AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

# FEDERAL REGISTER

Vol. 76 Thursday,
No. 87 May 5, 2011

Pages 25515–26176

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

**The seal of the National Archives and Records Administration authenticates the Federal Register** as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpo@custhelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

**How To Cite This Publication:** Use the volume number and the page number. Example: 76 FR 12345.

**Postmaster:** Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

## SUBSCRIPTIONS AND COPIES

**PUBLIC**

**Subscriptions:**

| | |
|---|---|
| Paper or fiche | **202–512–1800** |
| Assistance with public subscriptions | **202–512–1806** |

**General online information** **202–512–1530; 1–888–293–6498**

**Single copies/back copies:**

| | |
|---|---|
| Paper or fiche | **202–512–1800** |
| Assistance with public single copies | **1–866–512–1800 (Toll-Free)** |

**FEDERAL AGENCIES**

**Subscriptions:**

| | |
|---|---|
| Paper or fiche | **202–741–6005** |
| Assistance with Federal agency subscriptions | **202–741–6005** |

**FEDERAL REGISTER WORKSHOP**

**THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT**

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, May 10, 2011
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

# Contents

**Federal Register**

Vol. 76, No. 87

Thursday, May 5, 2011

**Agricultural Marketing Service**
RULES
User Fees for 2011 Crop Cotton Classification Services to Growers, 25533–25534
PROPOSED RULES
National Organic Program:
Amendments to the National List of Allowed and Prohibited Substances (Livestock), 25612–25617
Processed Raspberry Promotion, Research, and Information Order, 25618–25619
Watermelon Research and Promotion Plan; Redistricting and Importer Representation, 25619–25622
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25663–25664

**Agriculture Department**
*See* Agricultural Marketing Service
*See* Forest Service

**American Battle Monuments Commission**
NOTICES
No Fear Act, 25665–25666

**Centers for Disease Control and Prevention**
NOTICES
Meetings:
Partnerships To Advance the National Occupational Research Agenda, 25694–25695
Public Health Information Network Messaging Guide for Syndromic Surveillance, 25695–25696

**Centers for Medicare & Medicaid Services**
RULES
Changes Affecting Hospital and Critical Access Hospital Conditions of Participation:
Credentialing and Privileging of Telemedicine Physicians and Practitioners, 25550–25565
PROPOSED RULES
Medicare Program:
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates, 25788–26084

**Civil Rights Commission**
NOTICES
Meetings; Sunshine Act, 25666

**Coast Guard**
RULES
Safety Zones:
Blue Crab Festival Fireworks Display, Little River, Little River, SC, 25545–25548
Coast Guard Use of Force Training Exercises, San Pablo Bay, CA, 25548–25550
NOTICES
Meetings:
National Maritime Security Advisory Committee, 25702–25703

**Commerce Department**
*See* International Trade Administration
*See* National Oceanic and Atmospheric Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25666

**Corporation for National and Community Service**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25672–25674

**Defense Acquisition Regulations System**
RULES
Defense Federal Acquisition Regulation Supplement:
Electronic Ordering Procedures, 25566–25568
Guidance on Personal Services, 25565–25566
Minimizing Use of Materials Containing Hexavalent Chromium, 25569–25576

**Defense Department**
*See* Defense Acquisition Regulations System

**Department of Transportation**
*See* Pipeline and Hazardous Materials Safety Administration

**Education Department**
PROPOSED RULES
Negotiated Rulemaking Committees; Public Hearings, 25650–25652
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25674–25676
Applications for New Awards:
Technology and Media Services for Individuals with Disabilities, 25676–25682

**Employee Benefits Security Administration**
NOTICES
Proposed Exemptions from Certain Prohibited Transaction Restrictions, 25711–25723

**Employment and Training Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Growing America Through Entrepreneurship II Evaluation, 25723–25725

**Energy Department**
*See* Energy Efficiency and Renewable Energy Office
*See* Energy Information Administration
*See* Federal Energy Regulatory Commission
PROPOSED RULES
Energy Conservation Program for Certain Industrial Equipment:
Standards for Commercial Heating, Air-Conditioning, and Water-Heating Equipment, 25622–25648
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board, Idaho National Laboratory, 25682–25683
Environmental Management Site-Specific Advisory Board, Savannah River Site, 25682

**Energy Efficiency and Renewable Energy Office**
NOTICES
Meetings:
State Energy Advisory Board, 25683

**Energy Information Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25683–25685

**Environmental Protection Agency**
PROPOSED RULES
Approval and Promulgation of Air Quality Implementation Plans:
North Dakota; Revisions to the Air Pollution Control Rules, 25652–25656
NOTICES
Meetings:
Human Studies Review Board Public Teleconference, 25686–25688
Proposed Settlement Agreement, Clean Air Act Citizen Suit, 25688–25689

**Executive Office of the President**
*See* Presidential Documents

**Federal Aviation Administration**
RULES
Airworthiness Directives:
Dassault–Aviation Model FALCON 7X Airplanes, 25535–25537
Hamilton Sundstrand Propellers Model 247F Propellers; Correction, 25534–25535
Amendment of Class E Airspace:
McCall, ID, 25537–25538
PROPOSED RULES
Special Conditions:
Gulfstream Model GVI Airplane; Limit Engine Torque Loads for Sudden Engine Stoppage, 25648–25650
NOTICES
Waivers of Aeronautical Land-Use Assurances:
Marion Municipal Airport, Marion, IN, 25760

**Federal Deposit Insurance Corporation**
NOTICES
Meetings; Sunshine Act, 25689–25690

**Federal Energy Regulatory Commission**
NOTICES
Applications:
Pacific Gas and Electric Co., 25685
Filings:
Orlando Utilities Commission, 25685–25686
Requests Under Blanket Authorizations:
ANR Pipeline Co., 25686

**Federal Financial Institutions Examination Council**
NOTICES
Meetings:
Appraisal Subcommittee, 25690

**Federal Maritime Commission**
NOTICES
Ocean Transportation Intermediary Licenses; Applicants, 25690–25691
Ocean Transportation Intermediary Licenses; Reissuances, 25691
Ocean Transportation Intermediary Licenses; Rescissions of Orders of Revocations, 25691
Ocean Transportation Intermediary Licenses; Revocations:, 25692

**Federal Motor Carrier Safety Administration**
RULES
Hours of Service Exception for Railroad Signal Employees, 25588–25590
NOTICES
Commercial Driver's License Standards; Renewals of Exemptions:
Volvo Trucks North America, 25761–25762
Qualification of Drivers; Exemption Applications; Vision, 25762–25769
Qualifications of Drivers; Exemption Applications; Diabetes Mellitus, 25769–25773

**Federal Reserve System**
NOTICES
Changes in Bank Control;
Acquisitions of Shares of a Bank or Bank Holding Company, 25692–25693
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 25693
Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies Engaged in Permissible Nonbanking Activities, 25693

**Federal Transit Administration**
NOTICES
Limitation on Claims against Proposed Public Transportation Project, 25773

**Fiscal Service**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
List of Data (A) and List of Data (B), 25782–25783
Surety Companies Acceptable on Federal Bonds; Name Changes:
Odyssey America Reinsurance Corp., 25783

**Fish and Wildlife Service**
RULES
Endangered and Threatened Wildlife and Plants:
Establishment of a Nonessential Experimental Population of Sonoran Pronghorn in Southwestern Arizona, 25593–25611
Identification of Northern Rocky Mountain Population of Gray Wolf as Distinct Population Segment, 25590–25592
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
Initiation of Status Reviews for the Gray Wolf and for the Eastern Wolf (Canis lycaon), 26086–26145

**Food and Drug Administration**
RULES
Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption, 25538–25542
Information Required in Prior Notice of Imported Food, 25542–25545
NOTICES
Guidance for Industry; Availability:
Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products, 25696

**Foreign Assets Control Office**
NOTICES
Identification of Thirty Entities as Government of Libya Entities Pursuant to Executive Order 13566, 25783–25785

**Forest Service**
NOTICES
Meetings:
North Gifford Pinchot National Forest Resource Advisory Committee, 25664
Shasta County Resource Advisory Committee, 25664–25665

**Health and Human Services Department**
*See* Centers for Disease Control and Prevention
*See* Centers for Medicare & Medicaid Services
*See* Food and Drug Administration
*See* Health Resources and Services Administration
*See* National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25693–25694
Meetings:
President's Council on Fitness, Sports, and Nutrition; Correction, 25694

**Health Resources and Services Administration**
NOTICES
Meetings:
National Advisory Committee on Rural Health and Human Services, 25696–25697

**Homeland Security Department**
*See* Coast Guard

**Housing and Urban Development Department**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Assessment of Native American, Alaska Native and Native Hawaiian Housing Needs, 25703–25704
Announcement of Funding Awards:
Emergency Capital Repair Grant Program Fiscal Year 2010, 25704–25705
Buy American Exceptions under the American Recovery and Reinvestment Act of 2009, 25705–25706

**Interior Department**
*See* Fish and Wildlife Service

**International Trade Administration**
NOTICES
Final Results of Full Sunset Review and Revocation of the Countervailing Duty Order:
Stainless Steel Plate in Coils from Belgium, 25666–25668
Final Results of the Five-Year Review of the Antidumping Duty Order:
Stainless Steel Sheet and Strip in Coils from Mexico, 25668–25670
Final Results of the Full Five-Year Review of the Antidumping Duty Order:
Stainless Steel Sheet and Strip in Coils from Italy, 25670–25672

**International Trade Commission**
NOTICES
Complaints, 25706
Investigations:
Certain Flash Memory and Devices Containing Same, 25707–25709
Certain Multimedia Display and Navigation Devices and Systems, 25707
Meetings; Sunshine Act, 25709

**Justice Department**
NOTICES
Lodging of Consent Decrees:
U.S. v. Bunting Bearings, LLC, 25710
Lodging of Proposed Consent Decrees, 25710

**Labor Department**
*See* Employee Benefits Security Administration
*See* Employment and Training Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25710–25711

**National Aeronautics and Space Administration**
PROPOSED RULES
Cross-Waiver of Liability Clauses, 25657–25660
Responsibility; Suspension and Debarment, 25656–25657

**National Institutes of Health**
NOTICES
Government-Owned Inventions; Availability for Licensing, 25697–25699
Meetings:
Center for Scientific Review, 25701–25702
Eunice Kennedy Shriver National Institute Of Child Health & Human Development, 25699–25700
National Center for Research Resources, 25700
National Heart, Lung, and Blood Institute, 25701
National Institute of Allergy and Infectious Diseases, 25700–25701
National Institute of Diabetes and Digestive and Kidney Diseases, 25700
National Institute of Neurological Disorders and Stroke, 25702

**National Oceanic and Atmospheric Administration**
PROPOSED RULES
Endangered and Threatened Wildlife;
90-Day Finding on a Petition to Revise Critical Habitat for the Endangered Leatherback Sea Turtle, 25660–25662

**Nuclear Regulatory Commission**
NOTICES
Final Regulatory Guide: Issuance, Availability, 25725

**Pipeline and Hazardous Materials Safety Administration**
RULES
Pipeline Safety:
Applying Safety Regulations to All Rural Onshore Hazardous Liquid Low-Stress Lines, 25576–25588
NOTICES
Meetings:
International Standards on the Transport of Dangerous Goods, 25774

**Presidential Documents**
PROCLAMATIONS
Special Observances:
Asian American and Pacific Islander Heritage Month (Proc. 8659), 25515–25516
Jewish American Heritage Month (Proc. 8660), 25517–25518

Law Day, U.S.A. (Proc. 8665), 25527–25528
Loyalty Day (Proc. 8666), 25529–25530
National Charter Schools Week (Proc. 8664), 25525–25526
National Day of Prayer (Proc. 8667), 25531–25532
National Foster Care Month (Proc. 8661), 25519–25520
National Physical Fitness and Sports Month (Proc. 8662), 25521–25522
Older Americans Month (Proc. 8663), 25523–25524

**Public Debt Bureau**
*See* Fiscal Service

**Securities and Exchange Commission**
**NOTICES**
Applications for Deregistration, 25726
Meetings; Sunshine Act, 25726–25727
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Stock Exchange, Inc., 25727–25730
NASDAQ Stock Market LLC, 25730–25732
Suspension of Trading Orders:
Advanced Refractive Technologies, Inc., Bluebook International Holding Co., et al., 25732

**Small Business Administration**
**NOTICES**
Exemption Requests:
Emergence Capital Partners SBIC, LP, 25732–25733

**State Department**
**NOTICES**
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25733–25734
Bureau of Educational and Cultural Affairs Request for Grant Proposals:
Young Turkey/Young America; A New Relationship for a New Age, 25740–25748
Youth Leadership Program, 25734–25740
Grant Proposals; Requests:
International Visitor Leadership Program Assistance Award; Open Competition, 25748–25755
Requests for Grant Proposals; Funding Opportunities, etc.:
Future Leaders Exchange Program (FLEX), Organizational Component, 25755–25760

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

**Treasury Department**
*See* Fiscal Service
*See* Foreign Assets Control Office
**NOTICES**
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 25774
Exemption Determinations:
Foreign Exchange Swaps and Foreign Exchange Forwards, 25774–25782

**Veterans Affairs Department**
**RULES**
Caregivers Program, 26148–26176

---

**Separate Parts In This Issue**

**Part II**
Health and Human Services Department, Centers for Medicare & Medicaid Services, 25788–26084

**Part III**
Interior Department, Fish and Wildlife Service, 26086–26145

**Part IV**
Veterans Affairs Department, 26148–26176

---

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

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

## CFR PARTS AFFECTED IN THIS ISSUE

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


**3 CFR**

**Proclamations:**

8659 ..... 25515
8660 ..... 25517
8661 ..... 25519
8662 ..... 25521
8663 ..... 25523
8664 ..... 25525
8665 ..... 25527
8666 ..... 25529
8667 ..... 25531

**7 CFR**

28 ..... 25533

**Proposed Rules:**

205 ..... 25612
1208 ..... 25618
1210 ..... 25619

**10 CFR**

**Proposed Rules:**

431 ..... 25622

**14 CFR**

39 (2 documents) ..... 25534, 25535
71 ..... 25537

**Proposed Rules:**

25 ..... 25648

**21 CFR**

1 (2 documents) ..... 25531, 25542

**33 CFR**

165 (2 documents) ..... 25545, 25548

**34 CFR**

**Proposed Rules:**

Ch. VI ..... 25650

**38 CFR**

17 ..... 26148
71 ..... 26148

**40 CFR**

**Proposed Rules:**

52 ..... 25652

**42 CFR**

482 ..... 25550
485 ..... 25550

**Proposed Rules:**

412 ..... 25788
413 ..... 25788
476 ..... 25788

**48 CFR**

211 ..... 25565
216 ..... 25566
223 ..... 25569
237 ..... 25565
252 (2 documents) ..... 25666, 25569

**Proposed Rules:**

1809 ..... 25656
1812 ..... 25657
1828 ..... 25657
1852 ..... 25657

**49 CFR**

195 ..... 25576
395 ..... 25588

**50 CFR**

17 (2 documents) ..... 25590, 25593

**Proposed Rules:**

17 ..... 26086
226 ..... 25660

Federal Register
Vol. 76, No. 87
Thursday, May 5, 2011

# Presidential Documents

**Title 3—**

## The President

**Proclamation 8659 of April 29, 2011**

## Asian American and Pacific Islander Heritage Month, 2011

**By the President of the United States of America**

**A Proclamation**

This month, our Nation celebrates the contributions and accomplishments of Asian Americans and Pacific Islanders (AAPI). Our AAPI communities have roots that span the globe, but their stories of striving and success are uniquely American. As we celebrate Asian American and Pacific Islander Heritage Month, we recognize the entrepreneurship and fortitude of individuals who have helped build our country and shape the American dream for centuries.

Generations of Asian Americans and Pacific Islanders have helped develop and defend the United States, often in the face of tremendous racial and cultural prejudice. Despite these difficulties, AAPI men and women struggled, sacrificed, and persevered to build a better life for their children and all Americans.

Today, Asian Americans and Pacific Islanders have a profound impact on our society as leaders in all facets of American life, thriving as athletes and public servants, entrepreneurs and artists. Whether as small business owners or as proud members of the United States Armed Forces, Asian Americans and Pacific Islanders are helping to write the next chapter of the American story.

Although many Asian Americans and Pacific Islanders have achieved success, far too many still struggle to overcome obstacles of unemployment, poverty, and language barriers or face significant education, economic, and health disparities. To help address the diverse challenges affecting our AAPI communities, I reestablished the White House Initiative on Asian Americans and Pacific Islanders. The Initiative coordinates the efforts of agencies throughout the Federal Government to promote increased access to and participation in Federal programs for Asian Americans and Pacific Islanders who remain underserved, so we can continue to be a Nation where all things are possible for all people. All Americans can visit www.AAPI.gov to learn more about the important work of this Initiative.

From our earliest days, intrepid men and women from the Asia-Pacific region have forged enduring links between America and other nations as they moved across the Pacific. In today's globalized world, these bonds remain critical, reminding the United States of our rich shared history and integrated future with the dynamic Asia-Pacific region. During Asian American and Pacific Islander Heritage Month, let us celebrate the millions of Asian Americans and Pacific Islanders whose talents and contributions strengthen our economy, protect our security, and enliven our country every day.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2011 as Asian American and Pacific Islander Heritage Month. I call upon all Americans to visit www.AsianPacificHeritage.gov to learn more about the history of Asian Americans and Pacific Islanders, and to observe this month with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11062
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8660 of April 29, 2011**

## Jewish American Heritage Month, 2011

**By the President of the United States of America**

**A Proclamation**

Since before our Nation's founding, America's shores have been a safe harbor for people seeking shelter, hope, and new lives free from persecution. Here, people of all faiths have broken bread, come together, and built a better future for their families. The Jewish story is intertwined with the American story—one of overcoming great hardship, and one of commitment to building a more just world. This month, we embrace and celebrate the vast contributions Jewish Americans have made to our country.

Seeking a brighter future, a small band of Jewish refugees came to this land more than three centuries ago, to a place called New Amsterdam. Hundreds of years later, as Holocaust survivors and families caught behind the Iron Curtain made their way to America, their perseverance in the face of unimaginable tragedy inspired the world and proved that the Jewish people will not be defeated. Many endured bigotry even here, reminding us that we must continue to fight prejudice and violence at home and around the globe. In this spirit, President Truman recognized the small, fledgling nation of Israel within minutes of its creation. To this day, we continue to foster an unbreakable partnership with Israel, and we remain committed to pursuing peace in the region and ensuring Israel's security.

From those first days in New Amsterdam, Jewish Americans have dedicated their innovation, creativity, and hearts to the greater good—contributing scientific accomplishments, pioneering works of literature and musical genius, and performing distinguished service in our Nation's military. Jewish Americans have defended our country since the days of the American Revolution as devoted service members and chaplains, and they continue to serve with distinction in our Armed Forces.

Nearly 70 years ago, during World War II, the U.S.A.T. Dorchester suffered an explosion at sea while carrying almost a thousand soldiers and civilian workers. On board were four Army chaplains—two Protestant, one Catholic, and one Jewish. While the ship sank, the four chaplains gave their own life jackets to four men without any, calmed the wounded, and preached strength to the survivors, linking arms and praying together as the ship submerged. In a time of great need, these chaplains showed that their shared commitment to the lives of others was stronger than any division of faith or background.

This same spirit is found in the countless Jewish Americans who, through their every day actions, work to provide a better life for future generations by joining hands with all who seek equality and progress. This month, we remember that the history and unique identity of Jewish Americans is part of the grand narrative of our country, forged in the friendships and shared wisdom between people of different faiths.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2011 as Jewish American Heritage Month. I call upon all Americans to visit

www.JewishHeritageMonth.gov to learn more about the heritage and contributions of Jewish Americans and to observe this month with appropriate programs, activities, and ceremonies.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11063
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8661 of April 29, 2011**

## National Foster Care Month, 2011

**By the President of the United States**

**A Proclamation**

Progress in America can be measured by the opportunities we pass on to our children. For nearly half a million youth in foster care across our country, the best path to success we can give them is the chance to experience a loving home where they can feel secure and thrive. During National Foster Care Month, we renew our commitment to ensuring a brighter future for foster youth, and we celebrate the selfless individuals who make a meaningful difference in their lives.

Young people in foster care are in the system through no fault of their own, and each of our Nation's children deserves a stable home and a devoted family. Strong support structures provide children with the environment needed to learn, grow, and reach their greatest potential. Permanence is critical to the future success of foster youth and must be a key component of foster care initiatives.

My Administration is committed to achieving security for every child and supporting adolescents in foster care as they transition to adulthood. The Permanency Innovations Initiative, spearheaded by the Department of Health and Human Services, is providing support to public-private partnerships focused on decreasing the number of children in long-term foster care. Over the next 5 years, this program will invest $100 million in new intervention strategies to help foster youth move into permanent homes, test new approaches to reducing time spent in foster care placements, and remove the most serious barriers to finding lasting, loving environments. Over 110,000 children in foster care today are waiting to be adopted. Across America, there are families who need these children as much as these children need families. I encourage those interested in adopting a child in need of a home to explore the life-changing resources available at www.AdoptUSKids.org.

We are also investing in the health and well-being of our young people in foster care. Through the American Recovery and Reinvestment Act, we have significantly increased funding for the Title IV–E adoption and foster care assistance program to provide safe and stable out-of-home care for children. As a result of the Healthy, Hunger-Free Kids Act I signed into law last year, all children enrolled in foster care automatically qualify for free meals in all Department of Agriculture child nutrition programs. Additionally, beginning in 2014, the Affordable Care Act will require States to extend Medicaid coverage up to age 26 for all youth who have aged out of the foster care system.

As a Nation, we all have a responsibility to remain persistent in the charge to provide the best care possible for children when they cannot remain in their own homes. During National Foster Care Month, we recognize the efforts of foster families, social workers, faith-based and community organizations, and others that are improving the lives of young people in foster care across our country, and I encourage all Americans to partake in efforts to serve these children in the year ahead.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2011 as National Foster Care Month. I call upon all Americans to observe this month by taking an active role in activities across our country that recognize not only these cherished children and youth, but also the commitment of so many that touch their lives at a most challenging time.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11064
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8662 of April 29, 2011**

## National Physical Fitness and Sports Month, 2011

**By the President of the United States of America**

**A Proclamation**

National Physical Fitness and Sports Month shines a spotlight on the important role physical activity plays in our Nation's health and wellness. Participation in sports can strengthen both body and mind, and all kinds of active pastimes can help improve physical and mental well-being. During this month, we rededicate ourselves to educating, engaging, and empowering Americans of all backgrounds and abilities to live a healthy lifestyle.

Through the President's Council on Fitness, Sports and Nutrition, my Administration is encouraging Americans to make physical fitness and nutritious eating part of their daily lives. Regular physical activity and good nutrition are essential to staying healthy. A balanced diet and exercise can help reduce the risk of developing chronic and costly diseases like heart disease, diabetes, and obesity. For more information on the President's Council on Fitness, Sports, and Nutrition, and for tips on exercise and nutrition, visit: www.Fitness.gov.

The health of our sons and daughters is key to our Nation's future. Unfortunately, childhood obesity rates in America have tripled over the past three decades, and nearly one in three children in our country is either overweight or obese. With the help of adults serving as role models and encouraging positive behaviors, we can give our children the healthy future they deserve and turn around these troubling statistics. Playing a game of basketball or taking a walk through a park with a child may seem like small steps, but they can have an immeasurable impact on the conduct and health of a young person. When children see people in their lives making healthful decisions and encouraging them to do the same, they are more likely to emulate those actions.

