government Supply Sources**

Sec.
1451.102 Authorization to use Government supply sources.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

## Subpart 1451.1—Contractor Use of Government Supply Sources

### 1451.102 Authorization to use Government supply sources.

If the CO decides to authorize a contractor to use Government supply sources under the conditions prescribed in FAR 51.102, a written request for a FEDSTRIP activity address code (*See* FPMR 101–26.203) shall be made through the acquisition office FEDSTRIP point of contact.

# PART 1452—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Sec.
1452.000 Scope of part.

**Subpart 1452.2—Text of Provisions and Clauses**

1452.200 Scope of subpart.
1452.203–70 Restrictions on Endorsements.
1452.204–70 Release of Claims.
1452.215–70 Examination of Records by the Department of the Interior.
1452.215–71 Use and Disclosure of Proposal Information—Department of the Interior.
1452.224–1 Privacy Act Notification.
1452.226–70 Indian Preference.
1452.226–71 Indian Preference Program.
1452.227–70 Appeals of Use or Exceptions.
1452.228–7 Insurance—Liability to Third Persons.
1452.228–70 Liability Insurance.
1452.228–71 Aircraft and General Public Liability Insurance.
1452.228–72 Liability for Loss or Damage—Department of the Interior.
1452.228–73 Liability for Loss or Damage (Property Interest).
1452.233–2 Service of Protest.
1452.236–70 Prohibition Against Use of Lead-based Paint.
1452.236–71 Additive or Deductive Items.
1452.237–70 Information Collection.
1452.237–71 Utilization of Woody Biomass.

**Authority:** Sec. 205(c), 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 301.

### 1452.000 Scope of part.

This part prescribes Department of the Interior provisions and clauses for use in acquisition.

## Subpart 1452.2—Text of Provisions and Clauses

### 1452.200 Scope of subpart.

This subpart sets forth the texts of all DIAR provisions and clauses. Consistent with the numbering scheme prescribed in FAR 52.101 and the approach used in FAR Subpart 52.2, this subpart is arranged by subject matter, in the same order as, and keyed to, the parts of the DIAR in which provisions and clause requirements are addressed.

### 1452.203–70 Restrictions on Endorsements.

As prescribed in 1403.570–3, insert the following clause:

**RESTRICTION ON ENDORSEMENTS—DEPARTMENT OF THE INTERIOR (JUL 1996)**

The Contractor shall not refer to contracts awarded by the Department of the Interior in commercial advertising, as defined in FAR 31.205–1, in a manner which states or implies that the product or service provided is approved or endorsed by the Government, or is considered by the Government to be superior to other products or services. This restriction is intended to avoid the appearance of preference by the Government toward any product or service. The Contractor may request the Contracting Officer to make a determination as to the propriety of promotional material.

(End of clause)

### 1452.204–70 Release of Claims.

As prescribed in 1404.804–70, insert the following clause:

**RELEASE OF CLAIMS—DEPARTMENT OF THE INTERIOR (JUL 1996)**

After completion of work and prior to final payment, the Contractor shall furnish the Contracting Officer with a release of claims against the United States relating to this contract. The Release of Claims form (DI–137) shall be used for this purpose. The form provides for exception of specified claims from operation of the release.

(End of clause)

### 1452.215–70 Examination of Records by the Department of the Interior.

As prescribed in 1415.209–70, insert the following clause:

**EXAMINATION OF RECORDS BY THE DEPARTMENT OF THE INTERIOR (APR 1984)**

For purposes of the Examination of Records by the Comptroller General clause of this contract (FAR 52.215–1), the Secretary of the Interior, the Inspector General, and their duly authorized representative(s) from the Department of the Interior shall have the same access and examination rights as the Comptroller General of the United States.

(End of clause)

### 1452.215–71 Use and Disclosure of Proposal Information—Department of the Interior.

As prescribed in 1415.207–70, insert the following provision:

**USE AND DISCLOSURE OF PROPOSAL INFORMATION—DEPARTMENT OF THE INTERIOR (APR 1984)**

(a) Definitions. For the purposes of this provision and the Freedom of Information Act (5 U.S.C. 552), the following terms shall have the meaning set forth below:

(1) "Trade Secret" means an unpatented, secret, commercially valuable plan, appliance, formula, or process, which is used for making, preparing, compounding, treating or processing articles or materials which are trade commodities.