The First Lady's "*Let's Move!*" initiative is focused on solving the epidemic of childhood obesity within a generation by inspiring children to be physically active and empowering parents and caregivers to make healthy choices for their families. In its first year, "*Let's Move!*" made great strides in building awareness around the issue of childhood obesity, mobilizing support, garnering commitments across the country, and encouraging Americans from every sector of our society to get involved. This progress reminds us of what is possible when we work together as a Nation to promote healthy habits.

During National Physical Fitness and Sports Month, let us reaffirm our commitment to leading active lives and fostering healthy homes and communities for the next generation.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2011 as National Physical Fitness and Sports Month. I call upon the people of the United States to make daily physical activity, sports participation, and good nutrition a priority in their lives.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11065
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8663 of April 29, 2011**

## Older Americans Month, 2011

**By the President of the United States of America**

**A Proclamation**

Older Americans are now living longer, healthier, and richer lives than ever before. As the eldest of the baby boomers turn 65, our Nation can look forward to the contributions of a new generation of American seniors. Each year, we set aside the month of May to honor older Americans, celebrate their role in steering the course of our history, and recognize their valuable insights and wisdom.

The theme for this year's Older Americans Month, "Older Americans: Connecting the Community," reminds us that seniors are continually enriching lives and contributing to our country. This theme also highlights how technology, including social media and assistive devices, can help adults remain engaged in their communities and connected to friends and family who may live far away.

My Administration is committed to meeting the needs and aspirations of American seniors, both now and in the future. We are working to improve the health and well-being of older men and women with a focus on preventive care and community living. The historic Affordable Care Act gives America's seniors greater freedom and control over their health care. In addition to benefitting from more comprehensive prescription drug coverage, most people with Medicare will now be able to receive an annual wellness visit and many critical preventive services for free, including certain cancer screenings such as mammograms and colonoscopies.

Today, millions of our Nation's seniors are making a significant difference in society, strengthening our communities through their service. Older Americans support the arts and serve meals at soup kitchens. They mentor our children and stock the shelves at food pantries and libraries. Programs supported by the Corporation for National and Community Service and the Administration on Aging are working to connect men and women to community service, benefiting Americans of all ages. Interested individuals can visit www.SeniorCorps.gov for more information and local volunteer opportunities.

Having lived through many of our Nation's most challenging times, older Americans have shaped the story of America and secured the promise of our future. We are privileged to recognize these treasured citizens during Older Americans Month, and honor both the impact they have made and their accomplishments yet to come.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2011 as Older Americans Month. I invite Americans of all ages to acknowledge the contributions of older Americans during this month and throughout the year.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11066
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8664 of April 29, 2011**

## National Charter Schools Week, 2011

**By the President of the United States of America**

**A Proclamation**

In communities across our country, successful public charter schools help put children on the path to academic excellence by harnessing the power of new ideas, ground-breaking strategies, and the collective involvement of students, parents, teachers, and administrators. During National Charter Schools Week, we recognize these institutions of learning and renew our commitment to preparing our children with the knowledge and skills they will need to compete in the 21st century.

The unique flexibility afforded to charter schools places them at the forefront of innovation and in a unique position to spark a dialogue with other public schools on how to organize teaching and learning and enhance curricula. As part of our strategy for strengthening public education, my Administration has supported charter schools and rewarded successful innovation, encouraging States to improve their laws and policies so students can thrive.

Equally important to a world-class education system are actions taken by charter school authorizers and the charter community itself to strengthen effectiveness and deliver results that improve educational outcomes. My Administration will continue to encourage meaningful accountability, including closure of low-performing charter schools and replication of advances and reforms made at high-performing charter schools.

In order to win the global competition for new jobs and industries, we must win the global competition to educate our children. At their best, charter schools provide us with an opportunity to meet this challenge and produce the next generation of great American leaders.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 1 through May 7, 2011, as National Charter School Week. I commend our Nation's charter schools, teachers, and administrators, and I call on States and communities to support charter schools and the students they serve.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11067
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8665 of April 29, 2011**

## Law Day, U.S.A., 2011

**By the President of the United States of America**

**A Proclamation**

At the core of our Nation's values is our faith in the ideals of equality and justice under law. It is a belief embedded in our most cherished documents, and honored by President Eisenhower when he established Law Day in 1958 as "a day of national dedication to the principles of government under law." Each Law Day, we uphold our commitment to the rule of law and celebrate its protection of the freedoms we enjoy.

This year, we pay tribute to one of America's Founders and our second President, John Adams. As a young attorney in colonial Massachusetts, John Adams was asked to represent a British officer and eight British soldiers charged with firing into a crowd and killing five men in the Boston Massacre. In the face of mass public outcry and at great personal risk, he accepted the case and showed the world that America is a nation of laws and that a fair trial is the right of all people.

President Adams' legacy of dedication to fairness and the rights of the accused has been carried forward by members of the legal profession for more than two centuries. It is championed by those who represent the accused and exemplified by women and men who are devoted to securing equal rights for all, both in America and around the world.

On this Law Day, I encourage all Americans to celebrate and reflect upon the example left to us by President John Adams and our centuries of adherence to the rule of law. In so doing, we help ensure future generations will inherit and promote the ideals that help move our Nation forward.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, in accordance with Public Law 87–20, as amended, do hereby proclaim May 1, 2011, as Law Day, U.S.A. I call upon all Americans to acknowledge the importance of our Nation's legal and judicial systems with appropriate ceremonies and activities, and to display the flag of the United States in support of this national observance.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11068
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation 8666 of April 29, 2011**

## Loyalty Day, 2011

**By the President of the United States of America**

**A Proclamation**

When our Nation's Founders adopted the Declaration of Independence, they pledged to build a government that represented America's highest ideals, a Union that secured its people's sacred rights by "deriving [its] just powers from the consent of the governed." From the Revolutionary War to the formation of our young country, our Founders' commitment to this principle never wavered. In the fall of 1787, America launched its improbable experiment in democracy, embedding in our Constitution the core values of liberty, equality, and justice for all.

Throughout our proud history, Americans motivated by loyalty and fidelity to these principles have worked to perfect our Union. Our Constitution grants Americans unprecedented freedoms and opportunities. We are free to speak our minds, worship as we please, choose our leaders, and criticize them when we disagree. The liberties enshrined in our founding documents define us as a people and a Nation, ensuring that every American with the drive to work hard and play by the rules has the chance to build a better life for their children and grandchildren.

For over two centuries, Americans have looked with pride and devotion on a Nation that reflects its people's highest moral aspirations. On this day, we celebrate our brave men and women in uniform and honor those who gave their lives to keep our country safe and free. We also reflect on the contributions of patriotic civilians united by an understanding that citizenship is not just a collection of rights, but also a set of responsibilities.

The ideals upheld by our forebears have stirred the resolute devotion of the American people and inspired hope in the hearts of people from across the globe. With trust in a future that keeps faith with our history, we remain true to the promise of America and the spirit that unites us all.

In order to recognize the American spirit of loyalty and the sacrifices that so many have made for our Nation, the Congress, by Public Law 85–529 as amended, has designated May 1 of each year as "Loyalty Day." On this day, let us reaffirm our allegiance to the United States of America, our Constitution, and our founding values.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim May 1, 2011, as Loyalty Day. This Loyalty Day, I call upon all the people of the United States to join in support of this national observance, whether by displaying the flag of the United States or pledging allegiance to the Republic for which it stands.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11069
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Presidential Documents

**Proclamation of 8667 of April 29, 2011**

## National Day of Prayer, 2011

**By the President of the United States of America**

**A Proclamation**

Throughout our history, Americans have turned to prayer for strength, inspiration, and solidarity.

Prayer has played an important role in the American story and in shaping our Nation's leaders. President Abraham Lincoln once said, "I have been driven many times upon my knees by the overwhelming conviction that I had nowhere else to go. My own wisdom and that of all about me seemed insufficient for the day." The late Coretta Scott King recounted a particularly difficult night, during the Montgomery bus boycott, when her husband, the Reverend Dr. Martin Luther King, Jr., received a threatening phone call and prayed at the kitchen table, saying, "Lord, I have nothing left. I have nothing left. I have come to the point where I can't face it alone." Dr. King said, in that moment of prayer, he was filled with a sense of comfort and resolve, which his wife credited as a turning point in the civil rights movement.

It is thus fitting that, from the earliest years of our country's history, Congress and Presidents have set aside days to recognize the role prayer has played in so many definitive moments in our history. On this National Day of Prayer, let us follow the example of President Lincoln and Dr. King. Let us be thankful for the liberty that allows people of all faiths to worship or not worship according to the dictates of their conscience, and let us be thankful for the many other freedoms and blessings that we often take for granted.

Let us pray for the men and women of our Armed Forces and the many selfless sacrifices they and their families make on behalf of our Nation. Let us pray for the police officers, firefighters, and other first responders who put themselves in harm's way every day to protect their fellow citizens. And let us ask God for the sustenance and guidance for all of us to meet the great challenges we face as a Nation.

Let us remember in our thoughts and prayers those who have been affected by natural disasters at home and abroad in recent months, as well as those working tirelessly to render assistance. And, at a time when many around the world face uncertainty and unrest, but also hold resurgent hope for freedom and justice, let our prayers be with men and women everywhere who seek peace, human dignity, and the same rights we treasure here in America.

The Congress, by Public Law 100–307, as amended, has called on the President to issue each year a proclamation designating the first Thursday in May as a "National Day of Prayer."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim May 5, 2011, as a National Day of Prayer. I invite all citizens of our Nation, as their own faith or conscience directs them, to join me in giving thanks for the many blessings we enjoy, and I ask all people of faith to join me in asking God for guidance, mercy, and protection for our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–11070
Filed 5–4–11; 8:45 am]
Billing code 3195–W1–P

# Rules and Regulations

Federal Register
Vol. 76, No. 87
Thursday, May 5, 2011

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.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 28

**[AMS–CN–10–0111; CN–11–001]**

**RIN 0581–AD11**

## User Fees for 2011 Crop Cotton Classification Services to Growers

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Agricultural Marketing Service (AMS) will maintain user fees for cotton producers for 2011 crop cotton classification services under the Cotton Statistics and Estimates Act at the same level as in 2010. These fees are also authorized under the Cotton Standards Act of 1923. The 2010 crop user fee was $2.20 per bale, and this rule will continue the fee for the 2011 cotton crop at that same level. This fee and the existing reserve are sufficient to cover the costs of providing classification services for the 2011 crop, including costs for administration and supervision.

**DATES:** *Effective Date:* May 6, 2011.

**FOR FURTHER INFORMATION CONTACT:** Darryl Earnest, Deputy Administrator, Cotton and Tobacco Programs, AMS, USDA, Room 2635–S, STOP 0224, 1400 Independence Avenue, SW., Washington, DC 20250–0224. Telephone (202) 720–3193, facsimile (202) 690–1718, or e-mail *darryl.earnest@ams.usda.gov.*

**SUPPLEMENTARY INFORMATION:** A proposed rule detailing the revisions was published in the **Federal Register** on March 23, 2011 (76 FR 16321). A 15-day comment period was provided for interested persons to respond to the proposed rule. Three comments were received from three national cotton industry organizations in support of the service and the decision to maintain the fee at the level established for the 2010 crop.

### Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866; and, therefore has not been reviewed by the Office of Management and Budget (OMB).

### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

### Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities and has determined that its implementation will not have a significant economic impact on a substantial number of small businesses.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. There are an estimated 25,000 cotton growers in the U.S. who voluntarily use the AMS cotton classing services annually, and the majority of these cotton growers are small businesses under the criteria established by the Small Business Administration (13 CFR 121.201). Continuing the user fee at the 2010 crop level as stated will not significantly affect small businesses as defined in the RFA because:

(1) The fee represents a very small portion of the cost-per-unit currently borne by those entities utilizing the services. (The 2010 user fee for classification services was $2.20 per bale; the fee for the 2011 crop would be maintained at $2.20 per bale; the 2011 crop is estimated at 16,500,000 bales;

(2) The fee for services will not affect competition in the marketplace;

(3) The use of classification services is voluntary. For the 2010 crop, 17,611,000 bales were produced; and, almost all of these bales were voluntarily submitted by growers for the classification service; and

(4) Based on the average price paid to growers for cotton from the 2009 crop of 0.6210 cents per pound, 500 pound bales of cotton are worth an average of $311 each. The user fee for classification services, $2.20 per bale, is less than one percent of the value of an average bale of cotton.

### Paperwork Reduction Act

In compliance with OMB regulations (5 CFR part 1320) which implement the Paperwork Reduction Act (PRA) (44 U.S.C. 3501), the information collection requirements contained in the provisions amended by this final rule have been previously approved by OMB and were assigned OMB control number 0581–AC43.

*Fees for Classification Under the Cotton Statistics and Estimates Act of 1927*

This final rule maintains the user fee charged to producers for cotton classification at $2.20 per bale for the 2011 cotton crop. The 2011 user fee charged to farmers was calculated using new methodology, as was required by section 14201 of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234) (2008 Farm Bill). Prior to the changes made by the 2008 Farm Bill, the fee was determined using a user-fee formula mandated in the Uniform Cotton Classing Fees Act of 1987, as amended (Pub. L. 100–108, 728) (1987 Act). This formula used the previous year's base fee that was adjusted for inflation and economies of size (1 percent decrease/increase for every 100,000 bales above/below 12.5 million bales with maximum adjustment being ± 15 percent). The user fee was then further adjusted to comply with operating reserve constraints (between 10 and 25 percent of projected operating costs) specified by the 1987 Act.

Section 14201 of the 2008 Farm Bill provides that: (1) The Secretary shall make available cotton classification services to producers of cotton, and provide for the collection of classification fees from participating producers or agents that voluntarily agree to collect and remit the fees on behalf of the producers; (2) classification fees collected and the proceeds from the sales of samples submitted for classification shall, to the extent practicable, be used to pay the cost of the services provided, including administrative and supervisory costs; (3)

the Secretary shall announce a uniform classification fee and any applicable surcharge for classification services not later than June 1 of the year in which the fee applies; and (4) in establishing the amount of fees under this section, the Secretary shall consult with representatives of the United States cotton industry. At pages 313–314, the Joint Explanatory Statement of the committee of conference for section 14201 stated the expectation that the cotton classification fee would be established in the same manner as was applied during the 1992 through 2007 fiscal years. The classification fee should continue to be a basic, uniform fee per bale fee as determined necessary to maintain cost-effective cotton classification service. Further, in consulting with the cotton industry, the Secretary should demonstrate the level of fees necessary to maintain effective cotton classification services and provide the Department of Agriculture with an adequate operating reserve, while also working to limit adjustments in the year-to-year fee.

Under the provisions of section 14201, this final rule establishes a user fee (dollars per bale classed) for the 2011 cotton crop that, when combined with other sources of revenue, will result in projected revenues sufficient to reasonably cover budgeted costs—adjusted for inflation—and allow for adequate operating reserves to be maintained. Costs considered in this method include salaries, costs of equipment and supplies, and other overhead costs, such as facility costs and costs for administration and supervision. In addition to covering expected costs, the user fee is set such that projected revenues will generate an operating reserve adequate to effectively manage uncertainties related to crop size and cash-flow timing while meeting minimum reserve requirements set by the Agricultural Marketing Service, which require maintenance of a reserve fund amount equal to four months of projected operating costs.

Extensive consultations regarding the establishment of the classification fee with U.S. cotton industry representatives were held during the period from September 2010 through March 2011 during numerous publicly held meetings. Representatives of all segments of the cotton industry, including producers, ginners, bale storage facility operators, merchants, cooperatives, and textile manufacturers were addressed in various industry-sponsored forums.

The user fee established to be charged cotton producers for cotton classification in 2011 is $2.20 per bale, which is the same fee charged for the 2010 crop. This fee is based on the pre-season projection that 16.5 million bales will be classed by the United States Department of Agriculture during the 2011 crop year.

Accordingly, § 28.909, paragraph (b) will reflect the continuation of the cotton classification fee at $2.20 per bale.

As provided for in the 1987 Act, a 5 cent per bale discount will continue to be applied to voluntary centralized billing and collecting agents as specified in § 28.909(c).

Growers or their designated agents receiving classification data will continue to incur no additional fees if classification data is requested only once. The fee for each additional retrieval of classification data in § 28.910 will remain at 5 cents per bale. The fee in § 28.910(b) for an owner receiving classification data from the National database will remain at 5 cents per bale, and the minimum charge of $5.00 for services provided per monthly billing period will remain the same. The provisions of § 28.910(c) concerning the fee for new classification memoranda issued from the National Database for the business convenience of an owner without reclassification of the cotton will remain the same at 15 cents per bale or a minimum of $5.00 per sheet.

The fee for review classification in § 28.911 will remain at $2.20 per bale.

The fee for returning samples after classification in § 28.911 will remain at 50 cents per sample.

Pursuant to 5 U.S.C. 533, good cause exists for not postponing the effective date of this final rule until 30 days after publication in the **Federal Register** because this rule maintains uniform user fees for 2011 crop cotton classification services as mandated by the Cotton Statistics and Estimates Act, at the same level as 2010.

### List of Subjects in 7 CFR Part 28

Administrative practice and procedure, Cotton, Cotton samples, Grades, Market news, Reporting and recordkeeping requirements, Standards, Staples, Testing, Warehouses.

For the reasons set forth in the preamble, 7 CFR part 28 is amended to read as follows:

## PART 28—[AMENDED]

■ 1. The authority citation for 7 CFR part 28, Subpart D, continues to read as follows:

**Authority:** 7 U.S.C. 51–65; 7 U.S.C. 471–476.

■ 2. In § 28.909, paragraph (b) is republished to read as follows:

**§ 28.909 Costs.**

* * * * *

(b) The cost of High Volume Instrument (HVI) cotton classification service to producers is $2.20 per bale.

* * * * *

■ 3. In § 28.911, the last sentence of paragraph (a) is republished to read as follows:

**§ 28.911 Review classification.**

(a) * * * The fee for review classification is $2.20 per bale.

* * * * *

Dated: April 29, 2011.

**David R. Shipman,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2011–11047 Filed 5–4–11; 8:45 am]

BILLING CODE 3410–02–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2009–0113; Directorate Identifier 2008–NE–25–AD; Amendment 39–16602; AD 2011–04–02]**

**RIN 2120–AA64**

## Airworthiness Directives; Hamilton Sundstrand Propellers Model 247F Propellers

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

**ACTION:** Final rule; correction.

**SUMMARY:** The FAA is correcting an airworthiness directive (AD) that published in the **Federal Register**. That AD applies to the products listed above. The blade part number (P/N) 817370–1 in the **SUPPLEMENTARY INFORMATION**, the Applicability, and the Compliance sections is incorrect. We are also adding a statement to the Compliance section to clarify the applicability. This document corrects those errors. In all other respects, the original document remains the same.

**DATES:** This final rule is effective May 5, 2011.

**ADDRESSES:** 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 AD, the regulatory evaluation, any comments received, and other information. The address for the

Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Michael Schwetz, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7761; fax (781) 238–7170; *e-mail: michael.schwetz@faa.gov.*

**SUPPLEMENTARY INFORMATION:** Airworthiness Directive 2011–04–02, amendment 39–16602 (76 FR 7101, February 9, 2011), currently requires removing from service, certain part number and serial number propeller blades for Hamilton Sundstrand Propellers Model 247F Propellers.

As published, the propeller blade part number 817370–1 and ATR72–210 and ATR722–210E airplanes in the **SUPPLEMENTARY INFORMATION**, the Applicability, and the Compliance sections are incorrect.

No other part of the preamble or regulatory information has been changed; therefore, only the changed portion of the final rule is being published in the **Federal Register**.

The effective date of this AD remains March 16, 2011.

## Correction of Non-Regulatory Text

In the **Federal Register** of February 9, 2011, AD 2011–04–02; Amendment 39–16602 is corrected as follows:

On page 7101 in the third column, on line 26, **SUPPLEMENTARY INFORMATION**, change "817370–1" to "R817370–1".

On page 7101 in the third column, on line 33, **SUPPLEMENTARY INFORMATION**, change "817370–1" to "R817370–1".

## Correction of Regulatory Text

### § 39.13 [Corrected]

In the **Federal Register** of February 9, 2011, on page 7102, in the second column, paragraph (c) of AD 2011–04–02 is corrected to read as follows:

* * * * *

(c) This AD applies to Hamilton Sundstrand model 247F series propellers with blades part number (P/N) R817370–1, serial numbers (S/Ns) FR2018, FR2103, FR2108, FR2109, FR2111, FR2123, FR2183, FR2187, FR2262, FR2276 through FR2279 inclusive, FR 2398, FR2449 to FR2958 inclusive, FR20010710 to FR20010722 inclusive, and FR20010723RT to FR20020127RT inclusive, installed. Propeller blades reworked to Hamilton Sundstrand Service Bulletin 247F–61–54 with the part number re-marked as R817370R1 are in compliance with this AD.

* * * * *

In the **Federal Register** of February 9, 2011, on page 7102, in the second column, paragraph (f) of AD 2011–04–02 is corrected to read as follows:

* * * * *

**Removing Blades P/N R817370–1**

(f) Remove from service, blades P/N R817370–1, S/Ns FR2018, FR2103, FR2108, FR2109, FR2111, FR2123, FR2183, FR2187, FR2262, FR2276 through FR2279, FR2398, FR2449 to FR2958 inclusive, FR20010710 to FR20010722 inclusive, and FR20010723RT to FR20020127RT inclusive, within 30 days after the effective date of this AD.

* * * * *

Issued in Burlington, Massachusetts, on April 29, 2011.

**Peter A. White,**

*Acting Manager, Engine & Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 2011–10898 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–13–P**

---

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2010–1306; Directorate Identifier 2010–NM–112–AD; Amendment 39–16682; AD 2011–10–01]**

**RIN 2120–AA64**

## Airworthiness Directives; Dassault-Aviation Model FALCON 7X Airplanes

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A design review has revealed a potential dormant failure of the Ram Air Turbine (RAT) heating system. If this failure occurs, it could lead to the freezing of the RAT mechanism [the potential consequence of this heater being inoperative relates primarily to generator rotor/turbine assembly rotation—either the ability to rotate or to rotate at rated RPM for a given airspeed], and the consequent * * * [non-functioning] of the RAT when needed.

* * * * *

Non-functioning of the RAT could result in insufficient electrical power to operate the fly-by-wire system, and subsequent loss of control of the airplane. We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective June 9, 2011.

**ADDRESSES:** You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

**SUPPLEMENTARY INFORMATION:**

## Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on January 5, 2011 (76 FR 480). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

A design review has revealed a potential dormant failure of the Ram Air Turbine (RAT) heating system. If this failure occurs, it could lead to the freezing of the RAT mechanism [the potential consequence of this heater being inoperative relates primarily to generator rotor/turbine assembly rotation—either the ability to rotate or to rotate at rated RPM for a given airspeed], and the consequent * * * [non-functioning] of the RAT when needed.

The purpose of this AD is to require a repetitive functional test of the RAT heater * * *.

Non-functioning of the RAT could result in insufficient electrical power to operate the fly-by-wire system, and subsequent loss of control of the airplane. The corrective action is repairing. You may obtain further information by examining the MCAI in the AD docket.

## Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received.

### Request To Rephrase Summary and Reason Sections of the NPRM

Hamilton Sundstrand requested that we rephrase the Summary and Reason sections of the NPRM regarding the potential for RAT non-deployment due to freezing of the RAT mechanism. The commenter stated that the malfunction of the RAT heating system would not in itself prevent RAT deployment. The commenter stated that the heating system consists of only the RAT heater within the generator, and the potential consequence of this heater being inoperative relates primarily to freezing of the gap between the rotor and stator of the generator rotor/turbine assembly, leading to the RAT generator inability to rotate or to rotate at rated rotations per minute (RPM) for a given airspeed.

We agree to rephrase the Summary and Reason sections of the AD, as well as paragraph (e) of this AD, although the end result of the heater issue results in the identified insufficient electrical power to operate the fly-by-wire system, and subsequent loss of control of the airplane.

### Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

### Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

### Costs of Compliance

We estimate that this AD will affect 21 products of U.S. registry. We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $1,785, or $85 per product.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2011–10–01 Dassault-Aviation:** Amendment 39–16682. Docket No. FAA–2010–1306; Directorate Identifier 2010–NM–112–AD.

**Effective Date**

(a) This airworthiness directive (AD) becomes effective June 9, 2011.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to Dassault-Aviation Model FALCON 7X airplanes, certificated in any category, all serial numbers.

**Subject**

(d) Air Transport Association (ATA) of America Code 24: Electrical power.

**Reason**

(e) The mandatory continuing airworthiness information (MCAI) states:

A design review has revealed a potential dormant failure of the Ram Air Turbine (RAT) heating system. If this failure occurs, it could lead to the freezing of the RAT mechanism [the potential consequence of this heater being inoperative relates primarily to generator rotor/turbine assembly rotation—either the ability to rotate or to rotate at rated RPM for a given airspeed], and the consequent * * * [non-functioning] of the RAT when needed.

* * * * *

Non-functioning of the RAT could result in insufficient electrical power to operate the fly-by-wire system, and subsequent loss of control 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.

**Actions**

(g) At the applicable times specified in paragraph (g)(1) or (g)(2) of this AD, do a functional test of the RAT heater using a method approved by either the Manager,

International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent). Repeat the functional test of the RAT heater thereafter at the applicable time specified in paragraph (g)(1) or (g)(2) of this AD. If any functional test fails, before further flight, repair using a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA (or its delegated agent).

(1) For Falcon 7X airplanes on which modification M0305 has not been done and on which Dassault Service Bulletin 7X–018, dated March 6, 2009, has not been done: Within 650 flight hours after the effective date of this AD, do a functional test of the RAT heater and repeat the functional test of the RAT heater thereafter at intervals not to exceed 650 flight hours.

(2) For Falcon 7X airplanes on which modification M0305 has been done or on which Dassault Service Bulletin 7X–018, dated March 6, 2009, has been done: Within 1,900 flight hours after the effective date of this AD or after modification M0305 or Dassault Service Bulletin 7X–018, dated March 6, 2009, has been done, whichever occurs later, do a functional test of the RAT heater. Repeat the functional test of the RAT heater thereafter at intervals not to exceed 1,900 flight hours.

**Note 1:** Additional guidance for doing the functional test of the RAT heater required by paragraph (g) of this AD can be found in Task 24–50–25–720–801, Functional Test of the RAT Heater, dated January 16, 2009, of the Dassault Falcon 7X Aircraft Maintenance Manual (AMM).

**FAA AD Differences**

**Note 2:** This AD differs from the MCAI and/or service information as follows:

(1) The MCAI provides an option of inserting the MCAI into Chapter 5–40 of the Dassault Falcon 7X AMM, pending publication of the revised Chapter 5–40 of the Dassault Falcon 7X AMM. This AD does not have that option.

(2) The MCAI requires doing the actions in accordance with Task 24–50–25–720–801 of Chapter 5–40, of the Dassault Falcon 7X AMM. However, this AD requires that the actions be done using a method approved by the FAA or EASA (or its delegated agent).

**Other FAA AD Provisions**

(h) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

**Related Information**

(i) Refer to MCAI EASA Airworthiness Directive 2010–0033, dated March 3, 2010, for related information.

**Material Incorporated by Reference**

(j) None.

Issued in Renton, Washington, on April 20, 2011.

**Kalene C. Yanamura,**

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

[FR Doc. 2011–10690 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2011–0097; Airspace Docket No. 11–ANM–3]**

## Amendment of Class E Airspace; McCall, ID

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

**ACTION:** Final rule.

**SUMMARY:** This action will amend existing Class E Airspace at McCall Municipal Airport, McCall, ID. Decommissioning of the McCall Non-Directional Beacon (NDB) at McCall Municipal Airport has made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at the airport. This action also would correct the airport name from McCall Airport.

**DATES:** Effective date, 0901 UTC, August 25, 2011. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

**FOR FURTHER INFORMATION CONTACT:** Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

**SUPPLEMENTARY INFORMATION:**

### History

On February 14, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to amend controlled airspace at McCall, ID (76 FR 8324). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E Airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E Airspace designations listed in this document will be published subsequently in that Order.

### The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by amending Class E Airspace extending upward from 700 feet above the surface, at McCall Municipal Airport, for standard instrument approach procedures at the airport. Airspace reconfiguration is necessary due to the decommissioning of the McCall NDB and cancellation of the NDB approach. This also will correct the airport name from McCall Airport to McCall Municipal Airport.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with

prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at McCall Municipal Airport, McCall, ID.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

*Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

**ANM ID E5 McCall, ID [Amended]**

McCall Municipal Airport, ID

(Lat. 44°53′19″ N., long. 116°06′06″ W.)

That airspace extending upward from 700 feet above the surface within 5 miles west and 7 miles east of the 169° and 349° bearings from the McCall Municipal Airport extending from 21 miles south to 6 miles north of the McCall Municipal Airport; that airspace extending upward from 1,200 feet above the surface within a line from lat. 44°12′00″ N., long. 116°06′00″ W.; to lat. 45°05′00″ N., long. 117°28′00″ W.; to lat. 45°15′00″ N., long. 117°19′00″ W.; to lat. 45°05′30″ N., long. 115°52′00″ W.; to lat. 44°16′00″ N., long. 115°40′00″ W.; thence to the point of beginning.

Issued in Seattle, Washington, on 4/27/2011.

**Rob Henry,**

*Acting Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2011–10924 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 1

**RIN 0910–AG67**

**[Docket No. FDA–2011–N–0197]**

## Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Interim final rule; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations on administrative detention of food for human or animal consumption. As required by the FDA Food Safety Modernization Act (FSMA), FDA is issuing this interim final rule to change the criteria for ordering administrative detention of human or animal food. Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This will further help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.

**DATES:** *Effective date:* This interim final rule is effective July 3, 2011.

*Comment date:* Interested persons may submit either electronic or written comments on this interim final rule by August 3, 2011.

**FOR FURTHER INFORMATION CONTACT:** William A. Correll, Jr., Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1611.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2011–N–0197 and/or RIN number 0910–AG67, by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

**Written Submissions**

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Legal Background*

Each year about 48 million people (1 in 6 Americans) are sickened, 128,000 are hospitalized, and 3,000 die from food borne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 207 of FSMA amends the criteria for ordering administrative detention of human or animal food in section 304(h)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(h)(1)(A)). Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. Decisions regarding

whether FDA has a "reason to believe" a food is adulterated or misbranded would be made on a case by case basis because such decisions are fact specific. Section 207 also requires the Secretary of Health and Human Services to issue an interim final rule implementing this statutory change no later than 120 days following the date of enactment of FSMA and provides that the amendment made by section 207 takes effect 180 days after the date of enactment, which is July 3, 2011.

*B. Brief History of Administrative Detention*

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), was signed into law on June 12, 2002. Among other things, the Bioterrorism Act amended the FD&C Act by adding subsection (h) to section 304. This provision provided FDA the authority to order the detention of any article of food if during an inspection, examination, or investigation an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act also amended the FD&C Act by adding subsection (bb) to section 301 (21 U.S.C. 331), making it a prohibited act to move an article of food in violation of a detention order or to remove or alter any mark or label required by a detention order that identifies an article of food as detained.

In accordance with the Bioterrorism Act, FDA issued a notice of proposed rulemaking (proposed rule) in the **Federal Register** of May 9, 2003 (68 FR 25242), proposing procedures for the administrative detention of an article of food. In the **Federal Register** of June 4, 2004 (69 FR 31660), the Agency issued the final rule establishing the procedures for administrative detention, including among other provisions the criteria for ordering administrative detention. The administrative detention regulations have been codified at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart K (21 CFR part 1, subpart K). This interim final rule amends those regulations. Specifically, the interim final rule is amending §§ 1.378 and 1.393(a) by replacing the existing criteria used to order administrative detention with the new criteria required by section 207 of FSMA.

## II. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

FDA has examined the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB has determined that this is a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional costs per entity of this rule are negligible if any, the Agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this interim final rule to result in any 1-year expenditure that would meet or exceed this amount.

In the 2003 proposed rule, FDA analyzed the economic impact of the proposed rule to provide procedures for administrative detention of food for human or animal consumption under the Bioterrorism Act (68 FR 25242 at 25250). The Economic Impact Analysis of the June 4, 2004, final rule (69 FR 31660 at 31685) revised the analysis set forth in the 2003 proposed rule. The 2004 analysis explained that any costs and/or benefits of the rule can be generated only in those circumstances in which FDA would choose to order administrative detention instead of using other enforcement tools available to the Agency, such as requesting voluntary recall, instituting a seizure action, or referring the matter to State authorities. In the 2004 analysis, FDA noted that because administrative detention was a new enforcement tool, we were not able to directly estimate how often it would be used. FDA indirectly estimated the number of potential events that would trigger an administrative detention as a subset of other existing enforcement actions at the time. The analysis assumed that FDA would be likely to choose administrative detention only if it were the most effective enforcement tool available in a particular situation.

This Economic Impact Analysis explains and further revises the analysis set forth in the 2004 final rule by addressing the economic impact of the new requirement in section 207 of FSMA.

*A. Need for Regulation*

The need for this interim final rule arises from section 207 of FSMA which changed the criteria for ordering administrative detention of human or animal food. The current criteria in section 304(h)(1)(A) of the FD&C Act provide FDA the authority to order the detention of an article of food if during an inspection, examination, or investigation, an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. Section 207 of FSMA changes the criteria to allow the Agency to order detention if there is reason to believe that an article of food is adulterated or misbranded. The new criteria provide FDA enhanced authority to detain articles of food that may be adulterated or misbranded for 20 calendar days with a possible 10 calendar day extension if needed to initiate legal action under section 304 or 302 of the FD&C Act (21 U.S.C. 332). This authority will further help the Agency prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the food supply in the United States. This interim final rule implements section 207 of FSMA by amending 21 CFR part 1, subpart K, which is already in effect.

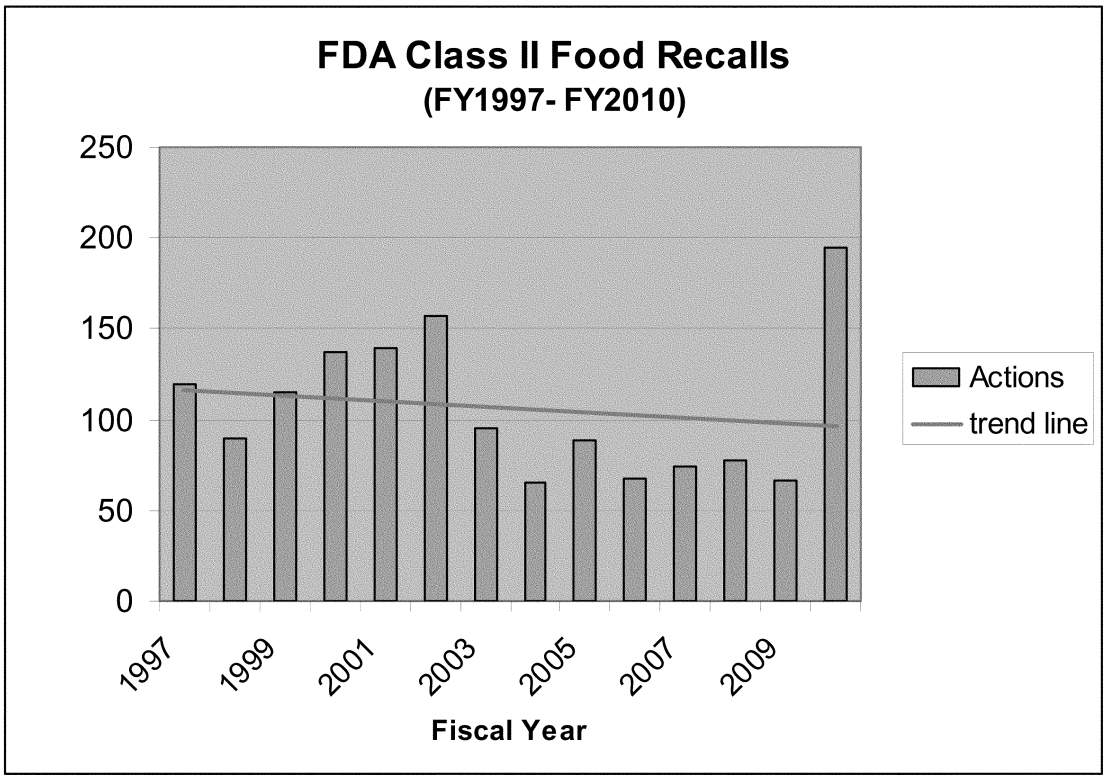
*B. Costs*

The economic impact analysis of the 2004 final rule estimated the costs of taking administrative detention actions relative to the costs of other

enforcement tools already available to FDA. Using these existing tools FDA could do the following: (1) Request a voluntary recall of the suspected product; (2) move directly to seize the food; or (3) refer the matter to State authorities. The 2004 analysis explained that the estimated number of potential events that would trigger an administrative detention could also trigger the existing enforcement actions. The number of actions was estimated as a range between 0 and 223 actions per year. The upper bound (223) is the sum of 184 Class I recalls, 16 direct seizures, and 23 or 10 percent of the referrals to State authorities in fiscal year 2002. This sum (223 actions) represents the upper bound number of times FDA anticipated using administrative detention, and the lower bound of 0 suggests the possibility that FDA may not order administrative detention at all in a given year. In the analysis FDA explained that the main costs of administrative detention are from the potential loss of the value of products detained that are not in fact adulterated. Although FDA did not know the fraction of detained food products that would prove not to be adulterated, FDA used 48 percent as an upper bound. This number represents the fraction of imported foods that we detain and later release. The lower bound used was 0 percent because FDA might only administratively detain adulterated food products. The total annual costs for the 2004 final rule were estimated to be between $0, if FDA never orders administrative detention, and $50 million, if FDA orders administrative detention against food products 48 percent of which are later determined not to be adulterated.

Since the Agency has had administrative detention authority, we have never administratively detained an article of food. Under the new criteria, we believe that we are more likely to use administrative detention against articles of food in situations which include, among others, where the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. These situations are analogous to the situations for ordering Class II recalls. FDA may choose to order administrative detention in a variety of situations, including Class II situations, therefore FDA has used the number of Class II recalls to estimate the costs and benefits of this interim final rule. Chart 1 below shows the number of Class II food recall actions reported in the last 14 years ranging from 65 to 195 (annual average of 160).

Chart 1. FDA Class II Food Recalls




To the extent that the changes made by this interim final rule provide FDA enhanced enforcement abilities in addition to other existing enforcement tools, the maximum number of times we can reasonably expect to order administrative detention in situations involving an article of food that meets the criteria for Class II recalls is bounded by the highest known number of times we have ordered a Class II recall. The highest number of Class II recall events in the last 14 years was 195 and the lowest number was 65. However, it is still possible that we may not use administrative detention in the event of a Class II recall situation. Therefore we estimate that the number of times we are likely to order administrative detention could range between 0 and 195 times per year. Although the 2004 cost estimates were based on the expectation that FDA would use administrative detention no more than 223 times per year, FDA has not used administrative detention as an enforcement tool. The upper bound cost

in the 2004 analysis was over estimated and given our present knowledge, we believe it is still likely to be an overestimate. By changing the criteria under which we can order administrative detention, we further reason that FDA will be more likely to order administrative detention a number of times greater than 0 but less than 195 times during any given year. We reason that any new potential costs attributable to this interim final rule are likely to be somewhat less than the upper bound costs previously estimated in the 2004 analysis, which were $50 million.

*C. Benefits*

The benefits of using administrative detention as a new enforcement tool were discussed in the Economic Impact Analysis of the 2004 final rule (68 FR 31660 at 31685) but were not definitively quantified because it was difficult to directly estimate how often FDA would order administrative detention of food. The primary benefits of administrative detention as described in the 2004 analysis are the value of the illnesses or deaths prevented because the Agency administratively detained food suspected of being adulterated. These benefits are generated if the following two conditions hold: (1) The food is in fact adulterated and (2) administrative detention prevents more illnesses or deaths than would have been prevented had we relied on our other enforcement tools. The more often these conditions hold, and the larger the amount of adulterated food administratively detained, the larger the estimated benefits of the final rule. The 2004 final rule analysis also discussed that additional benefits may be achieved in terms of deterrence to the extent that as the number of ordered administrative detentions increases so does the likelihood that adulterated products will not be shipped in the future. As described in the 2004 final rule, the expected benefits from new administrative detention authority depend upon FDA using administrative detention as an enforcement tool. Likewise, the expected benefits from this interim rule also depend on FDA using this authority. As mentioned in the cost analysis section, under the new criteria, FDA may choose to order administrative detention in a variety of situations, including Class II situations. We also reasoned that the expected number of future administrative detentions could increase as much as the number of Class II situations per year, which could be as many as 195. Either way, if FDA orders administrative detention 195 times in one year, the expected upper bound benefits are likely to be somewhat less than those described in the 2004 analysis as a result. At the same time, it is still possible that FDA will not use administrative detention as an enforcement tool in all of these situations, in which case the benefits would likely be 0 which is the same lower bound for benefits described in the 2004 analysis.

## III. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities.

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act this interim final rule will not have a significant impact on a substantial number of small businesses.

## IV. Paperwork Reduction Act of 1995

FDA concludes that the requirements of this interim final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3220).

## V. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Comments

The requirements in this interim final rule will be in effect July 3, 2011. FDA invites public comment on this interim final rule and will consider modifications to it based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

## PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.378 is revised to read as follows:

### § 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

■ 3. Section 1.393 is amended by revising paragraph (a) to read as follows:

### § 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has reason to believe that such

article of food is adulterated or misbranded.

* * * * *

Dated: April 28, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–10953 Filed 5–4–11; 8:45 am]

**BILLING CODE 4160–01–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 1

**[Docket No. FDA–2011–N–0179]**

**RIN 0910–AG65**

## Information Required in Prior Notice of Imported Food

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Interim final rule; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations on prior notice of imported food. As required by the FDA Food Safety Modernization Act, FDA is issuing this interim final rule to require an additional element of information in a prior notice of imported food. This change requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The new information can help FDA make better informed decisions in managing the potential risks of imported food into the United States.

**DATES:** This interim final rule is effective July 3, 2011. Interested persons may submit either electronic or written comments on this interim final rule by August 3, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by June 6, 2011 (see the "Paperwork Reduction Act of 1995" section of this document (section IV of this document).

**FOR FURTHER INFORMATION CONTACT:** Anthony C. Taube, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 12420 Parklawn Dr., ELEM–4051, Rockville, MD 20857, 866–521–2297.

**ADDRESSES:** You may submit comments on this interim final rule, identified by Docket No. FDA–2011–N–0179 and/or RIN number 0910–AG65 by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

**Written Submissions**

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. Legal Background*

Each year about 48 million people (1 in 6 Americans) are sickened, 128,000 are hospitalized, and 3,000 die from food borne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 304 of FSMA amends section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)) to require that additional information be provided in a prior notice of imported food submitted to FDA. This change requires a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, "any country to which the article has been refused entry." Section 304 of FSMA also requires the Secretary of Health and Human Services to issue an interim final rule implementing this statutory change no later than 120 days following the date of enactment of the legislation and provides that the amendment made by section 304 of FSMA takes effect 180 days after the date of enactment, which is July 3, 2011.

### *B. Brief History of Prior Notice*

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was signed into law on June 12, 2002. Among other things, the Bioterrorism Act amended the FD&C Act by adding section 801(m). This provision created the requirement that FDA receive certain information about imported foods before arrival in the United States. It also provided that an article of food imported or offered for import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA. The Secretary of Health and Human Services was directed to issue implementing regulations, after consultation with the Secretary of the Treasury, by December 12, 2003, requiring prior notice of imported food.

In accordance with the Bioterrorism Act, the Department of Health and Human Services (HHS) and the Department of the Treasury jointly published a notice of proposed rulemaking (proposed rule) in the **Federal Register** of February 3, 2003 (68 FR 5428), proposing requirements for submission of prior notice for human and animal food that is imported or offered for import into the United States. On October 10, 2003, HHS and the Department of Homeland Security (DHS) [1] issued the prior notice interim

[1] On May 15, 2003, the Treasury Department issued Treasury Department Order Number No. 100–16 delegating to the DHS its authority related to the customs revenue functions, with certain

final rule (2003 IFR) (68 FR 58974) (corrected by a technical amendment on February 2, 2004; 69 FR 4851). The 2003 IFR required that prior notice be submitted to FDA electronically using either the U.S. Customs and Border Protection (CBP) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (PNSI). The 2003 IFR also set forth the timeframes within which prior notice must be submitted.

In the **Federal Register** of November 7, 2008 (73 FR 66294), HHS and DHS published a final rule that made a number of changes to the 2003 IFR, including changes to certain provisions containing definitions, submission timeframes, and the information that must be submitted in a prior notice. The final rule went into effect on May 6, 2009. In calendar year 2010, 10,116,018 prior notices were submitted, 8,570,497 of which were submitted through the CBP system with the remaining 1,545,521 being submitted through the FDA system.

The prior notice regulations are codified at Title 21, Code of Federal Regulations (CFR) part 1, subpart I (21 CFR 1.276 to 1.285). Section 1.281 of the regulations describes the information that must be submitted in a prior notice. This interim final rule amends those regulations as required by section 304 of FSMA. Specifically, the interim final rule is amending paragraphs (a), (b), and (c) of § 1.281 to require that the prior notice include the identity of any country to which an article of food has been refused entry.

## II. Executive Orders 12866 and 13563: Cost Benefit Analysis

FDA has examined the impacts of this interim final rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB has determined that this is a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs per entity of this rule are small, the Agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The Economic Impact Analysis of the 2008 Final Rule: (1) Responded to comments received on the economic analysis of the 2003 IFR, (2) revised the analysis set forth in the 2003 IFR using new data, (3) presented an economic analysis of the leading alternative to the 2003 IFR using new data, and (4) explained the marginal benefits and costs of the final rule itself, relative to the 2003 IFR.

This Economic Impact Analysis further revises the analysis set forth in the 2008 final rule by addressing the economic impact of the new statutory requirement in FSMA.

### *A. Need for Regulation*

Section 304 of FSMA requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. Requiring notice of prior refusals allows FDA to better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. This interim final rule implements section 304 of FSMA by amending the rule that is already in effect.

### *B. Costs*

In the 2003 IFR (68 FR 58974 at 59027), FDA estimated that it takes 1 hour on average to submit the prior notices for each import entry, and this estimate was not revised for the 2008 final rule. In the final rule (73 FR 66294 at 66386), FDA estimated that, on average, one import entry includes 3.6 distinct food articles or lines and thus requires 3.6 prior notices per import entry. For the final rule the estimated cost of submitting prior notice was $75 per entry assuming 3.6 lines per entry. This estimate includes 45 minutes of an administrative worker's time to gather information to initially complete the prior notice, and then 15 minutes of a manager's time to verify that the information is correct.