(2) "Confidential commercial or financial information" means any business information (other than trade secrets) which is exempt from the mandatory disclosure requirement of the Freedom of Information Act, 5 U.S.C. 552. Exemptions from mandatory disclosure which may be applicable to business information contained in proposals include exemption (4), which covers "commercial and financial information obtained from a person and privileged or confidential," and exemption (9), which covers "geological and geophysical information, including maps, concerning wells."

(b) If the offeror, or its subcontractor(s), believes that the proposal contains trade secrets or confidential commercial or financial information exempt from disclosure under the Freedom of Information Act, (5 U.S.C. 552), the cover page of each copy of the proposal shall be marked with the following legend:

"The information specifically identified on pages _____ of this proposal constitutes trade secrets or confidential commercial and financial information which the offeror believes to be exempt from disclosure under the Freedom of Information Act. The offeror requests that this information not be disclosed to the public, except as may be required by law. The offeror also requests that this information not be used in whole or part by the government for any purpose other than to evaluate the proposal, except that if a contract is awarded to the offeror as a result of or in connection with the submission of the proposal, the Government shall have the right to use the information to the extent provided in the contract."

(c) The offeror shall also specifically identify trade secret information and confidential commercial and financial information on the pages of the proposal on which it appears and shall mark each such page with the following legend:

"This page contains trade secrets or confidential commercial and financial information which the offeror believes to be exempt from disclosure under the Freedom of Information Act and which is subject to the legend contained on the cover page of this proposal."

(d) Information in a proposal identified by an offeror as trade secret information or confidential commercial and financial information shall be used by the Government only for the purpose of evaluating the proposal, except that (i) if a contract is awarded to the offeror as a result of or in connection with submission of the proposal, the Government shall have the right to use the information as provided in the contract, and (ii) if the same information is obtained from another source without restriction it may be used without restriction.

(e) If a request under the Freedom of Information Act seeks access to information in a proposal identified as trade secret information or confidential commercial and financial information, full consideration will be given to the offeror's view that the information constitutes trade secrets or confidential commercial or financial information. The offeror will also be promptly notified of the request and given an opportunity to provide additional evidence and argument in support of its position, unless administratively unfeasible to do so. If it is determined that information claimed by the offeror to be trade secret information or confidential commercial or financial information is not exempt from disclosure under the Freedom of Information Act, the offeror will be notified of this determination prior to disclosure of the information.

(f) The Government assumes no liability for the disclosure or use of information contained in a proposal if not marked in accordance with paragraphs (b) and (c) of this provision. If a request under the Freedom of Information Act is made for information in a proposal not marked in accordance with paragraphs (b) and (c) of this provision, the offeror concerned shall be promptly notified of the request and given an opportunity to provide its position to the Government. However, failure of an offeror to mark information contained in a proposal as trade secret information or confidential commercial or financial information will be treated by the Government as evidence that the information is not exempt from disclosure under the Freedom of Information Act, absent a showing that the failure to mark was due to unusual or extenuating circumstances, such as a showing that the offeror had intended to mark, but that markings were omitted from the offeror's proposal due to clerical error.

(End of provision)

### 1452.224–1 Privacy Act Notification.

(a) As prescribed in 1424.104, the clause at FAR 52.224–1, Privacy Act Notification, shall be modified before insertion into solicitations and contracts by—

(1) Changing the title of the clause to read "PRIVACY ACT NOTIFICATION (JUL 1996) (DEVIATION)"; and

(2) Adding the following sentence to the end of the clause:

"Applicable Department of the Interior regulations concerning the Privacy Act are set forth in 43 CFR 2, Subpart D. The CFR is available for public inspection at the Departmental Library, Main Interior Bldg., 1849 C St. NW, Washington DC, at each of the regional offices of bureaus of the Department and at many public libraries."

(b) As prescribed in FAR 52.103(a) and 52.107(f), the clause at FAR 52.252–6, Authorized Deviation in Clauses, shall be inserted into solicitations and contracts containing the clause in paragraph (a) of this section.

**1452.226–70 Indian Preference.**

As prescribed in 1426.7003(a), insert the following clause in solicitations issued and contracts awarded by the Bureau of Indian Affairs except those pursuant to Title I and to Indian Tribes and Indian Organizations under Title II of Public Law 93–638 (25 U.S.C. 450 *et seq.* and 25 U.S.C. 455 *et seq.,* respectively); a contracting activity other than the Bureau of Indian Affairs when the contract is entered into pursuant to an act specifically authorizing contracts with Indian organizations, and a contracting activity other than the Bureau of Indian Affairs when the work to be performed is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

**INDIAN PREFERENCE—DEPARTMENT OF THE INTERIOR (APR 1984)**

(a) The Contractor agrees to give preferences to Indians who can perform the work required regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation for training and employment opportunities under this contract and, to the extent feasible consistent with the efficient performance of this contract, training and employment preferences and opportunities shall be provided to Indians regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation who are not fully qualified to perform under this contract. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts consistent with the efficient performance of this contract. The Contractor shall maintain such records as are necessary to indicate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall also provide opportunities for training incident to such employment. Such training shall include on-the-job, classroom, or apprenticeship training which is designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its training and employment needs after giving full consideration to Indians as required by this clause, those needs may be satisfied by selection of persons other than Indians in accordance with the clause of this contract entitled "Equal Opportunity."

(d) If no Indian organizations or Indian-owned economic enterprises are available for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, or labor surplus area concerns.

(e) As used in this clause:

(1) "Indian" means a person who is a member of an Indian Tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual within thirty (30) days to provide evidence from the Tribe concerned that the person is a member of that Tribe.

(2) "Indian organization" means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451); and

(3) "Indian-owned economic enterprise" means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit provided that such Indian ownership shall constitute not less than 51 percent of the enterprise.

(4) "Indian Tribe" means an Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 668; 43 U.S.C. 1601) which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(f) The Contractor agrees to include the provisions of the clause including this paragraph (f) in each subcontract awarded under this contract.

(g) In the event of noncompliance with this clause, the Contractor's right to proceed may be terminated in whole or in part by the Contracting Officer and the work completed in a manner determined by the Contracting Officer to be in the best interests of the Government.

(End of clause)

**1452.226–71 Indian Preference Program.**

As prescribed in 1426.7003(b), insert the following clause in all solicitations and contracts awarded by the contracting activity that may exceed $50,000, contain the clause at 1452.226–70, and where it is determined by the Contracting Officer, prior to solicitation, that the work under the contract will be performed in whole or in part on or near an Indian reservation(s). The clause may also be included in solicitations issued and contracts awarded by a contracting activity not exceeding $50,000 that contain the clause at 1452.226–70 and which, in the opinion of the Contracting Officer, offer substantial opportunities for Indian employment, training, and subcontracting.

**INDIAN PREFERENCE PROGRAM—DEPARTMENT OF THE INTERIOR (APR 1984)**

(a) In addition to the requirements of the clause of this contract entitled "Indian Preference—Department of the Interior," the Contractor agrees to establish and conduct an Indian preference program which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts and which will expand opportunities for Indians to receive preference for training and employment in connection with the work to be performed under this contract. In this connection, the Contractor shall —

(1) Designate a liaison officer who will:

(i) Maintain liaison with the Government and Tribe(s) on Indian preference matters;

(ii) Supervise compliance with the provisions of this clause; and

(iii) Administer the Contractor's Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all advertisements for employment that Indian applicants will be given preference in employment and training incident to such employment.

(3) Not less than twenty (20) calendar days prior to commencement of work under this contract, post a written notice in the Tribal office of any reservations on which or near where the work under this contract is to be performed, which sets forth the Contractor's employment needs and related training opportunities. The notice shall include the approximate number and types of employees needed, the approximate dates of employment; the experience or special skills required for employment, if any; training opportunities available; and all other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the Tribe(s) on or near whose reservation(s) the work is to be performed to provide assistance to the Contractor in filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact in regard to the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors and suppliers under this contract. Consistent with the efficient performance of this contract, the Contractor shall give public notice of existing subcontracting opportunities by soliciting bids or proposals only from Indian organizations or Indian-owned economic enterprises. The Contractor shall request assistance and information on Indian firms qualified as suppliers or subcontractors from the Tribe(s) on or near whose reservation(s) the work under the contract is to be performed. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to be contacted in regard to the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

(i) A clear description of the supplies or services required including quantities,

specifications, and delivery schedules which facilitate the participation of Indian firms;