Additional costs associated with implementing changes in this interim final rule will be borne by all persons who submit prior notice for an article of food that is imported or offered for import into the United States. These costs are estimated as the additional time it will take for a person to gather and verify the information about whether the article was refused entry and to enter the information into an electronic system. To the extent that the information is readily available and verifiable, we reason that it could take as few as 7 seconds to as many as 108 seconds per entry to do this. In 2010, FDA received 10,116,018 prior notices. In the 2008 economic analysis, FDA estimated an average of 3.6 prior notices (lines) per entry. For purposes of this analysis we consider 3.6 to be a likely approximation of the current number of lines per entry. By dividing the number of prior notices by the 3.6 lines per entry we estimate that there are currently 2.8 million imported food entries (10,116,018 divided by 3.6). By multiplying the number of entries by the additional seconds, we estimate the additional number of hours to provide the additional information for all prior notice submitters to be an average of about 45,000 hours per year. Table 1 of this document shows the possible additional time ranges that submitters may need in order to comply with this interim final rule. The economic impact analysis of the 2008 final rule estimated that the prior notice submissions for some entries (3.6 prior notices per entry) can take more than 1 hour to complete and others may take less than 1 hour. The amount of time needed to complete the submission for an entry can reasonably vary by several minutes. As seen in table 1 of this document, the

delineated exceptions in which the Treasury Department retained its authority. *See* Appendix to 19 CFR Part 0. The Treasury Department transferred to DHS its regulatory authority relating to the requirements for prior notices. Thus the Secretary of HHS issued the regulations implementing section 801(m) of the FD&C Act (21 U.S.C. 381(m)) jointly with the Secretary of Homeland Security. Similarly, this interim final rule is being issued jointly with the Secretary of Homeland Security.

additional average time of 58 seconds required to provide this information is estimated as the average of 7 and 108 seconds per entry. Since the additional time required to provide the new information is a small fraction of the variation in time it can take to complete the prior notice for an entry, the marginal cost for the additional 58 seconds (on average) that it would take to provide the additional information would be negligible.

TABLE 1—ESTIMATED RANGE OF TIME NEEDED FOR READING AND/OR ENTERING NEW INFORMATION

| | Calculation | | | |
|---|---|---|---|---|
| (A) Number of prior notices (lines) in 2010 * | A | 10,116,018 | 10,116,018 | 10,116,018 |
| (B) Lines per entry ** | B | 3.6 | 3.6 | 3.6 |
| (C) Food entries per year | C = A/B | 2,810,005 | 2,810,005 | 2,810,005 |
| (D) Number of submitters *** | D | 129,757 | 129,757 | 129,757 |
| (E) Entries per submitter | E = C/D | 22 | 22 | 22 |
| | | Lower bound | Average | Upper bound |
| (F) Additional time per line (seconds) | F | 2 | 16 | 30 |
| (G) Additional time per entry (seconds) | G = B × F | 7 | 58 | 108 |
| (H) Additional hours per entry | H = G/3,600 | 0.002 | 0.016 | 0.030 |
| (I) Additional hours per submitter per year | I = H × E | 0.04 | 0.35 | 0.65 |
| (J) Additional hours per year for all submitters | J = C × H | 5,620 | 44,960 | 84,300 |

* Data from FDA Prior Notice Center.
** Based on estimate in the **Federal Register** of November 7, 2008 (73 FR 66294 at 66386).
*** OASIS 2010 data.

*C. Benefits*

FDA's prior notice system provides us with enhanced knowledge of what articles of food are being imported or offered for import into the United States. Requiring prior notice of imported food shipments and defining the required data improves our ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Before prior notice was required, FDA received almost no advance notice information about food products entering the United States from foreign sources, or the location of the food's anticipated port of arrival. With the information required by prior notice, FDA does know what articles of food are being imported or offered for import before they arrive at the port. In the event of a credible threat for a specific product or a specific manufacturer or processor, for example, FDA will be able to mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals.

FDA's Prior Notice Center reviews prior notices and assesses the risk related to imported food shipments. FDA will be able to use the additional information from this interim final rule to better identify imported food shipments that may pose a safety or security risk to U.S. consumers. Personnel at the Prior Notice Center decide on a case-by-case basis whether the article of food needs to be held for examination upon arrival at the port. Having notice of an article of food imported or offered for import into the United States before it reaches a U.S. port allows FDA personnel to be ready at any time to respond to shipments that appear to pose a significant health risk to humans or animals.

## III. Small Entity Analysis

FDA examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities.

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. Because the compliance costs are negligible, FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act this interim final rule will not have a significant impact on a substantial number of small businesses.

## IV. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of these requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Information Required in Prior Notice of Imported Food.

*Description:* FDA is issuing regulations to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, "any country to which the article has been refused entry." Persons submitting prior notice will gather and verify information about whether the article was refused entry to any country and enter the information into an electronic system.

*Description of Respondents:* All persons who submit prior notice for an article of food that is imported or offered for import into the United States. FDA estimated that in 2010 there were about 129,757 prior notice submitters.

*Burden:* FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|---|---|---|---|---|---|
| 1.281 | 129,757 | 22 | 2.8 million | 0.016 | 44,960 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of annual responses is equivalent to the annual number of entries that are submitted. In 2010, FDA received 10,116,018 prior notices. By dividing the number of prior notices by the average number of lines per entry, we estimate 2.8 million entries. By further dividing the number of entries by the number of respondents, we estimate the average annual frequency per response to be 22. We estimate that it would take on average about 58 seconds (0.016 hours) for each respondent to submit the additional information as part of prior notice. By multiplying the number of entries by the additional 58 seconds, we estimate the total number of hours to provide the additional information to be an average of approximately 45,000 hours per year which also translates to about 20 minutes (0.35 hours) per year per respondent.

The information collection provisions for this interim final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. The requirements were approved and assigned OMB control number 0910–0683. This approval expires April 30, 2014. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Interested persons are requested to fax comments regarding information collection by June 6, 2011, to the Office of Information and Regulatory Affairs, OMB. 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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title, Information Required in Prior Notice of Imported Food.

## V. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Comments

The requirements in this interim final rule will be in effect on July 3, 2011. FDA invites public comment on this interim final rule, and will consider modifications to it based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

## PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.281 is amended by adding paragraphs (a)(18), (b)(12), and (c)(19) to read as follows:

### § 1.281 What information must be in a prior notice?

(a) * * *

(18) Any country to which the article has been refused entry.

(b) * * *

(12) Any country to which the article has been refused entry.

(c) * * *

(19) Any country to which the article has been refused entry.

Dated: April 29, 2011.

**Janet Napolitano,**

*Secretary of Homeland Security.*

Dated: April 29, 2011.

**Kathleen Sebelius,**

*Secretary of Health and Human Services.*

[FR Doc. 2011–10955 Filed 5–4–11; 8:45 am]

BILLING CODE 4160–01–P

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket No. USCG–2011–0097]**

**RIN 1625–AA00**

## Safety Zone; Blue Crab Festival Fireworks Display, Little River, Little River, SC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the waters of Little River in Little River, South Carolina during the Blue Crab Festival Fireworks Display on Friday,

May 13, 2011. The safety zone is necessary to protect the public from the hazards associated with launching fireworks over the navigable waters of the United States. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

**DATES:** This rule is effective from 9 p.m. until 10:30 p.m. on May 13, 2011.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0097 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0097 in the "Keyword" box, and then clicking "Search." They are also 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.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary final rule, call or e-mail Lieutenant Julie Blanchfield, Sector Charleston Waterways Management Division, Coast Guard; telephone 843–740–3184, e-mail *Julie.E.Blanchfield@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

## Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive notice of the Blue Crab Festival Fireworks Display with sufficient time to publish an NPRM and to receive public comments prior to the event. Any delay in the effective date of this rule would be contrary to the public interest because immediate action is needed to minimize the potential danger to the public during the fireworks display.

For the same reason discussed above, under 5 U.S.C. 553(d)(3) the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard will issue a Local Notice to Mariners and Broadcast Notice to Mariners to advise mariners of the restriction.

## Background and Purpose

On May 13, 2011, The Little River Blue Crab Festival Inc., in partnership with Zambelli Fireworks Manufacturing Co., will be conducting a fireworks display in Little River, South Carolina as part of the 30th Annual Blue Crab Festival. The fireworks will explode over the waters of Little River. The fireworks display is scheduled to commence at 9:30 p.m. and conclude at 9:45 p.m. This temporary safety zone is necessary to protect the public from the hazards associated with the launching of fireworks over navigable waters of the United States.

## Discussion of Rule

The safety zone encompasses certain waters of Little River in Little River, South Carolina. The safety zone will be enforced from 9 p.m. until 10:30 p.m. on May 13, 2011. The safety zone will be enforced from 9 p.m., 30 minutes prior to the scheduled commencement of the fireworks display at approximately 9:30 p.m., to ensure the safety zone is clear of persons and vessels. Enforcement of the safety zone will cease at 10:30 p.m., 45 minutes after the scheduled conclusion of the fireworks display, to account for possible delays.

Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within the safety zone may contact the Captain of the Port Charleston via telephone at 843–740–7050, or a designated representative via VHF radio on channel 16, to seek authorization. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

## Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

### Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, 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.

The economic impact of this rule is not significant for the following reasons: (1) The rule will be enforced for only one and a half hours; (2) vessel traffic in the area is expected to be minimal during the enforcement period; (3) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

### 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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of Little River encompassed within the safety zone from 9 p.m. until 10:30 p.m. on May 13, 2011. For the reasons discussed in the Executive Order 12866 and Executive Order 13563 section above, this rule will not have a significant economic impact on a substantial number of small entities.

**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 process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

**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).

**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.

**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 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.

**Taking of Private Property**

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

**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.

**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.

**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.

**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.

**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, 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.

**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 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 figure 2–1, paragraph (34)(g), of the Instruction. This rule involves establishing a temporary safety zone to protect the public on the waters of Little River that will be enforced for a total of one and a half hours. 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 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07–0097 to read as follows:

### § 165.T07–0097 Safety Zone; Blue Crab Festival Fireworks Display, Little River, Little River, SC.

(a) *Regulated Area.* The following regulated area is a safety zone: All waters of Little River encompassed within a 100 yard radius of position 33°52′08″ N, 78°36′42″ W. All coordinates are North American Datum.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the

Captain of the Port Charleston in the enforcement of the regulated area.

(c) *Regulations.*

(1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at 843–740–7050, or a designated representative via VHF radio on channel 16, to seek authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast notice to mariners, and on-scene designated representatives.

(d) *Effective Date.* This rule is effective from 9 p.m. until 10:30 p.m. on May 13, 2011.

Dated: April 26, 2011.

**Michael F. White Jr.,**

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

[FR Doc. 2011–10929 Filed 5–4–11; 8:45 am]

**BILLING CODE 9110–04–P**

---

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket No. USCG–2009–0324]**

**RIN 1625–AA00**

## Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard will establish a safety zone in San Pablo Bay for Coast Guard Use of Force Training exercises. This safety zone will be established to ensure the safety of the public and participating crews from potential hazards associated with fast-moving Coast Guard small boats and/or helicopters taking part in the exercise. Unauthorized persons or vessels will be prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative.

**DATES:** This rule is effective June 6, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0324 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–0324 in the "Keyword" box, and then clicking "Search." This material is also 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.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Lieutenant Simone Mausz, U.S. Coast Guard Sector San Francisco; telephone 415–399–7443, e-mail *D11-PF-MarineEvents@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

### Regulatory Information

On November 6, 2009, we published a Notice of Proposed Rulemaking (NPRM) entitled Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA in the **Federal Register** (74 FR 214). We received four comments on the proposed rule from the San Francisco Bay Conservation and Development Commission (BCDC), Audubon California, Beth Huning, and San Francisco Joint Venture. No public meetings were requested or held as part of this rulemaking.

### Basis and Purpose

The U.S. Coast Guard will establish a safety zone in the navigable waters of the San Pablo Bay, California that will apply to the navigable waters encompassing an area beginning at position 38°01′44″ N, 122°27′06″ W; 38°04′36″ N, 122°22′06″ W; 38°00′35″ N, 122°26′07″ W; 38°03′00″ N, 122°20′20″ W (NAD 83) and back to the starting point. U.S. Coast Guard Maritime Safety and Security Team (MSST) San Francisco, U.S. Coast Guard Air Station San Francisco, and various Coast Guard small boat stations will be conducting Use of Force training runs in the waters of San Pablo Bay. The exercises are designed to train and test Coast Guard personnel in the decision-making processes necessary to safely and effectively employ Use of Force from a small boat or helicopter during Homeland Security operations. The training will generally involve the use of several Coast Guard small boats and/or a helicopter to intercept fast-moving, evasive target vessels on the water. The small boat and helicopter crews will fire weapons at the target vessels using blank ammunition and catch bags to ensure that cartridges and other debris do not fall to the water. This safety zone is issued to establish a restricted area in San Pablo Bay around the training site.

### Background

The CG's primary missions include homeland security, search and rescue, and drug and environmental enforcement, and it is in the public interest for CG personnel to be trained and ready to serve the public at all times. Among the homeland security missions is port security training to develop the tactical qualifications and expertise necessary to fulfill this mission requirement. The small boats that conduct port security operations throughout San Francisco Bay are unable to conduct such training offshore due to conditions that often exceed the assets' operational parameters, frequent visibility restrictions, and unsuitability for the offshore environment. The San Pablo Bay safety zone provides an ideal location for the Coast Guard to conduct Use of Force training since it is at least 1.5 miles away from shore as well as a safe distance from shipping lanes, wildlife refuges, water trails and access points.

### Discussion of Comments and Changes

The CG conducted Use of Force training at this very same location in San Pablo Bay on average twice a month in 2009. The training went on as planned, without incidents or interference with public access, except for one occasion where the CG rescheduled one of its training sessions to avoid potential interference with a San Francisco Flyway Festival bird-watching group.

On July 29, 2009, the CG sent an email to various potentially interested parties including BCDC informing those parties of our intention to prepare a Notice of Proposed Rulemaking and a Categorical Exclusion Determination under NEPA for the establishment of a safety zone for Use of Force training in San Pablo Bay. In January 2010, in a letter to the CG, the San Francisco Bay Conservation and Development Commission raised concerns about the possible "effect on both motorized and non-motorized recreational boat traffic,

and on wildlife habitat that San Francisco Bay supports, especially the habitat of both migratory and non-migratory waterfowl as well as that of the wide variety of fish species" and requested the CG prepare a Consistency Determination or Negative Determination. In December and January, the CG received comments from the San Francisco Bay Joint Venture and Audubon California that addressed possible disturbances to waterfowl and referenced a study by the USGS confirming foraging areas in San Pablo Bay are used by diving ducks. In the Consistency Determination, the USGS was contacted and determined that the proposed area is too deep to affect any shorebirds. Additionally, a response from FWS reveals that the proposed safety zone is not expected to have any impacts on any of the endangered species in the San Pablo Bay that are under the jurisdiction of the FWS.

In December 2010, the CG completed and sent the Consistency Determination to BCDC that determined the proposed safety zone and AUF training in San Pablo Bay is consistent to the maximum extent practicable with the enforceable policies of BCDC's San Francisco Bay Plan. BCDC concurred with this determination in December 2010 and determined it was "complete" and acceptable.

**Regulatory Analyses**

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

**Regulatory Planning and Review**

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.

**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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

**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).

**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.

**Unfunded Mandates Reform Act**

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

**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.

**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.

**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.

**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.

**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.

**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, 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.

**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 this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. The rule involves establishing a safety zone. 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 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.1184 to read as follows:

### § 165–1184 Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA

(a) *Location.* This safety zone will apply to the navigable waters in the San Pablo Bay, and will encompass an area beginning at position 38°01′44″ N, 122°27′06″ W; 38°04′36″ N, 122°22′06″ W; 38°00′35″ N, 122°26′07″ W; 38°03′00″ N, 122°20′20″ W (NAD 83) and back to the starting point.

(b) *Enforcement.* The Coast Guard will notify the public via a Broadcast Notice to Mariners prior to the activation of this safety zone. The safety zone will be activated on average two times per month, but could be activated up to six times per month. It will be in effect for approximately three hours from 9 a.m. to 11:59 p.m. If the exercises conclude prior to the scheduled termination time, the Coast Guard will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners. Persons and vessels may also contact the Coast Guard to determine the status of the safety zone on VHF–16 or the 24-hour Command Center via telephone at (415) 399–3547.

(c) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or the 24-hour Command Center via telephone at (415) 399–3547.

Dated: March 31, 2011.

**Cynthia L. Stowe,**

*Captain, U.S. Coast Guard, Captain of the Port San Francisco.*

[FR Doc. 2011–10930 Filed 5–4–11; 8:45 am]

**BILLING CODE 9110–04–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Part 482 and 485

**[CMS–3227–F]**

**RIN 0938–AQ05**

## Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule will revise the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs). The final rule will implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. Currently, a hospital or CAH receiving telemedicine services must go through a burdensome credentialing and privileging process for each physician and practitioner who will be providing telemedicine services to its patients. This final rule will remove this undue hardship and financial burden.

**DATES:** *Effective Date:* These regulations are effective on July 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** CDR Scott Cooper, USPHS, (410) 786–9465. Jeannie Miller, (410) 786–3164.

**SUPPLEMENTARY INFORMATION:**

### I. Background

This final rule reflects the Centers for Medicare and Medicaid Services' commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review." The rule revises the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs) to: (1) Make current Federal requirements more flexible for rural and/or small hospitals and for CAHs; and (2) encourage innovative approaches to patient-service delivery.

CMS regulations currently require a hospital to have a credentialing and privileging process for all physicians and practitioners providing services to its patients. The regulations require a hospital's governing body to appoint all practitioners to its hospital medical staff and to grant privileges using the recommendations of its medical staff. In turn, the hospital medical staff must use a credentialing and privileging process, provided for in CMS regulations, to make its recommendations. CMS requirements do not take into account those practitioners providing only telemedicine services to patients. Consequently, hospitals apply the credentialing and privileging requirements as if all practitioners were onsite. This traditional and limited approach fails to embrace new methods and technologies for service delivery that may improve patient access to high quality care.

This final rule will permit hospitals and CAHs to implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. The removal of unnecessary barriers to the use of telemedicine may enable patients to receive medically necessary interventions in a more timely manner. It may enhance patient follow-up in the management of chronic disease conditions. These revisions will provide more flexibility to small hospitals and CAHs in rural areas and regions with a limited supply of primary care and specialized providers. In certain instances, telemedicine may be a cost-effective alternative to traditional service delivery approaches and, most

importantly, may improve patient outcomes and satisfaction.

As noted above, the current Medicare Hospital conditions of participation (CoPs) for credentialing and privileging of medical staff at 42 CFR § 482.12(a)(2) and § 482.22(a)(2) require the governing body of the hospital to make all privileging decisions based upon the recommendations of its medical staff after the medical staff has thoroughly examined and verified the credentials of practitioners applying for privileges, and after the staff has applied specific criteria to determine whether an individual practitioner should be privileged at the hospital. The current critical access hospital (CAH) CoPs at 42 CFR 485.616(b) similarly require every CAH that is a member of a rural health network to have an agreement for review of physicians and practitioners seeking privileges at the CAH. The agreement must be with a hospital that is a member of the network, a Medicare Quality Improvement Organization (QIO), or another qualified entity identified in the State's rural health plan. In addition, the services provided by each doctor of medicine or osteopathy at the CAH must be evaluated by one of these same three types of outside parties. These requirements apply to all physicians and practitioners seeking privileges at the hospital or CAH, respectively, regardless of whether services will be provided in person and onsite at the hospital or CAH, or remotely through a telecommunications system.

While hospitals may use third-party credentialing verification organizations to compile and verify the credentials of practitioners applying for privileges, the hospital's governing body is still legally responsible for all privileging decisions. Similarly, each CAH is required to have its privileging decisions made by either its governing body or the person responsible for the CAH.

In the past, hospitals that were accredited by The Joint Commission (TJC) were deemed to have met the Medicare CoPs, including the credentialing and privileging requirements, under TJC's statutory deeming authority. Section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA), terminated the statutory recognition of TJC's hospital accreditation program, effective July 15, 2010. The law now requires TJC to secure CMS approval of its standards in order to confer Medicare deemed status on hospitals.

Under its previous statutory deeming authority, TJC has permitted "privileging by proxy," which had allowed TJC-accredited hospitals to privilege "distant-site" (as that term is defined at section 1834(m)(4)(A) of the Social Security Act (the Act)) physicians and practitioners. TJC privileging by proxy standards allowed for one TJC-accredited facility to accept the privileging decisions of another TJC-accredited facility utilizing a streamlined independent determination process, rather than making an individualized decision based on the practitioner's credentials and record. Even though they were TJC-accredited, hospitals that have used this method to privilege distant-site medical staff technically did not meet the CMS requirements that applied to other hospitals. When we learned of specific instances of such noncompliance through on-site validation surveys by State survey agencies, the hospital was required to change its policies to come into compliance. However, the majority of Joint Commission-accredited hospitals were not routinely subjected to validation surveys of their privileging practices, and it appears that many of them were employing the practices permitted by The Joint Commission.

With the loss of statutory status for its hospital accreditation program, The Joint Commission is now required to conform its accreditation program to the Medicare requirements, including the provisions governing credentialing and privileging, and enforce it accordingly in all of its accredited hospitals.

TJC-accredited hospitals, therefore, have been concerned that they may be unable to meet the long-standing CMS privileging requirements while sustaining their current telemedicine agreements. Small hospital medical staffs, in particular, are concerned about the burden of privileging hundreds of specialty physicians and practitioners that large academic medical centers make available to them. Because of the complexity of the issues, and to minimize disruption to accredited hospitals and CAHs, we decided to allow additional time for The Joint Commission to ensure conformity to the Medicare Conditions of Participation (CoPs). Accordingly, we notified TJC that we would expect implementation of its new accreditation standards no later than the effective date of this final rule.

Upon reflection, we came to the conclusion that our present requirement is a duplicative and burdensome process for physicians, practitioners, and the hospitals involved in this process, particularly small hospitals and CAHs, which often lack adequate resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services. In addition to the costs involved, small hospitals and CAHs often do not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide through telemedicine services. The public comments we received on the proposed rule, which we discuss in this final rule, overwhelmingly reinforced this perception.

## II. Provisions of Proposed Rule and Response to Comments

We published a proposed rule in the **Federal Register** on May 26, 2010 (75 FR 29479). In that rule, we proposed to revise both the hospital and CAH credentialing and privileging requirements to eliminate regulatory impediments and to allow for the advancement of telemedicine nationwide.

While telemedicine is included under the broader scope of telehealth, we consider telemedicine, as the term is used in the proposed rule and as we use it here in this final rule, to be the provision of clinical services to patients by practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the hospital or CAH patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services. "Simultaneously" would mean that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the telemedicine practitioner, similar to the actions of an on-site practitioner when called in by a patient's attending physician to see the patient. Generally, payment for telehealth services under section 1834(m) of the Act, distinguished from "telemedicine services" as discussed here, requires that services be provided to a patient in real time while the patient is physically present at the originating site. "Non-simultaneously" means that while the telemedicine practitioner still provides clinical services to the patient upon a formal request from the patient's attending physician, such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in "real time." This would be similar to the services

provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings. In fact, the actual location (distant-site versus on-site) of the radiologist performing the readings is often the major distinguishing factor between in-house radiologists and teleradiologists. These services are not payable as "telehealth services" under section 1834(m) of the Act because in addition to not meeting the "real time" requirements, these services do not meet the telehealth patient location requirements also contained under this section of the Act and upon which the CMS telehealth payment requirements are based.