(ii) A statement indicating the preference will be given to Indian organizations and Indian-owned economic enterprises in accordance with Section 7(b) of Public Law 93–638; (88 Stat. 2205; 25 U.S.C. 450e(b));

(iii) Definitions for the terms "Indian organization" and "Indian-owned economic enterprise" as prescribed under the "Indian Preference—Department of the Interior" clause of this contract;

(iv) A representation to be completed by the bidder or offeror that it is an Indian organization or Indian-owned economic enterprise; and

(v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If after soliciting bids from Indian organizations and Indian-owned economic enterprises, no responsible bid is received, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference—Department of the Interior" clause of this contract. If one or more responsible bids are received, award shall be made to the low responsible bidder if the bid price is determined to be reasonable. If the low responsive bid is determined to be unreasonable as to price, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If a reasonable price cannot be agreed upon, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference—Department of the Interior" clause of the contract.

(5) Maintain written records under this contract which indicate:

(i) The names and addresses of all Indians seeking employment for each employment position available under this contract;

(ii) The number and types of positions filled by Indians and non-Indians, and the name, address and position of each Indian employed under this contract;

(iii) For those positions where there are both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Indian applicant was not selected;

(iv) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(v) Reasons why preference was not given to Indian firms as subcontractors or suppliers for each requirement where it was determined by the Contractor that such preference would not be consistent with the efficient performance of the contract, and

(vi) The names and addresses of all Indian organizations and Indian-owned economic enterprises contacted, and receiving subcontract awards under this contract.

(6) The Contractor shall submit to the Contracting Officer for approval a semiannual report which summarizes the Contractor's Indian preference program and indicates the number and types of available positions filled and dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises and all other firms.

(7) Records maintained pursuant to this clause will be kept available for review by the Government until expiration of one (1) year after final payment under this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(b) For purpose of this clause, the following definitions of terms shall apply:

(1) The terms "Indian," "Indian Tribe," "Indian Organization, and "Indian-owned economic enterprise" are defined in the clause of this contract entitled "Indian Preference."

(2) "Indian reservation" includes Indian reservations, public domain Indian allotments, former Indian reservations on Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act, (85 Stat. 688; 43 U.S.C. 1601 *et seq.*).

(3) "On or near an Indian Reservation" means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall be interpreted to preclude Indian Tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not hinder the Government's right to award contracts and to administer their provisions.

(d) The Contractor agrees to include the provisions of this clause including this paragraph (d) in each subcontract awarded under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contractor's right to proceed may be terminated in whole or in part by the Contracting Officer and the work completed in a manner determined by the Contracting Officer to be in the best interest of the Government.

(End of clause)

### 1452.227–70 Appeals of Use or Exceptions.

As prescribed in 1427.303(d)(1), insert the following clause:

**APPEALS OF USE OF EXCEPTIONS (JUL 1996)**

If the Contractor appeals the Contracting Officer determination to use one of the exceptions described in FAR 27.303(d)(1), such appeal shall be made by written notice specifically identifying the basis for the appeal within 30 working days from the receipt of the determination. Such appeal shall be mailed to the Associate Solicitor for General Law, U.S. Department of the Interior, Washington, DC 20240, who is designated as the appeals official.

(End of clause)

### 1452.228–7 Insurance—Liability to Third Persons.

(a) As prescribed in 1428.311–2, the clause at FAR 52.228–7, Insurance—Liability to Third Persons, shall be modified before insertion into solicitations and contracts by:

(1) changing the title of the clause to read: "INSURANCE—LIABILITY TO THIRD PERSONS (APR 1984) (DEVIATIONS)"; and

(2) changing the first sentence in subparagraph (c)(2) of the clause to read:

"For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise but subject to the 'Limitation of Cost' or 'Limitation of Funds' clause of this contract."

(b) As prescribed in FAR 52.103(a) and 52.107(f), the clause at FAR 52.252–6, Authorized Deviations in Clauses, shall be inserted into solicitations and contracts containing the clause in paragraph (a) of this section.