We also indicated that the proposed revisions would preserve and strengthen the core values of the credentialing and privileging process for all hospitals, provide accountability to all patients, and assure that medical staff are privileged to provide services in the hospital based on evaluation of the practitioner's medical competency.

We provided a 60-day public comment period in which we received a total of 113 timely comments from hospitals, CAHs, physicians, professional organizations, providers of teleradiology interpretation services, other specialty practitioners providing telemedicine services, and hospital systems. Overall, the majority of commenters were supportive of the proposed changes, but many also raised several separate issues. The most common comment expressed was that the proposed regulation did not go far enough in restructuring privileging and credentialing requirements for telemedicine providers. Summaries of the major issues and our responses are set forth below.

*Hospital CoPs (§ 482.12 and § 482.22)*

The proposed revisions to the hospital CoPs for the credentialing and privileging of telemedicine physicians and practitioners are contained within two separate CoPs: § 482.12, "Governing body," and § 482.22, "Medical staff."

For the Governing body CoP, we proposed to add a new paragraph, § 482.12(a)(8), which would require the hospital's governing body to ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a Medicare-participating hospital (the "distant-site" hospital as defined at section 1834(m)(4)(A) of the Act), the agreement must specify that it is the responsibility of the governing body of the distant-site hospital providing the telemedicine services to meet the existing requirements in § 482.12(a)(1) through (a)(7) with regard to its physicians and practitioners who are providing telemedicine services. These existing provisions cover the distant-site hospital's governing body responsibilities for its medical staff that all Medicare-participating hospitals must meet.

We proposed at § 482.12(a)(8) to allow the governing body of the hospital whose patients are receiving the telemedicine services to grant privileges based on its medical staff recommendations, which would rely on information provided by the distant-site hospital, as a more efficient means of privileging the individual distant-site physicians and practitioners providing the services.

This provision would be accompanied by the proposed requirement in the "Medical staff" CoP at § 482.22(a)(3), which would provide the basis on which the hospital's governing body, through its agreement as noted above, could choose to have its medical staff rely upon information furnished by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. We specified that this option would allow the hospital's medical staff to rely upon the credentialing and privileging decisions of the distant-site hospital in lieu of the current requirements at § 482.22(a)(1) and (a)(2), which require the hospital's medical staff to conduct individual appraisals of its members and examine the credentials of each candidate in order to make a privileging recommendation to the governing body. In the proposed rule, we stated that this option would not prohibit a hospital's medical staff from continuing to perform its own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the traditional credentialing and privileging process required under the current regulations. Our intent of this proposed requirement was to relieve burden for smaller hospitals by providing for a less duplicative and more efficient privileging scheme with regard to physicians and practitioners providing telemedicine services.

However, in an effort to ensure accountability to the process, we proposed within this same provision (§ 482.22(a)(3)) that the hospital, in order to choose this less burdensome option for privileging, would have to ensure that—(1) The distant-site hospital providing the telemedicine services was another Medicare-participating hospital; (2) the individual distant-site physician or practitioner was privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provides a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner held a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located; and (4) with respect to a distant-site physician or practitioner granted privileges by the hospital, the originating-site hospital had evidence of an internal review of the distant-site physician's or practitioner's performance under these telemedicine privileges and sent the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner. We also proposed that the information sent for use in the periodic appraisal would, at a minimum, have to include all adverse events that did result or could have resulted from telemedicine services provided by the distant-site physician or practitioner to the originating hospital's patients, and all complaints the originating site hospital had received about the distant-site physician or practitioner.

Within the revisions to the hospital CoPs, we also proposed that additional language be added to the current requirement at § 482.22(c)(6), which requires that the hospital's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges. We proposed to add language to stipulate that in cases where distant-site physicians and practitioners were requesting privileges to furnish telemedicine services through an agreement between hospitals, the criteria for determining those privileges and the procedure for applying the criteria would be subject to the proposed requirements at § 482.12(a)(8) and § 482.22(a)(3).

*Comment:* We received several comments that are outside the scope of this rule. Specifically, several commenters requested that we consider establishing a central credentialing bank that would provide overall clearance for telemedicine services, possibly through regional compacts or reciprocity agreements. A number of commenters recommended that all TJC-accredited facilities (including hospitals) be able to share credentialing. A few commenters suggested that we establish a national licensing process for physicians and other practitioners in order to ease the

burden associated with credentialing and privileging.

*Response:* We thank all commenters for their comments, but are not responding to these comments here because they are outside the scope of this rulemaking.

*Comment:* The majority of commenters supported the changes proposed. However, most of these commenters felt that the revisions to the CoPs did not go far enough in addressing the burdens borne by those small hospitals and CAHs that, through agreements and/or contracts, use the telemedicine services of practitioners who are not part of the medical staff of a Medicare-participating hospital. The commenters pointed out that, under the proposed requirements, small hospitals and CAHs would still be required to perform the duplicative and burdensome process of credentialing and privileging practitioners that provide telemedicine services through a distant-site telemedicine entity that is not a hospital.

Several commenters provided examples of simultaneous and non-simultaneous telemedicine services, such as teleradiology, teleICU, teleneurology, and telepathology, where distant-site physicians and practitioners provide radiology, ICU/critical care medicine, neurology, and pathology services to hospital and CAH patients under the auspices of a non-hospital entity that is nationally accredited as having met a national accreditation organization's (AO) standards for credentialing and privileging of medical staff (in addition to other standards established by the national AO). Many commenters specifically mentioned the TJC's Ambulatory Care accreditation program, which surveys and accredits nearly 2,000 ambulatory care entities (of which these non-hospital telemedicine entities, along with ambulatory surgery centers, imaging centers, and dentist offices, are included) out of approximately 30,500 ambulatory care entities nationwide. Commenters suggested that CMS include these telemedicine entities in the requirements so that small hospitals and CAHs would be able to enter into agreements with them.

Many commenters stated that including the medical staff of these distant-site telemedicine entities as part of an optional and streamlined credentialing and privileging process, as we have already proposed for distant-site Medicare-participating hospitals, would increase the overall effectiveness of this rule. They posited that if the goals of this rule were to greatly improve patient care by increasing patient access to specialty services and reduce the burdens and costs for hospitals and CAHs by removing the impediment of the traditional credentialing and privileging process, then excluding distant-site telemedicine entities would severely limit such goals. In addition, commenters stated that telemedicine practitioners are part of a growing national network that is supported by both hospitals and non-hospital telemedicine entities.

*Response:* We appreciate the comments supporting the rule as well as the suggestions for improving the rule. When drafting the proposed rule, we gave much thought and consideration to ideas that were similar to those that commenters have expressed regarding the inclusion of non-hospital telemedicine entities as part of these requirements. After careful consideration of the comments and the options available to us for revising the proposed rule, we have concluded that it is important that the medical staff of a distant-site telemedicine entity, which is not a Medicare-participating hospital, be included in an optional and streamlined credentialing and privileging process for those hospitals and CAHs electing to enter into agreements for telemedicine services with such entities. We believe that this inclusion would draw us significantly closer to accomplishing the stated goals of this rule, which are—(1) Increasing patient access to specialty services; and (2) reducing burden on small hospitals and CAHs.

However, this decision presented significant challenges to us as we sought to balance our desire to achieve the worthy goals noted above with the equally important mission of ensuring, through our regulatory authority and responsibility, the health and safety of all patients. As we contemplated revisions to the proposed rule that would broaden its application, the most significant challenge that we faced was reconciling inclusion of distant-site telemedicine entities into this new streamlined process without CMS having any regulatory or oversight authority over these entities. We also note that we do not have any oversight or approval process for accreditation programs (such as that of TJC) for these entities. This situation differs greatly from our proposed inclusion of other Medicare-participating hospitals, where we are assured through the State survey or Medicare-approved accreditation processes that distant-site hospitals providing telemedicine services are in compliance with our CoPs, particularly those pertaining to credentialing and privileging of medical staff.

In addition, we note that there is no statutory definition for a telemedicine entity contained in the Act. Therefore, for the purposes of this rule, we are defining a distant-site telemedicine entity as one that—(1) Provides telemedicine services; (2) is not a Medicare-participating hospital (therefore, a non-Medicare-participating hospital that provides telemedicine services would be considered a distant-site telemedicine entity also); and (3) provides contracted services in a manner that enables a hospital or CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital or CAH.

Taking all of these factors into consideration, we came to the conclusion that any revisions to the regulatory language finalized here would need to hold distant-site telemedicine entities accountable to the originating-site hospital for meeting CMS practitioner credentialing and privileging standards. Likewise, hospitals and CAHs using telemedicine services will need to provide, upon request when surveyed, the most current telemedicine services agreement showing that the distant-site entities providing the services are required to comply with the CMS standards (even though CMS has no direct authority over those entities) in order for the hospital or CAH to make use of the more streamlined process when credentialing and privileging practitioners from these distant-site telemedicine entities. Similar to our regulations proposed for hospitals and CAHs using the telemedicine services of distant-site Medicare-participating hospitals, the written agreement between the hospital or CAH and the distant-site telemedicine entity will be the foundation for ensuring accountability on both sides. However, due to the differences already discussed between Medicare-participating distant-site hospitals providing telemedicine services and distant-site telemedicine entities providing similar services, there must also be differences in the way the regulations are written.

Therefore, in addition to the proposed requirements, we are also finalizing new provisions that will apply to the credentialing and privileging process and the agreements between hospitals or CAHs and distant-site telemedicine entities (§ 482.12(a)(9) and § 482.22(a)(4) for hospitals; § 485.616(c)(3) and (c)(4) for CAHs). These new provisions will require the governing body of the hospital (or the CAH's governing body

or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the hospital (or CAH) to comply with all applicable conditions of participation and standards. For the contracted services, the applicable CoPs and standards include, but are not limited to, the credentialing and privileging requirements for distant-site physicians and practitioners providing telemedicine services.

For hospitals, we have directly linked this new requirement to an existing requirement at § 482.12(e), which requires the hospital's governing body to ensure that a contractor of services to the hospital (in this case, the distant-site telemedicine entity) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for contracted services. The applicable conditions of participation and standards would include the credentialing and privileging requirements as currently found at § 482.12(a)(1) through (a)(7) of this section and would apply (in accordance with the hospital's policy) to the telemedicine entity's physicians and practitioners that provide telemedicine services to the hospital's patients.

For CAHs, we also linked these new requirements to an existing requirement (at § 485.635(c)(4)) that, like § 482.12(e) for hospitals, pertains to contactors of services and the CAH governing body's (or responsible individual's) obligation to ensure that contracted services are furnished in a manner that enables the CAH to meet all applicable conditions of participation and standards. The standard also contains a provision, at § 485.635(c)(1), that requires the CAH to have agreements or arrangements with one or more *Medicare-participating* providers or suppliers in order to furnish other services to its patients. We see the "Medicare-participating" modifying provision as an impediment to the type of agreements that CAHs may now have with distant-site telemedicine entities under this final rule. Since these entities are not considered Medicare-participating providers or suppliers by CMS, we needed to make an exception to the requirement at § 485.635(c)(1). Therefore, in this final rule, we are adding a new paragraph at § 485.635(c)(5) to provide an exception to this "Medicare-participating" requirement for telemedicine entities in cases where a written agreement exists between a CAH and such entity.

We believe that the combination of the new requirements, as finalized here, and the existing requirements cited above and in the final requirements, which place responsibility on hospitals and CAHs to ensure that contracted services fully enable them to meet the CoPs, will allow hospitals and CAHs to make full use of the telemedicine services offered by non-hospital telemedicine entities without duplicating the credentialing and privileging process. This final rule will now allow hospitals and CAHs to take advantage of these streamlined credentialing and privileging options when using the telemedicine services of other Medicare-participating hospitals, non-Medicare-participating telemedicine entities, or a combination of both types of service providers. And with these new requirements dually aimed at increasing patient access to care and reducing the regulatory burden on hospitals and CAHs, CMS believes that the potential of telemedicine can be more fully realized while still maintaining essential health and safety protections.

*Comment:* A number of commenters stated that practitioner-to-practitioner "tele-emergency" video communications should not require credentialing and privileging of the distant-site practitioner. Another commenter requested that CMS consider that full credentialing and privileging should not be required when telemedicine services are only consultative in nature. However, the commenter did not clarify what he or she meant by "consultative" services.

*Response:* Any time services are provided to a patient in a hospital or CAH, the requirements regarding the credentialing and privileging of the practitioners providing the services would apply, whether such practitioners were onsite or available to the patient through telemedicine services.

Regarding "consultative" services as mentioned by the commenter, it is important to distinguish between informal consultation among practitioners (traditionally known as a "curbside consult"), and the furnishing of professional consultation services, which would include providing medical diagnosis and treatment recommendations to patients after a formal request for such services by the practitioner responsible for patient's care. The CMS privileging requirements do not apply in instances where, for example, the attending physician of record seeks informal advice from another physician(s) by whatever communications media the physicians choose to use. The physician whose advice is being sought is not providing clinical services to the patient, but is merely rendering an informal opinion on the patients' condition to the patient's attending physician, who may or may not make use of the opinion when treating the patient. Such discussions between medical professionals occur on a routine basis in hospitals across the nation and do not require that the practitioners involved be privileged at the same hospital in order for this exchange of medical opinions to take place; in fact, we believe such communications may promote safer, more effective care for patients. Only the attending physician, who is providing clinical services to the patient, would need to be privileged by the hospital or CAH to provide such services. However, a formal consult provided by a specialty or other type of practitioner, where the hospital or CAH patient receives clinical services from the specialty practitioner after the patient's attending physician requests such services be provided (either simultaneously as is often the case with teleICU services, or non-simultaneously as may be the case with many teleradiology services), would require that the practitioner is privileged to do so at the hospital or CAH where the patient is located.

*Comment:* One commenter stated that to further reduce burden, we should consider a "contract" approach to credentialing and privileging for telemedicine services, particularly for consultations requested by referring providers. Some commenters stated that such agreements or contracts, which essentially allow for credentialing and privileging by proxy, leave hospitals vulnerable to legal liabilities and risks and, therefore, should be prohibited under this rule. Another commenter suggested that, with regard to legal risks and liabilities, mandatory language addressing these issues should be required within the written agreements between distant-site hospitals and the hospital or CAH where the patient receives the services.

*Response:* The requirements, as proposed, are aimed at reducing the telemedicine credentialing and privileging burden for small hospitals and CAHs by specifically allowing for contracts or, as we refer to them, "agreements," between a distant-site hospital or telemedicine entity providing the telemedicine services and a hospital or CAH that uses these services for the benefit of its patients. In these agreements, it is the responsibility of the hospital or CAH using the services to ensure that the specifics of

the proposed requirements in this rule are explicitly laid out before entering into such an arrangement. Along these lines, we have corrected an oversight in the proposed rule and have revised the requirements in this final rule to clarify that these agreements must be "written." It has always been the intent of this rule to allow for hospitals and CAHs to have the option of credentialing and privileging the distant-site telemedicine practitioners using the traditional process. Hospitals and CAHs electing to use the traditional credentialing and privileging process must not be compelled by a distant-site telemedicine hospital (or distant-site telemedicine entity) to enter into an agreement that requires the use of the more streamlined approach as outlined here.

Regarding the legal risks and liabilities of such agreements, the governing body of each individual hospital and CAH must weigh the risks and benefits of opting for this more streamlined process of credentialing and privileging telemedicine practitioners. We understand that there are many complex legal issues, including issues of liability, inherent to contracts and agreements between institutions. However, we believe that these issues are beyond the scope of this rule, and that any relevant legal issues must be worked out between the parties entering into the agreements in accordance with other laws and regulations governing such contracts or agreements.

*Comment:* One commenter cited § 482.12(b), under the "Exercise of rights" standard in the Patients Rights CoP, to state that the rule must contain language that requires the hospital or CAH to inform the patient about the use of telemedicine services for diagnostic care, so that the patient (or the patient's representative as allowed under State law) may make an informed decision about whether to accept or decline care provided in this way. The commenter believes that the patient's informed consent must be obtained by the hospital or CAH before it makes use of the telemedicine services.

*Response:* We respectfully disagree with the commenter. In accordance with 42 CFR 482.24(c)(2)(v), the medical staff generally specifies procedures and treatments, in addition to those required by applicable Federal or State law, that require informed consent. As long as the telemedicine practitioner is performing his or her duties within the privileges granted by the hospital or CAH, there is no difference between distant-site practitioners and in-house or on-site practitioners in this regard. If they provide treatment that, under medical staff policy, requires informed consent, then this consent must be obtained, regardless of whether the treatment is furnished using telemedicine or not. Likewise, if, as is typical, hospital medical staff or CAH professional staff policies do not require the patient's informed consent in order for an on-site radiologist to interpret an x-ray or CT scan that had been performed on the patient, then consent also would not be required when a distant-site telemedicine radiologist, who is privileged by the hospital or CAH to interpret such diagnostic radiological tests, performs the same services.

*Comment:* One commenter expressed concern that there is no incentive for a distant-site hospital to provide these services for independent physician groups without corporate affiliation, even if they happen to be on the distant-site hospital medical staff.

*Response:* While it is not clear to whom this comment is referring ("* * * independent physician groups without corporate affiliation, even if 'they' happen to be on the distant-site hospital medical staff * * *"), the intent of this rule is not to provide business incentives for the provision of telemedicine services (as we believe they exist already), but to provide a more streamlined process for credentialing and privileging telemedicine practitioners that would be more efficient and less burdensome for all of the hospitals, CAHs, and distant-site hospitals involved in this process. We believe that by allowing for such an optional process, the incentives for distant-site hospitals to provide telemedicine services and for hospitals and CAHs to make use of these services will not diminish, but will greatly increase. Ultimately, we believe this will lead to even greater patient access to timely care that might not otherwise be available.

*Comment:* A commenter questioned the long-run sustainability of increased workload associated with telemedicine (both at the patient-site and at the distant-site facility), which, in the commenter's opinion, seems inevitable. The commenter also questioned whether our revisions would meet quality of care objectives within the commenter's facility.

*Response:* The goal of this proposed rule is to ensure that all patients have access to quality care in their communities. We believe that this rule provides the framework for such care. We also believe that providers and practitioners will continue to schedule patient visits and appropriately refer patients in such a manner as to not overwhelm either facility or its practitioners. We believe that this rule will increase patient access to specialty services and reduce burden on facilities and providers.

*Comment:* One commenter believes that CMS should assess the impact of the final rulemaking on practitioners. A few commenters stated that these requirements will increase burden on practitioners, because they will experience significant downstream reporting requirements for purposes of medical licensure renewal.

*Response:* It is not clear from the comments as to whom the commenters are referring with the term, "practitioners." Assuming that the commenters means those physicians and practitioners who are providing telemedicine services, we do not believe that this rule will increase the burden of reporting requirements for license renewal any more than the traditional credentialing and privileging processes presently do.

*Comment:* Two commenters expressed support for the proposed regulation and requested that it be expanded to include small hospitals under 100 beds, as opposed to just rural hospitals that are participating in a State-approved telemedicine program. One commenter expressed concern that community-based facilities, which are neither hospitals nor CAHs (such as rural health clinics and federally qualified health centers), are not included in this rule as patient-site facilities. Another commenter requested that we expand the scope of the rule to all facilities regulated by Medicare.

*Response:* We would like to thank the commenters for their support of the proposed rule. However, we would like to clarify that this rule applies to all Medicare-participating hospitals, regardless of facility size, as well as to all Medicare-participating CAHs. Rural health clinics and federally qualified health centers are subject to separate Medicare Conditions for Coverage that do not require credentialing and privileging of their physicians and practitioners, and thus there is no basis for extending this rule to those types of facilities. However, it should be noted that many insurers, including Medicare, may place limits or restrictions on their payment for telehealth services, depending on the location of the patient who receives those services.

*Comment:* Two commenters stated their opposition to the proposed rule because they felt that it allowed privileging by proxy to which they are opposed. One commenter stated that the changes only invite misuse by hospital and CAH governing bodies seeking to sidestep medical staff decisions regarding credentialing and privileging

and to place direct economic pressure on hospital-based practitioners (with the threat of replacing them with distant-site practitioners). The commenter further stated that the changes will effectively remove the local medical staff from any obligation that they may have in determining the qualifications of each individual applying for privileges.

*Response:* We respectfully disagree with the commenter. As we have stated previously, the requirements being finalized here are an option for hospitals and CAHs as they approach the credentialing and privileging process for telemedicine practitioners. Though we cannot estimate the numbers, we fully expect some hospitals and CAHs to continue credentialing and privileging telemedicine practitioners through the traditional process. Such decisions will have to be determined and agreed upon by each hospital and CAH, after the risks and benefits of each process are fully analyzed. Furthermore, since the practice of privileging by proxy has been common for TJC-accredited hospitals for several years now, there has been ample time for problems, such as the ones the commenter mentions, to come to light. We are not aware of any evidence that indicates these problems have arisen from this process.

*Comment:* A few commenters expressed belief that some language we used throughout the proposed rule is ambiguous and confusing and suggested that the terms "distant-site hospital" and "patient-site facility" be used consistently. Another commenter requested that we use the terms "distant site" and "originating site" to ensure consistency among CMS publications and avoid confusion. Another commenter requested that we clarify the nomenclature within the regulation so the responsibilities of each facility are explicit.

*Response:* In drafting the proposed rule, we gave much thought to the terms that we would use to describe, and distinguish between, the hospital that provides the telemedicine services and the hospital or CAH that receives the telemedicine services on behalf of its patients. We came to the conclusion that it would only be more confusing (for a number of reasons) to use the terms "distant site" and "originating site," as they are contained in both the Act and the payment rules. First among these reasons is the fact that, under the Act, there are sites (for example, rural health clinics, federally qualified health centers, and physician and practitioner offices) that are defined as "originating," but which do not apply in the context of the hospital and CAH CoPs. Additionally, the Act applies restrictions to these originating sites for specific Medicare payment purposes, which have no bearing on the hospital and CAH CoPs.

We also considered other terms, such as "patient-site facility," but found them too vague and inappropriate as well. Upon final analysis and consideration, we decided that distant-site hospital was an appropriate term to describe those larger hospitals that provide telemedicine services to patients of smaller hospitals and CAHs.

In considering which term to use for a hospital or CAH whose patients receive telemedicine services, it became readily apparent to us that the clarity of the language in the proposed requirements was best served if we continued to use the terms used throughout the current hospital and CAH CoPs to describe the facility to which the CoPs applied and to which a survey (through either the State agencies or the national accreditation organizations) for compliance with the CoPs would be performed. Put simply, the hospital would be referred to as the "hospital" and the CAH as the "CAH." Any qualifying language preceding these terms might change the meaning and confuse which facility these CoPs applied. In some areas, we found it necessary to use qualifying phrases such as "the distant-site hospital providing the telemedicine services" and "the hospital (or CAH) whose patients are receiving the telemedicine services." Therefore, we are finalizing these terms as proposed.

*Comment:* One commenter requested that we define and distinguish the differences between telemedicine and telehealth.

*Response:* In drafting this rule, we reviewed a variety of existing definitions of telemedicine and telehealth. The American Telemedicine Association states that "videoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education, and nursing call centers are all considered part of telemedicine and telehealth." Other organizations describe telemedicine as one part of a larger category of telehealth. The Institute of Medicine of the National Academy of Science defines telemedicine as "the use of electronic information and communication technologies to provide and support health care when distance separates the participants." According to the California Telemedicine and eHealth Center, "telehealth refers to a broader scope of services that includes telemedicine, but it also includes other services that can be provided remotely using communication technologies." And the federal Office for the Advancement of Telehealth, describes telehealth as "including telemedicine and a variety of other services." In addition, Section 1834(m) of the Social Security Act (the Act) addresses Medicare payment for "telehealth services." In accordance with those statutory provisions, telehealth services are certain services provided by practitioners via a telecommunications system to patients of certain types of healthcare facilities (including hospitals and CAHs) and physician or practitioner offices that are located in rural areas.

The consensus in the telemedicine/telehealth community appears to be that telemedicine refers to the provision of clinical services to patients by practitioners from a distance via electronic communications and that it is included under the broader scope of telehealth, while the statutory Medicare telehealth payment provisions are considerably narrower. At § 1834(m) of the Act, telehealth services are defined as professional consultations, office visits, and office psychiatry services, and any additional service specified by the Secretary. Most significantly, the statute allows payment for services that are provided to patients in a variety of settings (otherwise known as "originating sites" and which include physician or practitioner offices, CAHs, rural health clinics, and hospitals), but requires that all of these originating sites must be located in one of three areas: (1) An area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)); (2) in a county that is not included in a Metropolitan Statistical Area; or (3) from an entity that participates in a Federal telemedicine demonstration.

However, for the purposes of this rule, we see telemedicine as encompassing the overall delivery of healthcare to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education all via a telemedicine link (for example, audio, video, and data telecommunications as may be utilized by distant-site physicians and practitioners), and which is not restricted to only patients in rural areas of the nation. Therefore, in order to make clear that the credentialing and privileging provisions finalized here apply to all Medicare-participating hospitals and CAHs and not to the narrower subset of services and sites eligible for Medicare telehealth payment, we chose to use the term,

"telemedicine," throughout this rule instead of "telehealth."

*Comment:* Two commenters stated that they do not support using the phrase "hospital's patients." They stated that often individuals who are not registered patients make use of a rural hospital's telemedicine facilities without being registered patients. Two other commenters encouraged us to recognize and apply the proposed credentialing and privileging model to "all types of patients." One commenter requested clarification of the word "patient" and suggests we further define that any reference to patient applies solely to inpatient services.

*Response:* We are aware that individuals that are not patients sometimes make use of a rural hospital's or CAH's facilities and telemedicine equipment in order to effect what are essentially office visits with distant-site telemedicine practitioners. Since these individuals are not patients of the hospital or CAH, and the distant-site telemedicine practitioners are not seeing them as patients of the hospital or CAH, the CoPs would not apply in these situations. This speaks directly to the other comments above requesting that these requirements be applied to all types of patients and, conversely, that we clarify that these requirements apply only to inpatients. Simply stated, the hospital and CAH CoPs are intended to ensure the health and safety of those patients, inpatients as well as outpatients, who are hospital and CAH patients.

*Comment:* A commenter expressed concern that patient-site hospitals may not have staff with appropriate expertise that would allow them to evaluate credentialing and privileging information for specialists.

*Response:* The proposed and final rules address the commenter's concern. Small hospitals and CAHs that believe they lack the expertise to perform credentialing and privileging for the telemedicine services of specialized practitioners already privileged at a distant-site hospital or telemedicine entity would have the option of relying upon the distant site's privileging process instead.

*Comment:* A commenter questioned whether it is sufficient for a distant-site hospital to provide the information in an agreement with the partnering patient-site institution. The commenter asked if the distant-site hospital is expected to provide the patient-site hospital with detailed information that may be contained in the physician's credentialing file at the distant-site hospital.

*Response:* We would expect the parties engaged in the agreement to determine, within the written details of the agreement or contract, how much information would need to be included and sent for each practitioner providing telemedicine services to the hospital or CAH. At the very least, as part of its agreement with the distant-site hospital, we would expect a hospital or CAH to have access to the complete credentialing and privileging file upon request for each practitioner who is covered by the agreement.

*Comment:* We received a number of comments concerning the issue of State licensure and telemedicine practitioners. A few commenters stated that a telemedicine practitioner must be licensed in the State in which he or she is located as well as in any State(s) that he or she provides telemedicine services to patients. Other commenters asked for clarification on the term "recognized" as used in the proposed rule and asked if it was equivalent to the "privilege to practice" authority provided for by Nurse Licensure Compact States. A few commenters also stated that the licensure language was not clear and further stated that if it was intended that the requirements would allow for reciprocity agreements, endorsements, other compact arrangements, or situations where a State does not require local licensure, then the requirements should be amended to reflect this.

*Response:* We appreciate the suggestions offered by commenters. However, we believe that the proposed licensure language provides enough flexibility to hospitals and CAHs so that they may address these issues in their required agreements with distant-site telemedicine hospitals and entities. In fact, our intention was that they should address such licensure issues in accordance with their respective State laws and regulations. We neither endorse nor prohibit licensure arrangements among States, which are mentioned above. Practitioners providing telemedicine services, as well as the distant-site hospitals and entities under whose auspices they provide these services, must be aware of the licensure laws in the States where they are located in addition to the laws, compacts, and arrangements of those States in which they look to provide their services to patients.

CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to pre-empt State authority in this matter. We believe that the proposed requirements regarding State licensure leave room for the laws that exist today as well as any changes to these laws that may occur in the future, including any increase in the number of States that decide to engage in compacts, privilege to practice or reciprocity agreements, endorsements, and other arrangements regarding practitioner licensure. Therefore, we are finalizing this aspect of the requirements as proposed.

*Critical Access Hospital (CAH) CoPs (§ 485.616 and § 485.641)*

We proposed to make revisions to the CAH CoPs at § 485.616, "Agreements," and § 485.641, "Periodic evaluation and quality assurance review." We specified in the proposed rule that the majority of the proposed revisions, particularly those which mirror the proposed hospital revisions, are found in the "Agreements" CoP, specifically § 485.616(c). At § 485.616(c), we proposed a new standard entitled, "Agreements for credentialing and privileging of telemedicine physicians and practitioners."

The proposed telemedicine credentialing and privileging requirements for CAHs are modeled after the hospital requirements, with almost no differences in the regulatory language. Since the only existing requirements in the CAH CoPs specific to the responsibility of the governing body to grant medical staff privileges concerns surgical privileges for practitioners, we proposed to add language that follows the language in the hospital requirements at § 482.12(a). This language delineates the responsibilities of the governing body for the professional staff privileging process.

At § 485.641(b)(4)(iv), which does not have an equivalent provision in the hospital CoPs, we proposed to make a minor change to the CAH CoPs here. We proposed to add a new provision that would allow the distant-site hospital to evaluate the quality and appropriateness of the diagnosis and treatment furnished by its own staff when providing telemedicine services to the CAH. This proposed change would add distant-site hospitals to the three other entities already allowed to perform this function under the existing regulations.

*Comment:* One commenter noted that we use slightly different language in the requirements for CAHs than we do for the hospital requirements, and stated that we do not discuss the reasons for the differences in the preamble to the proposed rule. The commenter noted that we state at § 485.616(c)(2) that the CAH's "governing body or responsible individual may choose to rely upon the credentialing and privileging *decisions*

made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners."

*Response:* We thank the commenters for pointing out the discrepancy between the regulatory language for hospitals and that for CAHs in this instance. We have revised the hospital language to be consistent with that for CAHs.

## III. Provisions of the Final Rule

Based on public comment and our own internal discussions, we are adding new provisions to this final rule that will apply to the credentialing and privileging process and the agreements between hospitals and CAHs and non-hospital, distant-site telemedicine entities that provide telemedicine services (§ 482.12(a)(9) and § 482.22(a)(4) for hospitals; § 485.616(c)(3) and § 485.616(c)(4) for CAHs). These new provisions will require the governing body of the hospital (or the CAH's governing body or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the hospital (or CAH) to comply with all applicable conditions of participation and standards for the contracted services, including, but not limited to, the credentialing and privileging requirements regarding its physicians and practitioners providing telemedicine services.

Essentially, the new provisions will allow for the governing body of the hospital (or the CAH's governing body or responsible individual) to rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making its own decisions on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body (or the CAH's governing body or responsible individual) ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity's medical staff credentialing and privileging processes and standards meet or exceed the standards at § 482.12(a)(1) through § 482.12(a)(7) and § 482.22(a)(1) through § 482.22(a)(2) for hospitals, and at § 485.616(c)(1)(i) through § 485.616(c)(1)(vii) for CAHs. Additionally, the hospital's governing body (or the CAH's governing body or responsible individual) must ensure that the distant-site telemedicine entity, through a written agreement, meets three other provisions finalized here (and similar to those proposed and finalized here for agreements between hospitals/CAHs and distant-site hospitals providing telemedicine services).

Accordingly, we have made revisions to § 482.22(c)(6) and § 485.641(b)(4) to reference these new provisions pertaining to distant-site telemedicine entities as finalized in this rule.

Additionally, we have made a revision to § 485.635(c). This standard currently requires a CAH to have agreements or arrangements with one or more *Medicare-participating* providers or suppliers in order to furnish other services to its patients. We saw that as an impediment to the agreements that CAHs may have with distant-site telemedicine entities under this final rule. Since these entities do not participate in Medicare, we needed to make an exception to the requirement at § 485.635(c)(1). We have added a new paragraph at § 485.635(c)(5) to provide an exception to this requirement in cases where a written agreement exists between a CAH and a distant-site telemedicine entity for the entity's distant-site physicians and practitioners to provide telemedicine services to the CAH's patients.

In this final rule, we have made two significant clarifying revisions to the language of the proposed rule.

In the requirements for both hospitals and CAHs pertaining to the agreement with a distant-site hospital providing telemedicine services, we have corrected an oversight in the proposed rule and have revised the requirements in this final rule to clarify that these agreements or contracts must be written.

We have also revised the hospital language to be more consistent with that for CAHs, where we now state that the hospital's governing body may choose to have its medical staff "rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners."

Finally, we have made a few minor clarifying revisions to the proposed rule in those places where we found inconsistencies in regulatory language and/or instances where we believe the language was not as clear as it should have originally been.

## IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

### *A. ICRs Regarding Condition of Participation: Governing Body (§ 482.12)*

Section 482.12(a)(8) requires the governing body of a hospital to ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (1) through (7) of this section with regard to its physicians and practitioners providing telemedicine services. The burden associated with this requirement is the time and effort necessary for a hospital's governing body to develop, review, and update as necessary the agreement with a distant-site hospital. We estimate that 4,860 hospitals (not including 1,314 CAHs) must develop the aforementioned written agreement. We also estimate that the initial development of the agreement will take 1,440 minutes at an estimated cost of $1,996. Assuming at most an annual update, the review will take 360 minutes at an estimated cost of $516. The total cost associated with this requirement is $2,512.

Section 482.12(a)(9) requires the governing body of a hospital to ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with § 482.12(e), furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services,

including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to its physicians and practitioners providing telemedicine services. The burden associated with this requirement is the time and effort necessary for a hospital's governing body to develop, review, and update as necessary the agreement with a distant-site telemedicine entity. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 482.12(a)(8).

*B. ICRs Regarding Condition of Participation: Medical Staff (§ 482.22)*

Section 482.22(a)(3) states that when telemedicine services are furnished to a hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. To do this, a hospital's governing body must ensure that all of the provisions listed at § 482.22(a)(3)(i) through (iv) are met. Specifically, § 482.22(a)(3)(iv) contains a third-party disclosure requirement. Section 482.22(a)(3)(iv) requires that with respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

The burden associated with this third-party disclosure requirement is the time and effort necessary for a hospital to send evidence of a distant-site physician's or practitioner's performance review to the distant-site hospital with which it has an agreement for providing telemedicine services. We estimate 4,860 hospitals (not including 1,314 CAHs) must comply with this requirement. We estimate that each disclosure will take 60 minutes and that there will be approximately 32 annual disclosures. The estimated cost associated with this requirement is $1,088.

Section 482.22(a)(4) states that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. To do this, a hospital's governing body must ensure that all of the provisions listed at § 482.22(a)(4)(i) through (iv) are met. Specifically, § 482.22(a)(4)(iv) contains a third-party disclosure requirement. Section 482.22(a)(4)(iv) states that with respect to a distant-site physician or practitioner, who hold current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance and sends the distant-site telemedicine entity such information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided to the hospital's patients by the distant-site physician or practitioner and all complaints the hospital has received about the distant-site physician or practitioner. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 482.22(a)(3).

*C. ICRs Regarding Condition of Participation: Agreements (§ 485.616)*

Section 485.616(c)(1) states that the governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements listed at § 485.616(c)(1)(i) through (vii) and § 485.616(c)(2). The burden associated with this requirement is the time and effort necessary for a CAH's governing body to develop, review, and update as necessary the agreement with a distant-site hospital. We estimate that 1,314 CAHs must develop and review the aforementioned written agreement. We also estimate that development of the agreement will take 1,440 minutes initially and, assuming at most an annual update, the review will take 360 minutes annually. The total cost associated with this requirement is $2,512.

Section 485.616(c)(2) states that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital for individual distant-site physicians or practitioners, if the CAH's governing body or responsible individual ensures that all of the provisions listed at § 485.616(c)(2)(i) through (iv) are met. The burden associated with this third-party disclosure requirement at § 485.616(c)(2)(iv) is the time and effort necessary for a CAH to send evidence of a distant-site physician's or practitioner's performance review to the distant-site hospital with which it has an agreement for providing telemedicine services. We estimate 1,314 CAHs must comply with this requirement. We estimate that each disclosure will take 60 minutes and that there will be approximately 32 annual disclosures. The estimated cost associated with this requirement is $1,088.

Section 485.616(c)(3) states that the governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with § 485.635(c)(4)(ii), furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

The burden associated with this requirement is the time and effort necessary for a CAH's governing body to develop, review, and update as necessary the agreement with a distant-site telemedicine entity. We estimate that 1,314 CAHs must develop and review the aforementioned written

agreement. We also estimate that development of the agreement will take 1,440 minutes (that is, 24 hours) initially and, assuming at most an annual update, the review will take 360 minutes (six hours) annually. The total cost associated with this requirement is $2,512.

Section 485.616(c)(4) states that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that all of the provisions listed at § 485.616(c)(4)(i) through (iv) are met. The burden associated with this third-party disclosure requirement at § 485.616(c)(4)(iv) is the time and effort necessary for a CAH to send evidence of a distant-site physician's or practitioner's performance review to the distant-site telemedicine entity with which it has an agreement for providing telemedicine services. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 485.616(c)(2).

TABLE 1—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

| Regulation section(s) | OMB Control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting ($) | Total labor cost of reporting ($) | Total capital/maintenance costs ($) | Total cost ($) |
|---|---|---|---|---|---|---|---|---|---|
| § 482.12(a)(8) and (9). | 0938–New .... | 4,860 | 4,860 | 24 | 116,640 | ** | 9,700,560 | 0 | 9,700,560 |
| | ..... | 4,860 | 4,860 | 6 | 29,160 | ** | 2,507,760 | 0 | 2,507,760 |
| § 482.22(a)(3) and (4). | 0938–New .... | 4,860 | 155,520 | 1 | 155,520 | 34 | 5,287,680 | 0 | 5,287,680 |
| § 485.616(c)(1) and (3). | 0938–New .... | 1,314 | 1,314 | 24 | 31,536 | ** | 2,622,744 | 0 | 2,622,744 |
| | ..... | 1,314 | 1,314 | 6 | 7,884 | ** | 678,024 | 0 | 678,024 |
| § 485.616(c)(2) and (4). | 0938–New .... | 1,314 | 42,048 | 1 | 42,048 | 34 | 1,429,632 | ..... | 1,429,632 |
| Total ..... | ..... | 6,174 | 209,916 | ..... | 382,788 | ..... | ..... | ..... | 22,226,400 |

** Wage rates vary by level of staff involved in complying with the information collection request (ICR). The wage rates associated with the aforementioned information collection requirements are listed in Tables 2–7 in the regulatory impact analysis of this final rule.

## V. Regulatory Impact Analysis

### *A. Statement of Need*

Currently, a hospital or CAH receiving telemedicine services must go through a burdensome credentialing and privileging process for each physician and practitioner who will be providing telemedicine services to its patients. In the past, under the Joint Commission's (TJC) statutory deeming authority, hospitals that were accredited by TJC were deemed to have met the CMS credentialing and privileging requirements. TJC's "privileging by proxy" standards allowed for one Joint Commission-accredited facility to accept the privileging decisions of another Joint Commission-accredited facility. TJC has been statutorily required to meet or exceed our requirements regarding credentialing and privileging since July 15, 2010.

This final rule will revise the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs) and will implement a new credentialing and privileging process for physicians and practitioners furnishing telemedicine services. Additionally, and perhaps more significantly, failure to publish this final rule will place undue hardship and financial burden on those hospitals and CAHs who have been credentialing and privileging telemedicine practitioners under TJC's "privileging by proxy" model. These hospitals and CAHs will have to take on the burden of credentialing and privileging a significant number of telemedicine practitioners in a relatively short period of time or they will have to consider canceling their telemedicine services. Cancellation of telemedicine services by small hospitals and CAHs will drastically reduce access to needed specialty services for a great number of patients, many of whom are Medicare beneficiaries.

### *B. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not an economically significant rule and does not impose significant costs. The benefits of finalizing this rule greatly outweigh any costs imposed. Conversely, the negative impacts on overall patient health and safety as well as on the operating costs of individual hospitals and CAHs were this rule not to be finalized would be significant compared to the minimal cost imposed by finalizing it here. Accordingly, we have prepared a regulatory impact analysis, which to the best of our ability, presents the costs and benefits of the rulemaking.

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 businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of hospitals, including CAHs, are small entities as that term is used in the RFA. Individuals and States are not included in the definition of a small entity. While we do not believe that this final rule will have a significant impact on small entities, we do believe that this rule will have a positive impact by providing immediate regulatory relief for these small entities and will negatively impact them if not finalized here. Therefore, we are voluntarily preparing a Regulatory Flexibility Analysis.

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. This rule will not have a significant impact on small rural hospitals as it is intended to relieve the burden on hospitals, particularly on small rural hospitals and CAHs, and to reduce or eliminate the impact of the current regulatory impediments to efficient operation and patient access to essential healthcare services. Therefore, the Secretary has determined that this final rule will not have a significant negative impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $136 million.

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. This final rule will not have a substantial direct effect on State or local governments, preempt State laws, or otherwise have a Federalism implication.

*C. Anticipated Effects*

1. Effects on Hospitals and Critical Access Hospitals (CAHs)

We estimate the costs to hospitals and CAHs to implement this final rule with comment period to be minimal, particularly when weighed against the significant benefits that the rule would bring about by reducing the regulatory burden for hospitals and CAHs. The major costs are related to developing the agreement between the distant-site hospital or distant-site telemedicine entity and the hospital or CAH at which patients who receive the telemedicine services are located. Many hospitals and CAHs may already have such telemedicine service agreements in place and therefore would not incur the initial costs of developing such an agreement.

Our figures, as of March 31, 2010, indicate that there were 4,860 hospitals and 1,314 CAHs (for a total of 6,174) participating in Medicare in the United States. However, we have no way of determining an exact number on which of these hospitals provide telemedicine services and which of these hospitals and CAHs receive telemedicine services, nor can we determine how many hospitals and CAHs already have telemedicine agreements. We do not have any reliable figures on the number of non-hospital, distant-site telemedicine entities that provide telemedicine services to hospitals and CAHs. Accordingly, we have based our cost estimates on the higher costs that would be incurred if every hospital and CAH in the United States was required to develop an agreement and review and update it annually. We prepared the cost estimates for hospitals and CAHs separately. However, all sides of this equation will require the initial services of a hospital or CAH attorney at an average of $86/hour; a hospital or CAH chief of the medical/professional staff (a physician) at an average of $103/hour; and a hospital or CAH administrator at an average of $69/hour. For the third-party disclosure requirements, we also prepared the cost estimates for hospitals and CAHs separately, though both will require the annual services of a medical staff credentialing manager or a medical staff coordinator at an average of $34/hour. Our salary figures are the most recent wage estimates from the Bureau of Labor Statistics (*http://www.bls.gov/home.htm*) with 33% added to the hourly wage to account for benefits. Our estimates of time and cost for each aspect of the agreement (development and initial cost, and annual review), as well as for the third-party disclosure, is as follows:

TABLE 2—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO DEVELOP AN AGREEMENT FOR TELEMEDICINE SERVICES: INITIAL COST

| Individual | Hourly wage | Number of hours | Cost per individual | Total cost |
|---|---|---|---|---|
| Attorney | $86 | 12 | $1,032 | |
| Physician | 103 | 4 | 412 | $1,996 |
| Hospital Administrator | 69 | 8 | 552 | |

TABLE 3—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO REVIEW AND UPDATE AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

| Individual | Hourly wage | Number of hours | Cost per individual | Total cost |
|---|---|---|---|---|
| Attorney | $86 | 2 | $172 | |
| Physician | 103 | 2 | 206 | $516 |
| Hospital Administrator | 69 | 2 | 138 | |

Therefore, we estimate the total initial cost to develop the agreement for all 4,860 hospitals to be $9.7 million. The annual cost to review agreements for all hospitals is estimated at $2.5 million.

TABLE 4—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO DEVELOP AN AGREEMENT FOR TELEMEDICINE SERVICES: INITIAL COST

| Individual | Hourly wage | Number of hours | Cost per individual | Total cost |
|---|---|---|---|---|
| Attorney | $86 | 12 | $1,032 | |
| Physician | 103 | 4 | 412 | $1,996 |
| CAH Administrator | 69 | 8 | 552 | |

TABLE 5—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO REVIEW AND UPDATE AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

| Individual | Hourly wage | Number of hours | Cost per individual | Total cost |
|---|---|---|---|---|
| Attorney | $86 | 2 | $172 | |
| Physician | 103 | 2 | 206 | $516 |
| Hospital Administrator | 69 | 2 | 138 | |

Therefore, we estimate the total initial cost to develop the agreement for all 1,314 CAHs to be $2.6 million. The annual cost to review agreements for all CAHs is estimated at $678,024.

TABLE 6—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO PREPARE AND SEND INDIVIDUAL PERFORMANCE REVIEWS FOR TELEMEDICINE SERVICES (THIRD-PARTY DISCLOSURE): ANNUAL COST

| Individual | Hourly wage | Number of hours | Total cost |
|---|---|---|---|
| Medical Staff Coordinator or Medical Staff Credentialing Manager | $34 | 32 | $1,088 |

Therefore, we estimate the total annual cost to prepare and send individual performance reviews for telemedicine services (third-party disclosure) for all 4,860 hospitals to be $5.3 million.

TABLE 7—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO PREPARE AND SEND INDIVIDUAL PERFORMANCE REVIEWS FOR TELEMEDICINE SERVICES (THIRD-PARTY DISCLOSURE): ANNUAL COST

| Individual | Hourly wage | Number of hours | Total cost |
|---|---|---|---|
| Medical Staff Coordinator or Medical Staff Credentialing Manager | $34 | 32 | $1,088 |

Therefore, we estimate the total annual cost to prepare and send individual performance reviews for telemedicine services (third-party disclosure) for all 1,314 CAHs to be $1.4 million.

The total cost of the information collection requirements for both hospitals and CAHs is estimated to be $22.2 million.

*D. Conclusion*

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**

*42 CFR Part 482*

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 485*

Grant programs—health, Health facilities, Medicaid, Medicare, 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 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

**Authority:** Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

### Subpart B—Administration

■ 2. Section 482.12 is amended by adding new paragraphs (a)(8) and (a)(9) to read as follows:

**§ 482.12 Condition of participation: Governing body.**

* * * * *

(a) * * *

(8) Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with § 482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with § 482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with § 482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

* * * * *

## Subpart C—Basic Hospital Functions

■ 3. Section 482.22 is amended by—

■ A. Adding new paragraphs (a)(3) and (a)(4).