### 1452.228–70 Liability Insurance.

As prescribed in 1428.301, insert the following clause:

**LIABILITY INSURANCE—DEPARTMENT OF THE INTERIOR (JUL 1996)**

(a) The Contractor shall procure and maintain during the term of this contract and any extension thereof liability insurance in form satisfactory to the Contracting Officer by an insurance company which is acceptable to the Contracting Officer. The named insured parties under the policy shall be the Contractor and the United States of America. The amounts of the insurance shall be not less than as follows:

$___each person*
$___each occurrence*
$___property damage*

(b) Each policy shall have a certificate evidencing the insurance coverage. The insurance company shall provide an endorsement to notify the Contracting Officer 30 days prior to the effective date of cancellation or termination of the policy or certificate; or modification of the policy or certificate which may adversely affect the interest of the Government in such insurance. The certificate shall identify the contract number, the name and address of the Contracting Officer, as well as the insured, the policy number and a brief description of contract services to be performed. The contractor shall furnish the Contracting Officer with a copy of an acceptable insurance certificate prior to beginning the work.

*These amounts to be set by the Contracting Officer.

(End of clause)

### 1452.228–71 Aircraft and General Public Liability Insurance.

As prescribed in 1428.306–70(c)(1), insert the following clause:

**AIRCRAFT AND GENERAL PUBLIC LIABILITY INSURANCE DEPARTMENT OF THE INTERIOR (MAR 1989)**

(a) The Contractor, at the Contractor's expense, agrees to maintain, during the continuance of this contract, aircraft liability and general public liability insurance with limits of liability for:

(1) Bodily injury to or death of aircraft passengers of not less than $75,000 for any one passenger and a limit for each occurrence in any one aircraft of at least an amount equal to the sum produced by multiplying $75,000 by 75 percent of the total number of passenger seats installed in the aircraft;

(2) Bodily injury to or death of persons (excluding passengers) of not less than $75,000 for any one person in any one occurrence and $300,000 for occurrence; and

(3) Property damage of not less than $100,000 for each occurrence; or

(4) a single limit of liability for each occurrence equal to or greater than the combined required minimums set forth in paragraphs (a)(1) through (3) of this clause.

(b) The Contractor also agrees to maintain worker's compensation and other legally required insurance with respect to the Contractor's own employees and agents.

(End of clause)

**1452.228–72 Liability for Loss or Damage—Department of the Interior.**

As prescribed in 1428.306–70(c)(2), insert the following clause:

**LIABILITY FOR LOSS OR DAMAGE—DEPARTMENT OF THE INTERIOR (APR 1984)**

(a) The Contractor shall indemnify and hold the Government harmless from any and all loss or damage to the aircraft furnished under this contract except as provided in paragraph (d) of this clause. For the purpose of fulfilling its obligation under this clause, the Contractor shall procure and maintain during the term of this contract, and any extensions thereof, full insurance acceptable to the Contracting Officer. The Contractor's insurance coverage shall apply to pilots furnished by the Government who operate the aircraft. The contractor may request a list of Government pilots by name and qualification who are potential pilots.

(b) Prior to the commencement of work hereunder, the Contractor shall furnish to the Contracting Officer a copy of the insurance policy or policies or a certificate of insurance issued by the underwriter(s) showing that the coverage required by this clause has been obtained.

(c) Each policy or certificate evidencing the insurance shall contain an endorsement which provides that the insurance company will notify the Contracting Officer 30 days prior to the effective date of any cancellation or termination of any policy or certificate or any modification of a policy or certificate which adversely affects the interests of the Government in such insurance. The notice shall be sent by registered mail and shall identify this contract, the name and address of the contracting office, the policy, and the insured.

(d) If the aircraft is damaged or destroyed while in the custody and control of the Government, the Government will reimburse the Contractor for the deductible stipulated in the insurance coverage (if any) as follows:

(1) In-Motion Accidents—Up to 5 percent of the current insured value of the aircraft stated in the policy, or $10,000, whichever is less.

(2) Not In-Motion Accidents—Up to $250 per accident. Such reimbursement shall not be made, however, for loss or damage to the aircraft resulting from:

(i) Normal wear and tear,

(ii) Negligence or fault in maintenance of the aircraft by the Contractor, or

(iii) A defect in construction of the aircraft or a component thereof.

(e) If damage to the aircraft is established to be the fault of the Government, rental payments to the Contractor during the repair period will be made as set forth elsewhere in this contract. The Government may, at its option, make necessary repairs or return the aircraft to the Contractor for repair. In the event the aircraft is lost, destroyed, or damaged so extensively as to be beyond repair, no rental payment will be made to the Contractor thereafter.

(f) Any failure to agree as to the responsibility of the Government or the Contractor under this clause shall, after a final finding and determination by the Contracting Officer, be considered a dispute within the meaning of the "Disputes" clause of this contract.