■ B. Revising paragraph (c)(6).

The addition and revision read as follows:

### § 482.22 Condition of participation: Medical staff.

* * * * *

(a) * * *

(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.

* * * * *

(c) * * *

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 482.12(a)(8) and (a)(9), and § 482.22(a)(3) and (a)(4).

* * * * *

## PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 4. The authority citation for part 485 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

## Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 5. Section 485.616 is amended by adding a new paragraph (c) to read as follows:

### § 485.616 Condition of participation: Agreements.

* * * * *

(c) *Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.* (1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

(i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(iii) Assure that the medical staff has bylaws.

(iv) Approve medical staff bylaws and other medical staff rules and regulations.

(v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(vii) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:

(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital;

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with § 485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

(4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at paragraphs (c)(1)(i) through (c)(1)(vii) of this section.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

■ 6. Section 485.635 is amended by adding a new paragraph (c)(5) to read as follows:

### § 485.635 Condition of participation: Provision of services.

* * * * *

(c) * * *

(5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

* * * * *

■ 7. Section 485.641 is amended by revising paragraph (b)(4) to read as follows:

**§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.**

* * * * *

(b) * * *

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (b)(4)(i) through (iii) of this section; and

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program). (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: January 27, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: April 29, 2011.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2011–10875 Filed 5–2–11; 11:15 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF DEFENSE

## Defense Acquisition Regulations System

## 48 CFR Parts 211 and 237

**RIN 0750–AG72**

## Defense Federal Acquisition Regulations Supplement; Guidance on Personal Services (DFARS Case 2009–D028)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD has adopted as final, with changes, the interim rule that amended the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 831 of the National Defense Authorization Act for Fiscal Year 2009, which required DoD to develop guidance on personal services contracts.

**DATES:** *Effective Date:* May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** Mr. Dustin Pitsch, 703–602–1014.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 831 required DoD to mitigate the risks associated with personal services by developing guidance enabling contracting officers to better distinguish between personal services and nonpersonal services. The interim rule amended DFARS parts 211 and 237 to (1) require that statements of work or performance work statements clearly distinguish between Government employees and contractor employees and (2) ensure that procedures are adopted to prevent contracts from being awarded or administered as unauthorized personal services contracts. The interim rule included an internal requirement for a program manager, or equivalent, certification that the service contract requirement does not include an unauthorized personal services arrangement. Because of the differing missions of DoD agencies, the interim rule required agencies to adopt their own procedures.

DoD published an interim rule at 75 FR 54524 on September 8, 2010, to implement section 831 of the National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417, enacted October 28, 2009). The period for public comment closed on November 8, 2010. Five respondents provided public comments on the interim rule.

### II. Discussion and Analysis

*A. Support for DoD Actions*

*Comment:* A respondent noted the DFARS requirement for agency-level procedures to ensure that service contract requirements are vetted and approved in a manner that will prevent them from being awarded or administered as unauthorized personal services contracts. The respondent stated its support for Defense agencies taking internal action to ensure that no unauthorized personal services contracts are requested. Another respondent expressed support for the rule and stated that it "helps create a boundary separating contractor and government employees in all workplace environments."

*Response:* The respondents' support is noted. No change to the DFARS in this area was requested or made.

*B. Limit Applicability*

*Comment:* Two respondents specified that the DFARS should highlight and limit applicability of this rule solely to personal services contracts, not the general service contract population.

*Response:* No change was made in the final rule in response to this comment. It is precisely because of the potential for a migration of a "general service contract" into what is effectively a "personal services contract" that the rule is necessary. DoD, with strong encouragement from the DoD Office of Inspector General, has determined that there is a need to review all services for the purpose of ensuring the services do not become personal services.

*C. Add More Guidance*

*Comment:* A respondent stated that DFARS 211.106 provides no actual guidance to the agencies as to what the distinction between Government employees and contractor employees is or how an agency is to make such a determination. At a minimum, the respondent states, it may be appropriate to include in DFARS 211.106 a cross reference to the characteristics and descriptive elements in FAR 37.104. The respondent thinks the rule does not provide any actionable direction to contractors on what behaviors would be acceptable for contractor employees based on the policies and practices of the location where the contractor employee is assigned.

*Response:* A cross reference to FAR 37.104 and the characteristics and descriptive elements therein has been added to DFARS 211.106. However, the DFARS cannot unnecessarily repeat, paraphrase, or otherwise restate material contained in the FAR (see FAR 1.304(b)), so the DFARS addition was limited to a reference. Further, the agency-level procedures are the appropriate location for the actionable, agency-specific direction to contractors on acceptable behaviors.

*D. Add More Specific Contract Administration Procedures*

*Comment:* A respondent noted the absence in the interim rule, in DFARS parts 237 or 242, of procedures, guidance, or information focusing on postaward contract administration to prevent actual administration of a contract as an unauthorized personal services contract. The respondent recommended (a) referencing FAR 37.104(d) in DFARS 237.503 and (b)

possibly adding coverage in DFARS part 242 relating to contract administration.

*Response:* DoD has added a cross reference to FAR 37.104(d) at DFARS 237.503. In this final rule, no changes are made to DFARS subpart 242.

*E. Editorial Recommendations*

*Comment:* A respondent proposed several clarifying edits. The respondent suggested moving some coverage from DFARS 237.503 to DFARS 237.104 and providing additional cross references. The respondent also proposed to revise the title of the form at PGI 237.503(c).

*Response:* Some of these recommendations have been accommodated in the changes noted above and as follows:

- New coverage at DFARS 237.104(d) has been added to point readers to the section entitled "Agency-head responsibilities" at DFARS 237.503 to ensure awareness of the certification requirement.
- The title of the certification at PGI 237.503(c) has been changed to "Certification of Nonpersonal Services."

**III. Executive Order 12866 and Executive Order 13563**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. This rule is not a major rule under 5 U.S.C. 804.

**IV. Regulatory Flexibility Act**

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the change solely impacts internal Government operating procedures and will therefore not have a significant cost or administrative impact on contractors, subcontractors, or offerors. An initial regulatory flexibility analysis was not performed. No comments were received from small entities on this rule.

**V. Paperwork Reduction Act**

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Parts 211 and 237**

Government procurement.

**Mary Overstreet,**

*Editor, Defense Acquisition Regulations System.*

Therefore, the Defense Acquisition Regulations system confirms as final the interim rule published at 75 FR 54524 on September 8, 2010, with the following changes:

■ 1. The authority citation for 48 CFR parts 211 and 237 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 211—DESCRIBING AGENCY NEEDS

■ 2. Revise section 211.106 to read as follows:

**211.106 Purchase descriptions for service contracts.**

Agencies shall require that purchase descriptions for service contracts and resulting requirements documents, such as statements of work or performance work statements, include language to provide a clear distinction between Government employees and contractor employees. Agencies shall be guided by the characteristics and descriptive elements of personal-services contracts at FAR 37.104. Service contracts shall require contractor employees to identify themselves as contractor personnel by introducing themselves or being introduced as contractor personnel and displaying distinguishing badges or other visible identification for meetings with Government personnel. In addition, contracts shall require contractor personnel to appropriately identify themselves as contractor employees in telephone conversations and in formal and informal written correspondence.

## PART 237—SERVICE CONTRACTING

■ 3. Amend section 237.104 by adding paragraph (d) as follows:

**237.104 Personal services contracts.**

* * * * *

(d) See 237.503(c) for requirements for certification and approval of requirements for services to prevent contracts from being awarded or administered in a manner that constitutes an unauthorized personal services contract.

* * * * *

■ 4. Revise section 237.503 to read as follows:

**237.503 Agency-head responsibilities.**

(c) The agency head or designee shall employ procedures to ensure that requirements for service contracts are vetted and approved as a safeguard to prevent contracts from being awarded or administered in a manner that constitutes an unauthorized personal services contract. Contracting officers shall follow the procedures at PGI 237.503, include substantially similar certifications in conjunction with service contract requirements, and place the certification in the contract file. The program manager or other official responsible for the requirement, at a level specified by the agency, should execute the certification. In addition, contracting officers and program managers should remain aware of the descriptive elements at FAR 37.104(d) to ensure that a service contract does not inadvertently become administered as a personal-services contract.

[FR Doc. 2011–10878 Filed 5–4–11; 8:45 am]

BILLING CODE 5001–08–P

---

## DEPARTMENT OF DEFENSE

## Defense Acquisition Regulations System

## 48 CFR Parts 216 and 252

**RIN 0750–AH20**

## Defense Federal Acquisition Regulation Supplement (DFARS); Electronic Ordering Procedures (DFARS Case 2009–D037)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to address electronic business procedures for placing orders. This final rule adds a new DFARS clause to clarify this process.

**DATES:** *Effective date:* May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** Mr. Julian Thrash, Telephone 703–602–0310.

**SUPPLEMENTARY INFORMATION:**

## I. Background

DoD published a proposed rule in the **Federal Register** at 75 FR 60690, on October 1, 2010. This case establishes a standard method for the issuance of orders via electronic means. DoD currently has the capability to distribute orders electronically on a routine basis and can post to a Web site that any contractor can access. In order to make this possible, the DFARS needs to provide language that will make those procedures a routine part of contract order distribution. This will enable DoD to further the goals of the E-Government Act of 2002 (Pub. L. 107–347).

The public comment period closed November 30, 2010. Five respondents submitted comments to the proposed rule, which are addressed below.

## II. Discussion and Analysis

*A. Effective Way To Do Business*

*Comment*: One respondent opined that requiring vendors and the Government to communicate exclusively via electronic means will be the most effective way for the Government to do business in the future.

*Response*: Concur this could be the most effective way to communicate, however, e-mail and facsimile will continue to be permitted as a means of communication.

*B. Elements of an Order*

*Comment:* One respondent expressed concern that many elements of an order are not universal, and are not automatically posted to the Electronic Document Access (EDA) system from the contract writing systems (*i.e.,* attachments and appendices). The respondent opined that ordering officials would thus be forced to either use e-mail to get some elements of the order to the contractor or, alternatively, to manually replace the automatically uploaded documents in EDA with manually compiled complete documents. The respondent suggested that neither approach would be efficient.

*Response:* As a matter of policy, DoD already requires posting of the contract or order, including its attachments, to EDA. This rule merely leverages that existing requirement to codify rules for electronic issuance of orders. Use of e-mail will not be necessary.

*C. Use of E-Mail*

*Comment:* A respondent questioned whether it is wise to take e-mail totally off the table, when FAR 52.216–18, Ordering, currently permits ordering officials to specify e-mail as an "electronic commerce method" so long as it is authorized in the schedule. The respondent recommended that the DFARS clause should explicitly permit the use of e-mail as a recognized electronic commerce method. The respondent recommended, in the alternative, that the Government permit the use of e-mail on a "by-exception basis" or at the discretion of the contracting officer.

*Response:* DoD considered the use of e-mail as a primary method of distribution, but rejected its use because of the lack of an audit trail. DoD was also concerned that the delivery and receipt of e-mail is subject to interruption without notice due to firewall and spam filter configurations.

*D. Changes to 252.216–70XX(c)(1), Ordering*

*Comment:* A respondent suggested that the term "notice" in 252.216–70XX(c)(1), Ordering, should be defined. Another respondent stated the final rule should be clearer about who in the company will be receiving the awards to reduce the possibility for miscommunication. Another respondent stated that electronic commerce is a term specifically identified in Federal Acquisition Regulation (FAR) Part 2, and is broader than just the EDA, which is not defined in the FAR or DFARS. The respondent further stated that limiting the Government's electronic communication options to the EDA only will prevent ordering officials from using other means of electronic commerce in the event EDA is not accessible (e.g., system is down or contingency contracting where EDA may not be available), and that use of the broader term "electronic commerce" would allow for the flexibility to adopt the use of new methods of electronic communication as they arise.

*Response:* Contract load notification lists can be set up in EDA for a specific contract or delivery order. Each contract or delivery order requires its own notification list. Notification lists may be created for contracts that do not yet exist in EDA. When a contract loads into EDA, the notification process activates and EDA e-mails the notification to the addresses on the lists. Notification e-mail messages are sent once per day. Therefore, it is not necessary to define what constitutes a notice.

DoD has chosen EDA as its primary means of establishing an official shared copy of the contract. This case leverages that decision. This case is not intended to prohibit the use of other electronic commerce tools to transmit data about the contract, but only to address EDA as the location of the document.

*E. Encryption*

*Comment:* A respondent suggested that DoD should allow for an alternate means of electronic communication that provides for secure transmission of files (such as deliverables, reports, financial, and Privacy Act data) back to the issuer. The respondent further stated that e-mail is a very simple, widespread, and known technology, and that many regulations require strong encryption when sending sensitive (controlled unclassified information, personally identifiable information, *etc.*) data over the internet. The respondent recommended that DoD should be encrypting files before transmitting them, and that including (in the clause) the option to use e-mail would set the stage for enhanced, electronic communications between DoD and its many small contractors, via the Internet's ubiquitous direct communication tool.

*Response:* EDA shares data using secure hypertext transfer protocol (https), which encrypts all data in transit, and is universally used by both industry and Government to protect sensitive data. EDA fulfills DoD's requirement for the secure transmission of data.

*F. Registration in EDA*

*Comment:* A respondent asked whether contractor registration in EDA will eventually become mandatory like Central Contractor Registration (CCR) (*i.e.,* a pre-condition for receiving a contract). The respondent went on to suggest that DoD would have a difficult time getting industry (and particularly small businesses) to use EDA without a mandatory registration requirement.

*Response:* An implicit condition of this ordering clause is that vendors who wish to receive notice of electronic orders must create an account in EDA. In order to create an account, the vendor must know the Commercial and Government Entity (CAGE) or the Data Universal Numbering System (DUNS) number for the business unit, and specify it in their EDA registration. The electronic business point of contact for that CAGE/DUNS as identified in CCR must authorize, via e-mail, the applicant for the EDA vendor user account as someone who may access documents for that CAGE/DUNS.

*G. Access to EDA*

*Comment:* A respondent noted that there is a general lag between the time when an order is released in the contract writing system, and the time when it is available in EDA, and that this is a practical downside of not

permitting the use of e-mail to issue orders. Two respondents expressed concern that there may be occasions when contractors cannot readily gain access to EDA or that there may be contractors who object to registering in the EDA system.

*Response:* Historical data shows that, on average, actions are posted to EDA within one to two days. This average compares very favorably with the averages associated with mailing or any other distribution process. There are two EDA sites, one at *http://eda.ogden.disa.mil/,* and the other at *http://eda.cols.disa.mil/,* to ensure connectivity. These two sites allow for an overall 99.1% average system availability. EDA is a very reliable means of conducting DoD's business, and the issue of EDA nonavailability is not considered significant.

*H. Exceptions*

*Comment:* A respondent recommended striking facsimile and mail as acceptable methods of issuing orders in order to more firmly promote the use of electronic business.

*Response:* The objective of the case is not to eliminate paper methods but to establish a regular process for electronic methods.

DoD has considered the public comments, and has decided to make no major changes to the text that was proposed in the **Federal Register** at 75 FR 60690, on October 1, 2010. However, there is one small change made at 216.506(a), where the name "Ordering" was added to the clause prescription as the title for FAR 52.216–18. This final rule makes the following DFARS changes:

- Adds DFARS 216.506(a) to require a new clause 252.216–7006, Ordering, in lieu of the clause at 52.216–18, Ordering, in solicitations, and contracts when a definite-quantity contract, a requirements contract, or an indefinite-quantity contract is contemplated; and
- Add a new clause at DFARS 252.216–7006, Ordering.

## III. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

## IV. Regulatory Flexibility Act

DoD has prepared a final regulatory flexibility analysis consistent with 5 U.S.C. 604 and is summarized below. A copy of the analysis may be obtained from the point of contact specified herein.

The objective of this rule is to establish a standard method for distributing orders via electronic means. DoD currently has the capability to distribute orders electronically on a routine basis, and posts those orders to a Web site that any contractor can access.

This DFARS change will provide standard contract language that will make those order distribution procedures a routine part of contract order placement. This rule will enable DoD to further the goals of the E-Government Act of 2002.

For Fiscal Year 2009, DoD made awards to 6,097 small business unique Data Universal Numbering System (DUNS) numbers using the clause at FAR 52.216–18, Ordering. The benefit of this rule to small business is that it will make electronic distribution procedures a routine part of order issuance. This change will ultimately help improve the management, and promotion of electronic Government services and processes, and will establish a framework to improve public access to Government information, and services.

This rule was published as a proposed rule in the **Federal Register** at 75 FR 60690, on October 1, 2010. No comments were received from small entities on the affected DFARS subpart with regard to small businesses. We anticipate that there will be limited, if any, additional costs imposed on small businesses.

## V. Paperwork Reduction Act

This rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

## List of Subjects in 48 CFR Parts 216 and 252

Government procurement.

**Mary Overstreet,**

*Editor, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 216 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 216 and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 216—TYPES OF CONTRACTS

■ 2. Amend section 216.506 by adding paragraph (a) to read as set forth below.

### 216.506 Solicitation provisions and contract clauses.

(a) Insert the clause at 252.216–7006, Ordering, in lieu of the clause at 52.216–18, Ordering, in solicitations and contracts when a definite-quantity contract, a requirements contract, or an indefinite-quantity contract is contemplated.

* * * * *

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Add section 252.216–7006 to read as follows:

### 252.216–7006 Ordering.

As prescribed in 216.506(a), use the following clause:

ORDERING (MAY 2011)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the contract schedule. Such orders may be issued from _____ through _____ [*insert dates*].

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c)(1) If issued electronically, the order is considered "issued" when a copy has been posted to the Electronic Document Access system, and notice has been sent to the Contractor.

(2) If mailed or transmitted by facsimile, a delivery order or task order is considered "issued" when the Government deposits the order in the mail or transmits by facsimile. Mailing includes transmittal by U.S. mail or private delivery services.

(3) Orders may be issued orally only if authorized in the schedule.

(End of Clause)

[FR Doc. 2011–10967 Filed 5–4–11; 8:45 am]

BILLING CODE 5001–08–P

**DEPARTMENT OF DEFENSE**

**Defense Acquisition Regulations System**

**48 CFR Parts 223 and 252**

**RIN 0750–AG35**

## Defense Federal Acquisition Regulation Supplement; Minimizing the Use of Materials Containing Hexavalent Chromium (DFARS Case 2009–D004)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the requirements for minimizing the use of materials containing hexavalent chromium in items acquired by DoD (deliverables and construction materials hereafter referred to as deliverables). Hexavalent chromium is a chemical that has been used in numerous DoD weapons systems and platforms due to its corrosion protection properties. However, hexavalent chromium is a known carcinogen. This rule codifies a DoD policy for addressing the serious human health and environmental risks related to the use of hexavalent chromium. The rule prohibits the delivery of items containing more than 0.1 percent by weight hexavalent chromium in any homogeneous material under DoD contracts unless there is no acceptable alternative to the use of hexavalent chromium.

**DATES:** *Effective Date:* May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** Ms. Amy Williams, 703–602–0328.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD published a proposed rule on hexavalent chromium in the **Federal Register** at 75 FR 18041 on April 8, 2010. This final rule amends the DFARS to implement requirements to minimize the delivery of materials containing hexavalent chromium in DoD acquisitions. The DFARS governs only DoD procurements, therefore, this action establishes requirements that DoD personnel must follow when making acquisitions for new systems.

Hexavalent chromium is a chemical that has been used in numerous DoD weapons systems and platforms due to its corrosion protection properties. However, hexavalent chromium is recognized as an inhalation carcinogen. The National Toxicology Program's Report on Carcinogens, Eleventh Edition, lists hexavalent chromium compounds as known human carcinogens. (See *http://ntp.niehs.nih.gov/ntp/roc/eleventh/known.pdf.*) The Environmental Protection Agency (EPA) classifies hexavalent chromium as a known human carcinogen by the inhalation route of exposure. (See *http://www.epa.gov/iris/subst/0144.htm.*)

In response to the serious human health and environmental risks associated with the use of hexavalent chromium, there has been an increase in national and international restrictions and controls. For example, in 2006, the Occupational Safety and Health Administration (OSHA) lowered the permissible exposure limit (PEL) ten-fold from 52 to 5 micrograms-per-cubic-meter, making it among the most stringently regulated materials used in manufacturing and maintenance operations. Similarly, the European Union Restriction of Hazardous Substances Directive restricts the use of hexavalent chromium in the manufacturing of certain types of electronic and electrical equipment. Finally, a number of defense-related industries are minimizing or eliminating the use of hexavalent chromium where proven substitutes are available.

Such restrictions and industry practices have decreased the availability of materials containing hexavalent chromium and have increased the regulatory burden and life cycle costs for DoD. Indeed, DoD and the industry have made substantial investments in finding suitable replacements for hexavalent chromium. To protect future access for critical applications and to implement its commitments pursuant to Executive Orders 13514 and 13423, on April 8, 2009, the Under Secretary of Defense (Acquisition, Technology and Logistics) issued a policy memorandum to minimize the use of materials containing hexavalent chromium in the acquisition of new systems throughout DoD. Among other things, the policy memorandum directed DoD personnel (specifically the Program Executive Offices in conjunction with the Military Department's Corrosion Control and Prevention Executive) to certify that "no acceptable alternative" exists before using any material containing hexavalent chromium on a new system and directed the Defense Acquisition Regulation Council to develop a clause for defense contracts that prohibits the use of materials containing hexavalent chromium in all future procurements unless specifically approved by the Government. This final rule implements those aspects of the policy memorandum. The final rule adds a new DFARS subpart and a corresponding contract clause to minimize hexavalent chromium in deliverables acquired under DoD contracts.

### II. Analysis of Public Comments

Eleven respondents submitted comments on the proposed rule. A discussion of those comments and the revisions made to the rule as a result of those comments is provided below. The comments are organized and presented in ten overall categories. Some comments did not pertain to the DFARS rule itself; however, they are addressed to assist in further clarifying the rule. Six of the eleven respondents supported the objective of minimizing the use of hexavalent chromium or indicated that they were already compliant. The remaining five respondents did not express support or object to the rule, but provided implications and examples of actions that will be required to minimize hexavalent chromium in deliverables. Three respondents questioned the need for the rule since DoD and industry have been working for years to develop substitutes. Despite reservations about the need for the rule, these respondents provided recommendations for improving the rule. A number of the most significant recommendations have been incorporated in the revised rule as discussed in more detail below.

#### *A. Clarification of Definitions, Terms, or Language*

*Comment:* Two respondents requested clarification of contractor responsibility for identifying alternatives or obtaining approvals for hexavalent chromium use.

*DoD Response:* A DoD solicitation for a new deliverable may contain specifications for approved hexavalent chromium substitutes. In other solicitations, or for other components in the same solicitation, DoD may provide specifications that require hexavalent chromium where its use is deemed necessary to meet performance requirements and/or where proven substitutes are not available. Consideration of substitutes will include evaluation of the factors described in the DoD policy memo including—

- Cost effectiveness of alternative materials or processes;
- Technical feasibility of alternative materials or processes;
- Environment, safety, and occupational health risks associated with the use of the hexavalent

chromium or substitute materials in each specific application;

- Achieving a DoD Manufacturing Readiness Level of at least eight (8) for any qualified alternative;
- Materiel availability of hexavalent chromium and the proposed alternatives over the projected life span of the system; and
- Corrosion performance difference of alternative materials or processes as determined by agency corrosion subject matter experts.