(End of clause)

**1452.228–73 Liability for Loss or Damage (Property Interest).**

As prescribed in 1428.311–2(c), insert the following clause:

**LIABILITY FOR LOSS OR DAMAGE (PROPERTY INTEREST)—DEPARTMENT OF THE INTERIOR (APR 1984)**

(a) The Government assumes all risk and liability for damage to or loss of the aircraft for the term of this contract, while the aircraft is in the Government's possession, except for;

(1) Normal wear and tear to the aircraft, or

(2) Loss which occurs as a result of negligence or fault in maintenance of the aircraft by the Contractor, or

(3) Loss resulting from a latent defect in the construction of the aircraft or a component thereof.

(b) In the event of damage to the aircraft, the Government may, at its option, make the necessary repairs with its own facilities, or by contract, or pay the Contractor the reasonable cost of repair of the aircraft. if damage to the aircraft is established to be the fault of the Government, rental payments to the Contractor during the repair period will be made as set forth elsewhere in this contract.

(c) In the event the aircraft is lost, destroyed, or damaged so extensively as to be beyond repair, no rental payment will be made to the Contractor thereafter, but the Government will pay to the Contractor a sum equal to the fair market value of the aircraft just prior to such loss, destruction, or extensive damage, less the salvage value of the aircraft.

(d) The Contractor certifies that the contract price does not include any cost attributable to insurance or to any reserve fund it has established to protect its interests in or use of the aircraft, regardless of whether or not the insurance coverage applies for the period during which the Government has possession of the aircraft. If, in the event of loss or damage to the aircraft, the Contractor receives compensation for such loss or damage, in any form, from any source, the amount of such compensation shall be credited to the Government in determining the amount of the Government's liability under this clause; except that this shall not apply to proceeds of insurance received solely as an advance of insurance pending determination of Government liability, or for an increment of value of the aircraft beyond the value for which the Government is responsible.

(e) In the event of loss or damage, the Government shall be subrogated to all rights of recovery by the Contractor against third parties for such loss or damage and such rights shall be immediately assigned to the Government. Except as the Contracting Officer may permit in writing, the Contractor shall neither release nor discharge any third party from liability for such loss or damage nor otherwise compromise or adversely affect the Government's subrogation or other rights hereunder. The Contractor shall cooperate with the Government in any suit or action undertaken by the Government against any such third party.

(f) Any failure to agree as to the responsibility of the Government or the Contractor under this clause shall, after a final finding and determination by the Contracting Officer, be considered a dispute within the meaning of the "Disputes" clause of this contract.

(End of clause)

**1452.233–2 Service of Protest.**

As prescribed in 1433.106, the provision at FAR 52.233–2, Service of Protest, shall be modified before insertion into solicitations and contracts by changing the title of the provision to read: "SERVICE OF PROTEST DEPARTMENT OF THE INTERIOR (JUL 1996) (DEVIATION)"; and adding the following sentence to the end of the provision:

"(c) A copy of the protest served on the Contracting Officer shall be simultaneously furnished by the protester to the Department of the Interior Assistant Solicitor, Acquisitions and Intellectual Property, 1849 C Street, NW., Room 6511, Washington, DC 20240."

**1452.236–70 Prohibition Against Use of Lead-based Paint.**

As prescribed in 1436.570(b), insert the following clause:

**PROHIBITION AGAINST USE OF LEAD-BASED PAINT—DEPARTMENT OF THE INTERIOR (JUL 1996)**

Paint containing more than .06 percent by weight of lead in paint, or the equivalent measure of lead in the dried film of paint already applied, shall not be used in the construction or rehabilitation of residential structures under this contract or any resulting subcontracts.

(End of clause)

**1452.236–71 Additive or Deductive Items.**

As prescribed in 1436.571, insert the following provision:

## ADDITIVE OR DEDUCTIVE ITEMS—DEPARTMENT OF THE INTERIOR (JUL 1996)

So that the Government may obtain the most desirable features of work within the limit of its funds available at time of bid evaluation, award may be made to the bidder having the lowest total of the base bid and a combination of additive and deductive items. All bids shall be evaluated on the basis of the same additive and deductive bid items using the order of priority of the items listed in the schedule.

(End of provision)

### 1452.237–70 Information Collection.

As prescribed in 1437.7102, insert the following clause:

## INFORMATION COLLECTION—DEPARTMENT OF THE INTERIOR (JUL 1996)

If performance of this contract requires the contractor to collect information on identical items from ten or more public respondents, no action shall be taken or funds expended in the solicitation or collection of such information until the contractor has received from the Contracting Officer written notification that approval has been obtained from the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980. The Contractor agrees to provide all information requested by the Contracting Officer which is necessary to obtain approval from OMB.

(End of clause)

### 1452.237–71 Utilization of Woody Biomass.

As prescribed in § 1437.7202, insert the following clause:

## UTILIZATION OF WOODY BIOMASS (MAY 2005)

(a) The contractor may remove and utilize woody biomass, if:

(1) Project work is progressing as scheduled; and

(2) Removal is completed before contract expiration.

(b) To execute this option, the contractor must submit a written request to the Government.

(c) Following receipt of the written request, and if appropriate, the Government and the contractor will negotiate and execute a separate timber/vegetative sales contract. Payment under the timber/vegetative sales contract must be at a price equal to or greater than the appraised value of the woody biomass. The contractor must make any appropriate payment specified in the related timber/vegetative sales contract before removal may be authorized.

(d) If required by law, regulation or Bureau policy, the Government will prepare a timber/vegetative sales notice and/or prospectus, including volume estimates, appraised value and any appropriate special provisions.

(e) The contractor must treat any woody biomass not removed in accordance with the specifications in the service contract.

(f) The sales contract and service contract are severable; default or termination under either contract does not remove the contractor from payment or performance obligations under the other contract.

(g) Definitions:

*Timber/vegetative sales contract and/or notice* means the agency-specific authorized contract instrument for the sale, barter, exchange, billing or other compensation for the payment, removal, and/or transportation of woody biomass material.

*Woody biomass* means the trees and woody plants, including limbs, tops, needles, leaves, and other woody parts, grown in a forest, woodland, or rangeland environment, that are the by-products of management, restoration and/or hazardous fuel reduction treatment.

[FR Doc. 2010–7967 Filed 4–14–10; 8:45 am]

BILLING CODE P

Federal Register

Thursday,
April 15, 2010

# Part IV

# The President

**Proclamation 8497—Honoring the Victims of the Montcoal, West Virginia, Mine Disaster**

**Executive Order 13536—Blocking Property of Certain Persons Contributing to the Conflict in Somalia**

Federal Register
Vol. 75, No. 72
Thursday, April 15, 2010

# Presidential Documents

**Title 3—**

## The President

**Proclamation 8497 of April 12, 2010**

## Honoring the Victims of the Montcoal, West Virginia, Mine Disaster

**By the President of the United States of America**

**A Proclamation**

As a mark of respect for the memory of those who perished in the mine explosion in Montcoal, West Virginia, I hereby order, by the authority vested in me by the Constitution and the laws of the United States of America, that the flag of the United States shall be flown at half-staff at all public buildings and grounds and at all military facilities and naval stations of the Federal Government in the State of West Virginia until sunset on April 18, 2010.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of April, in the year of our Lord two thousand ten, and of the Independence of the United States of America the two hundred and thirty-fourth.

[FR Doc. 2010–8864
Filed 4–14–10; 11:15 am]
Billing code 3195–W0–P

# Presidential Documents

**Executive Order 13536 of April 12, 2010**

## Blocking Property of Certain Persons Contributing to the Conflict in Somalia

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 5 of the United Nations Participation Act, as amended (22 U.S.C. 287c) (UNPA), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, find that the deterioration of the security situation and the persistence of violence in Somalia, and acts of piracy and armed robbery at sea off the coast of Somalia, which have repeatedly been the subject of United Nations Security Council resolutions (including Resolution 1844 of November 20, 2008; Resolution 1846 of December 2, 2008; Resolution 1851 of December 16, 2008; and Resolution 1897 of November 30, 2009), and violations of the arms embargo imposed by the United Nations Security Council in Resolution 733 of January 23, 1992, and elaborated upon and amended by subsequent resolutions (including Resolution 1356 of June 19, 2001; Resolution 1725 of December 6, 2006; Resolution 1744 of February 20, 2007; Resolution 1772 of August 20, 2007; Resolution 1816 of June 2, 2008; and Resolution 1872 of May 26, 2009), constitute an unusual and extraordinary threat to the national security and foreign policy of the United States, and I hereby declare a national emergency to deal with that threat.

I hereby order:

**Section 1.** (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person, including any overseas branch, of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(i) the persons listed in the Annex to this order; and

(ii) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(A) to have engaged in acts that directly or indirectly threaten the peace, security, or stability of Somalia, including but not limited to:

(1) acts that threaten the Djibouti Agreement of August 18, 2008, or the political process; or

(2) acts that threaten the Transitional Federal Institutions, the African Union Mission in Somalia (AMISOM), or other international peacekeeping operations related to Somalia;

(B) to have obstructed the delivery of humanitarian assistance to Somalia, or access to, or distribution of, humanitarian assistance in Somalia;

(C) to have directly or indirectly supplied, sold, or transferred to Somalia, or to have been the recipient in the territory of Somalia of, arms or any related materiel, or any technical advice, training, or assistance, including financing and financial assistance, related to military activities;

(D) to have materially assisted, sponsored, or provided financial, material, logistical, or technical support for, or goods or services in support of, the activities described in subsections (a)(ii)(A), (a)(ii)(B), or (a)(ii)(C) of

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

(b) I hereby determine that, among other threats to the peace, security, or stability of Somalia, acts of piracy or armed robbery at sea off the coast of Somalia threaten the peace, security, or stability of Somalia.

(c) I hereby determine that, to the extent section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) may apply, the making of donations of the type of articles specified in such section by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to subsection (a) of this section would seriously impair my ability to deal with the national emergency declared in this order, and I hereby prohibit such donations as provided by subsection (a) of this section.

(d) The prohibitions in subsection (a) of this section include but are not limited to:

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

(ii) the receipt of any contribution or provision of funds, goods, or services from any such person.

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

**Sec. 2.** (a) Any transaction by a United States person or within the United States that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

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

**Sec. 3.** For the purposes of this order:

(a) the term "person" means an individual or entity;

(b) the term "entity" means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(c) the term "United States person" means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States;

(d) the term "Transitional Federal Institutions" means the Transitional Federal Charter of the Somali Republic adopted in February 2004 and the Somali federal institutions established pursuant to such charter, and includes their agencies, instrumentalities, and controlled entities; and

(e) the term "African Union Mission in Somalia" means the mission authorized by the United Nations Security Council in Resolution 1744 of February 20, 2007, and reauthorized in subsequent resolutions, and includes its agencies, instrumentalities, and controlled entities.

**Sec. 4.** For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in this order, there need be no prior notice of a listing or determination made pursuant to section 1(a) of this order.

**Sec. 5.** The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA and the UNPA, as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government consistent with applicable law. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order.

**Sec. 6.** The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to submit the recurring and final reports to the Congress on the national emergency declared in this order, consistent with section 401(c) of the NEA (50 U.S.C. 1641(c)) and section 204(c) of IEEPA (50 U.S.C. 1703(c)).

**Sec. 7.** The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to determine that circumstances no longer warrant the blocking of the property and interests in property of a person listed in the Annex to this order, and to take necessary action to give effect to that determination.

**Sec. 8.** 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.

**Sec. 9.** This order is effective at 12:01 a.m. eastern daylight time on April 13, 2010.

THE WHITE HOUSE,

*April 12, 2010.*

Billing code 3195–W9–P

## ANNEX

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1. Abshir ABDILLAHI [born circa 1966]
2. Hassan Abdullah Hersi AL-TURKI [born circa 1944]
3. Hassan Dahir AWEYS [born 1935]
4. Ahmed Abdi AW-MOHAMED [born 10 July 1977]
5. Yasin Ali BAYNAH [born circa 1966]
6. Mohamed Abdi GARAAD [born circa 1973]
7. Yemane GHEBREAB [born 21 July 1951]
8. Fuad Mohamed KHALAF [born circa 1965]
9. Bashir Mohamed MAHAMOUD [born circa 1979-1982]
10. Fares Mohammed MANA'A [born 8 February 1965]
11. Mohamed SA'ID [born circa 1966]

Entity

1. al-Shabaab

[FR Doc. 2010–8878
Filed 4–14–10; 11:15 am]
Billing code 4811–33–C

# Reader Aids

**Federal Register**

Vol. 75, No. 72

Thursday, April 15, 2010

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