A performance-based solicitation may not provide specifications for a substitute or pre-approval for hexavalent chromium. In such cases, the contractor is responsible for either providing a substitute that meets performance requirements or providing a request to the contracting officer for providing a deliverable containing hexavalent chromium. The contracting officer will forward the request to the authorized approving official (DFARS 223.7305(a)) for decision.

The Advanced Surface Engineering Technologies for a Sustainable Defense (ASETSDefense) Web site at *http://www.assetsdefense.org* has been established to provide information about hexavalent chromium substitutes. The site has a database that can be searched by type of process for substitute information. The site also contains briefings and summary reports from DoD-industry workshops on sustainable coatings and processes. The site helps reduce duplication in testing for the same or similar applications.

*Comment:* Two respondents requested that "legacy system" be defined, with one respondent stating that it should be any system that is past Material Development Decision, as the milestone defined in DoD Instruction 5000.02.

*DoD Response:* A "legacy system" means any program that has passed Milestone A, as defined in DoD Instruction 5000.02. At the Material Development Decision (MDD) stage in the acquisition process, far too little is known about a system. The MDD simply indicates that an acquisition of a system, equipment, or item will be required to satisfy a military capability. Milestone A occurs after the MDD. At Milestone A, the system concept has been refined and technology development can begin. Milestone A represents a very early stage in the acquisition process. Thus, by defining a legacy system as one that has already passed Milestone A, it provides a phase-in period for the rule to take effect. In other words, the rule affects only new systems that are pre-Milestone A. This provides a sufficient period, typically two years or more, for companies that contract with DoD to make any necessary adjustments.

*Comment:* Two respondents requested clarification of the term "homogeneous material." One respondent stated that the definition proposed is overly broad and appears to be taken verbatim from the European Union Restriction of Hazardous Substances Directive. Another respondent suggested that the definition be abandoned as unusable or be clarified by naming common types of materials to be considered homogeneous and those which should be excluded from the definition.

*DoD Response:* The definition of "homogeneous material" was adopted from the European Union Restriction of Hazardous Substances Directive because it is widely understood by industry given the global nature of supply chains. The definition was supplemented by providing examples to assist the contracting activity and the offeror. The intent of the examples is not to be extensive or all inclusive. "Homogeneous material" means a material that cannot be mechanically disjointed into different materials and is of uniform composition throughout. This definition can be applied to any material or article in order to determine the percent by weight of hexavalent chromium in the material. Surface coatings are considered to be a separate homogeneous material from the underlying material such as aluminum. The painted aluminum article as a whole is not a homogenous material because the paint can be mechanically disjointed (sanded or grinded) from the underlying aluminum. Also, the paint and aluminum are each of separate, uniform compositions. Conversion coatings are not considered homogeneous materials because they bond with and chemically modify the underlying material and cannot be mechanically disjointed.

*Comment:* Two respondents requested that the prohibition of hexavalent chromium not apply to "use" but only to products that "contain" hexavalent chromium. Two respondents requested that the phrase "or use materials [that contain hexavalent chromium] in performance of this contract" in 252.223–7XXXX (b) be deleted, so that the restriction would only apply to deliverables that contain hexavalent chromium.

*DoD Response:* DFARS 223.7303 was revised to provide clarity that hexavalent chromium may be used in manufacturing or testing of an article, as long as it will not appear as hexavalent chromium in the final product. As an example, in chrome plating, only the metallic form of chromium remains. Thus, articles plated with the metal chromium are acceptable and the rule will have minimum affect on businesses that plate chromium. Based on an industry comment, DoD modified the rule to indicate that the "prohibition does not apply to hexavalent chromium produced as a by-product of manufacturing processes" such as hard chrome plating. This was a primary concern of one of the industry associations. The phrase "or use materials in performance of this contract" in paragraph (b) of the clause at 252.223–7XXX has been deleted.

*Comment:* Two respondents requested clarification of the definitions of "unapproved" and "damages" in paragraph (c) of the clause 252.223–7XXX.

*DoD Response:* Paragraph (c) of the clause 252.223–7XXX was deleted in its entirety (see section II.I. of this preamble addressing contractor liability).

*Comment:* One respondent expressed an opinion that the title of proposed DFARS Subpart 223.73 is at variance with other parts of the rule. Specifically: "The proposed subpart 223.73 is entitled 'Minimizing the use of hexavalent chromium', but paragraphs 223.7302, 223–7303, and the proposed clause 252.223–7XXX use the term 'prohibition.' "

*DoD Response:* Review of the rule as a whole does not support a finding of a conflict and edits have been made to clarify this. While proposed DFARS 223.7302 and the proposed clause at DFARS 252.223–7XXX use the term "prohibition," the prohibition exists only where proven substitutes are available that provide acceptable performance for the application. Consideration of cost effectiveness, technical feasibility, corrosion control performance, and other factors described in the DoD policy memo must be taken into account. Read in its entirety, proposed DFARS Subpart 223.73 and the clause at proposed DFARS 252.223–7XXX do not impose an absolute ban on the use of hexavalent chromium. Rather, DFARS Subpart 223.73 minimizes the incorporation of hexavalent chromium into deliverables to the extent practicable, considering all the factors described in the DoD policy memo.

*B. Limitation to Not More Than 0.1 Percent Hexavalent Chromium*

*Comment:* One respondent indicated that their products are already compliant with the prohibition on hexavalent chromium in the European Union Restriction of Hazardous Substances Directive. The respondent

further noted that trace amounts of hexavalent chromium remain in the products but are well below the 0.1% threshold noted in the rule.

*DoD Response:* No change in the rule is necessary to address this comment. The decision to allow trace amounts of hexavalent chromium of less than 0.1 percent is consistent with worldwide standards, including Europe's Restriction of Hazardous Substances; thus these products will also be compliant with the this rule.

*Comment:* One respondent noted that the proposal does not reference any background or guidance document for testing for hexavalent chromium percent by weight.

*DoD Response:* There are a number of test procedures that could be used for testing for hexavalent chromium and the choice is dependent on the material being tested. Listing test methods is beyond the scope of the rule. Providers will have flexibility to choose the test method best suited to their application. International standard IEC 62321 "Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) is the most widely used and was finalized in May 2009. ISO Standard 3613 for metallic and organic coatings was updated in November 2010 and is also widely used.

*C. Need for the Rule and Adequacy of Current Regulations*

*Comment:* Three respondents questioned the need for the rule. One respondent stated that existing environmental, safety, and health regulations provide adequate safeguards. Another stated that it considered the rule to be premature without additional study, testing, and proof of performance and since it is limited to one federal department, it should be withdrawn. Another respondent suggested that DoD should consider a phased-in approach.

*DoD Response:* The rule will help to facilitate DoD's compliance with the requirements established in Executive Orders 13514 and 13423 to reduce the use of toxic and hazardous substances. In addition, it allows for the codification of the policy outlined in the DoD policy memo for the acquisition community to effectively implement the guidance in contract requirements. This rule is intended for DoD program managers and contracting officers by prohibiting the use of a DoD specification or solicitation that will result in a deliverable containing hexavalent chromium unless authorized by a senior level DoD official. This addresses a key complaint from industry that DoD specifications are preventing them from eliminating hexavalent chromium despite their desire to do so.

The rule also provides incentive for industry to adopt substitutes for hexavalent chromium. The rule has been modified to provide that a "legacy system" means a program that has passed Milestone A in the defense acquisition management system, as defined in DoD Instruction 5000.02, prior to the effective date of the rule. This is an early entry point into the defense acquisition system and, as noted in section II.A. of this preamble, provides a phasing in of the mandatory requirements of the rule for new acquisitions still only in the development phases. In regard to the need for further testing, DoD and industry have spent years testing substitutes and will continue to do so. The DoD policy does not require use of substitutes unless they can meet a DoD Manufacturing Readiness Level (MRL) of at least eight. Essentially, this means that the substitute has been proven to meet performance requirements. An item at MRL eight must have detailed designs and/or specifications, proven manufacturing and quality processes, and an established and stable supply chain.

*D. Cost to Industry and Mission Readiness*

*Comment:* Seven respondents stated that this rule will increase costs but did not provide substantiation. In one case, the respondent indicated that "elimination of hexavalent chromium compounds * * * might result in increased level of performance risk and increased procurement costs." Another respondent referred to an increase in life cycle costs but did not appear to account for savings in using safer chemicals or the fact that substitutes must perform as well.

*DoD Response:* It should be noted that cost-related comments were made before revisions in the rule that address the most significant concerns such as plating, conversion coatings, and hexavalent chromium as a by-product of manufacturing. The final rule will not affect these activities. Only one respondent provided an estimate. That estimate is instructive and is discussed further below.

Based on numerous conversations with industry and small businesses, DoD believes that the rule will have a positive impact on industry and small business profits and, at worst, be revenue neutral over time. Web sites maintained under DoD's Strategic Environmental Research and Development Program (SERDP) contain briefings describing DoD and industry efforts to develop hexavalent chromium substitutes. For example, the 2010 SERDP conference had a special session on hexavalent chromium minimization. One of the presentations by the Aerospace Industries Association described the aerospace industry's minimization strategy. (Reference: *http://symposium.serdp-estcp.org/Technical-Sessions/2B*). The Web site at *asetsdefense.org* also contains briefings and summaries of DoD-industry conferences.

A number of small businesses have developed non-chromate processes but have been hindered in their ability to market these processes to DoD by existing DoD specifications. In one example, a small manufacturer of fasteners told DoD that they can provide non-chromate fasteners that can meet DoD performance requirements but the DoD specification calls for chromate and the requiring military office sees no reason to change it. The rule will help to remedy this problem. Subpart 223.7203 of the rule provides direction for DoD contracting officers. It prohibits contracts that include a specification or standard that results in a deliverable or construction material containing more than 0.1% hexavalent chromium by weight. In another example, a small family-run business has developed a non-chromate coating for aircraft. While the company has had success with marketing the process to commercial airlines and the Air Force, it has had limited success DoD-wide. Apparently, further motivation is needed for DoD program managers to change existing requirements for use of materials containing hexavalent chromium. The rule implements the DoD policy memo in the procurement world and will thus increase the adoption of this non-chromate coating and similar paints and coatings by small businesses DoD-wide. The rule will also help make businesses more competitive in the world market. Many large companies are requiring suppliers to provide products with a smaller "environmental footprint" by using lifecycle assessment of human health and environmental impacts. For example, over 1800 organizations are now reporting their sustainability status under the Global Reporting Initiative. (See *http://www.globalreporting.org/Home*.)

Non-hexavalent chromium processes should be less costly over the lifecycle of the process due to the use of less hazardous materials and related control and disposal cost. (See examples of documented cost savings in Section III.) The rule was modified so that plating

and anodizing are not covered by the rule. Thus, capital costs for conversions are *de minimis.* For the most part, compliance with the rule will only require switching to non-chromate paints and primers.

The one respondent that provided an estimate indicated a cost of $384,000 to convert to non-hexavalent processes. The company produces lightweight shelters for the military and customers that are primarily Government agencies. The company's main processes are metal surface "cleaning and chemical conversion." The rule, as revised, will not affect cleaning and chemical conversion (conversion coatings) and thus there will be no cost to convert related to these processes. However, the respondent's main concern was not the conversion cost but the concern that one branch of the military will require a hexavalent chromium conversion coating and other branches will require non-hexavalent conversion coatings. The DoD policy and this rule are designed to reduce this problem of maintaining dual systems because they will cause DoD-wide changes in specifications to non-hexavalent processes. While this rule does not affect the respondent's conversion coating process, DoD has other initiatives underway to eliminate inconsistent requirements by DoD program managers by modifying DoD-wide specifications where hexavalent chromium has been required and suitable substitutes are available. As an example, DoD has qualified a non-hexavalent conversion coating for wide federal use (Reference Military Standard MIL–DTL–81706).

*Comment:* Four respondents stated that the rule will increase lifecycle cost due to less corrosion protection.

*DoD Response:* The rule does not necessarily require the use of substitutes for hexavalent chromium if lifecycle costs are higher. Lifecycle costs must be considered when deciding if proven substitutes exist (see factors listed in Section II A. above).

Many often overlooked costs (e.g., costs associated with the use of restrictive protective equipment and related productivity losses, air monitoring, reporting, medical surveillance programs, collection and treatment systems, and hazardous waste disposal) can be avoided with the use of less toxic chemicals.

*Comment:* Three respondents stated that the rule will decrease corrosion protection thereby adversely impacting mission readiness.

*DoD Response:* This rule does not decrease mission readiness as this factor must be considered when determining if proven substitutes exist. To eliminate any confusion, the factors to be considered have been added to DFARS 223.7305.

*Comment:* One respondent inquired about the funding strategy for research and development.

*DoD Response:* This comment is outside of the scope of this case. DoD has a robust program for developing and testing substitutes. (See the program area "Weapons Systems and Platforms" at *http://www.serdp.org.*)

*Comment:* Two respondents recommended that DoD limit review time of the waiver to not more than 30 days.

*DoD Response:* DoD assumes the respondent meant "authorization" for the use of hexavalent chromium vice "waiver." DoD program managers are establishing efficient procedures for reviewing and granting authorizations for programs they manage. Timing for reviews and authorizations will depend on the complexity of the system but program managers have an incentive to ensure that schedules are not adversely affected by the review process.

*E. Legacy Systems*

*Comment:* Three respondents requested clarification of the exceptions at DFARS 223.7303 (now 223.7304), regarding the repair or replacement of legacy systems.

*DoD Response:* The exception for legacy systems has been clarified. Legacy system is now defined and an exception has been added for sustainment related contracts (e.g., parts and services) for existing systems with hexavalent chromium. However, Section 223.7304(a) of the rule requires program managers to consider alternatives during system modifications, follow-on procurements of legacy systems, or maintenance procedure updates if it is deemed feasible and needed to achieve the objectives of the DoD policy. Consideration of alternatives will require analysis of the factors described in the DoD policy memo.

*Comment:* One respondent requested that DoD clarify that there is no expectation to sample and analyze legacy systems and their related parts, subsystems, and components for the sole purpose of identifying hexavalent chromium.

*DoD Response:* DFARS does not have a requirement that legacy systems and their related parts, subsystems, and components be sampled or analyzed for the purpose of identifying hexavalent chromium. Legacy systems are clearly excepted from the rule.

*F. Exceptions*

*Comment:* Four respondents requested clarification of the process for approval of exemptions.

*DoD Response:* Exemption is not a term used in the rule. The respondent evidently means the process for obtaining authorizations to provide a deliverable or construction material with hexavalent chromium as described at DFARS 223.7305. Military departments have established or are establishing internal procedures for processing authorizations for use of hexavalent chromium. These procedures are necessitated by the individual needs of the Service and/or each program office. The approval process will be provided as part of the solicitation. It is in the best interest of DoD and individual program managers to have speedy, efficient processes for handling hexavalent chromium authorizations.

*Comment:* One respondent noted that it would be difficult to achieve the specification requirement under MIL–DTL–38999 for circular connectors if hexavalent chromium is removed from the sealer used in manufacturing circular connectors, noting that current test data suggests that replacing hexavalent chromium with trivalent chromium is not effective for circular connectors with cadmium-free plating.

*DoD Response:* Given the wide range of applications and the longstanding use of hexavalent chromium, DoD recognizes that the transition to proven substitutes will take time and recognizes that it will need to make exceptions to this rule while adequate alternatives continue to be developed. This amendment to the DFARS is one component of DoD's overall strategy to minimizing the use of materials containing hexavalent chromium in Defense acquisitions. As stated in the DoD policy memo, to adequately address the environmental and health concerns associated with the use of materials containing hexavalent chromium, DoD is going beyond its established hazardous materials management processes. In fact, this change to the DFARS specifically acknowledges that there may be particular specifications, such as MIL–DTL–38999, that require case-by-case authorizations for materials that contain hexavalent chromium. Section 223.7305 allows the appropriate DoD official to authorize the use of materials that contain hexavalent chromium when necessary, and if consistent with DoD policy. Any one that seeks such an authorization should follow the procedures in the DFARS Procedures,

Guidance, and Information (PGI) at 223.7305.

Furthermore, DoD appreciates the information regarding the performance of circular connectors using trivalent chromium. DoD continues to make major investments to minimize the use of hexavalent chromium in defense acquisitions. DoD has sponsored efforts that range from fundamental research through advanced development to testing and evaluation for proven substitutes. As discussed earlier, the Strategic Environmental Research and Development Program (SERDP) and the Environmental Security Technology Certification Program (ESTCP) sponsor the Advanced Surface Engineering Technologies for a Sustainable Defense (ASETSDefense), which is a database that facilitates the implementation of new, environmentally friendly technologies for surface engineering (coatings and surface treatments) by providing ready access to background information and technical data from research, development, test, and evaluation efforts as well as the status of approvals and implementations. This database is continually growing as more documents are added, concentrating on coatings that avoid the use of hexavalent chromium. DoD will continue these efforts to provide proven substitutes for an ever increasing range of applications and materials to foster the widespread implementation of alternatives to hexavalent chromium. ASETSDefense's relational database is designed with a search capability to provide access to the available information needed to make informed decisions on the use of alternatives to materials and technologies for surface engineering that pose environmental or health hazards. This information includes detailed engineering data, background documents, and information on processes and products that have been validated, authorized, or implemented. For more information and to access the database go to: *http://www.assetsdefense.org/databasedescription.aspx.*

*Comment:* One respondent requested an exception for all commercial items.

*DoD Response:* To provide an exception for all commercial items will jeopardize the intent of the rule and be contrary to DoD policy. It is the responsibility of the prime contractor to require suppliers to provide content information. There is currently a requirement to provide content information for articles that contain hazardous substances such as hexavalent chromium in Material Safety Data Sheets (see FAR 52.223–3, Hazardous Material Identification and Material Safety Data).

*Comment:* One respondent stated that paragraph (d) of the clause requires that the prohibition will always flow down to the subcontractor and does not provide for a situation where the subcontractor's items qualify for an exemption.

*DoD Response:* Similar to change order requests and other types of approvals, subcontractors may submit proposals for approvals of necessary hexavalent chromium use through the prime contractor for approval. Since the clause flows down, the same approval process for exemptions applies to the subcontractor as well.

*Comment:* One respondent asked if the liability language exempts legacy systems/or components.

*DoD Response:* The paragraph on liability was deleted from the final text of the clause because existing law is sufficient.

*Comment:* One respondent stated that data such as cost effectiveness and corrosion protection be considered in rendering exemptions.

*DoD Response:* The respondent is correct. The DoD policy of April 8, 2009, contains requirements for weighing hexavalent chromium versus substitutes. The following factors, at a minimum, must be considered—

- Cost effectiveness of alternative materials or processes;
- Technical feasibility of alternative materials or processes;
- Environment, safety, and occupational health risks associated with the use of the hexavalent chromium or substitute materials in each specific application;
- Achieving a DoD Manufacturing Readiness Level of at least eight (8) for any qualified alternative;
- Materiel availability of hexavalent chromium and the proposed alternatives over the projected life span of the system; and
- Corrosion performance difference of alternative materials or processes as determined by agency corrosion subject matter experts.

Section 223.7305 has been revised to include the above factors from the DoD policy memo.

*Comment:* One respondent inquired if another exception is required if an exception has been allowed under the original contract. Another respondent asked about exemptions for follow-on procurements, or maintenance procedures.

*DoD Response:* The rule has an exception for legacy systems, which are now defined. An exception has been added for sustainment related contracts (e.g., parts, services) for existing systems with hexavalent chromium approved.

*G. Dollar Threshold*

*Comment:* One respondent requested that a dollar threshold be established for waiver of the rule.

*DoD Response:* Cost effectiveness will be considered in deciding whether to prohibit hexavalent chromium or authorize a deliverable containing hexavalent chromium.

*H. Statutes, Regulations, and Government-Wide Application*

*Comment:* One respondent stated that the rule is contrary to existing statutes such as the Resource Conservation and Recovery Act (RCRA), which sets strict requirements for manifesting and disposing of hazardous waste but does not prohibit use of materials such as hexavalent chromium.

*DoD Response:* The rule is not contrary to existing statutes. The rule is consistent with the 1984 Federal Hazardous and Solid Waste Amendments to RCRA that focused on waste minimization. RCRA prescribes "that the manifest required by subsection (a)(5) shall contain a certification by the generator that the generator of the hazardous waste has a program in place to reduce the volume or quantity and toxicity of such waste to the degree determined by the generator to be economically practicable."

*Comment:* Two respondents stated that the rule is not consistent with national and international regulations because laws such as the Clean Water Act and the Clean Air Act, and regulations such as OSHA and the European Union's Restriction on Hazardous Substances control the release of hexavalent chromium but do not prohibit its use.

*DoD Response:* As with the referenced statutes and regulations, the objective of this rule is the protection of human health and the environment while balancing other considerations. Protection of human health and the environment has historically been accomplished through the reduction of releases and/or managing exposure. This rule reduces releases and exposure by minimizing the incorporation of hexavalent chromium into products acquired by DoD. The DoD approach to minimizing hexavalent chromium does consider factors such as cost effectiveness and technical feasibility as described at 223.7305. Since this rule does not address the use of hexavalent chromium in the manufacturing process or completely ban the use of hexavalent chromium in end items delivered to DoD, other statutes and regulations

addressing releases and managing human exposure will complement this rule when hexavalent chromium is used in or is a byproduct of the manufacturing process or is incorporated into the end item.

*Comment:* One respondent stated that the rule should be applicable Governmentwide.

*DoD Response:* The rule is only applicable to DoD. It is based on the April 8, 2009, policy memorandum, issued by the Under Secretary of Defense (AT&L).

*I. Contractor Liability*

*Comment:* Two respondents requested the removal of the liability provisions of the clause because existing law is sufficient. These respondents stated that the proposed paragraph (c) of 252.223–7XXX poses an unreasonable legal and financial risk.

*DoD Response:* DoD agrees with the respondents. Existing law is sufficient to address any issues regarding deliverables with hexavalent chromium. Paragraph (c) of the clause was removed from the final rule.

*J. Alternatives, List of Preapproved Products, and Government or Third-Party Furnished Components*

*Comment:* One respondent stated that where there are "viable and effective alternatives available," the respondent encourages the use of such alternatives. The respondent provided trivalent chromium processes as an example. Another respondent stated that the prohibition clause will "inadvertently prohibit the use of hexavalent chromium solutions that convert to trivalent chromium or other environmentally friendly compounds."

*DoD Response:* The rule does not prohibit the use of trivalent chromium. The rule is designed to encourage the use of environmentally friendly alternatives as authorization is required to use hexavalent chromium.

*Comment:* Two respondents requested a list or matrix of preapproved hexavalent chromium products. One respondent recommended that the Government and the contractor manage a list of classes of exemptions based on the current state of the art.

*DoD Response:* A comprehensive list of applications that are approved for the use of hexavalent chromium is not feasible for the rule. Such a list will be outdated immediately. However, individual solicitations will contain pre-approved uses of hexavalent chromium for specific applications where its use is deemed necessary to meet performance requirements and/or proven substitutes, considering relevant factors, do not exist. DoD program managers will maintain lists of pre-approved applications based on the criteria for approving substitutes pursuant to the April 8, 2009, memorandum, while taking into consideration the current state of art.

*Comment:* One respondent stated that contractors may be required to incorporate Government-furnished components or equipment in the final products assembled. Therefore, the contractor should not be held liable or responsible for screening such items if the finished product contains hexavalent chromium content in the supplied items from a third party or Government.

*DoD Response:* If any Government-furnished component contains hexavalent chromium, the use will be authorized by the Government. With regard to components supplied by a third party to a prime contractor, it is the responsibility of the prime contractor to know what subcontractors and suppliers provide and comply with the rule. The prime contractor should require subcontractors and suppliers to provide information regarding the content of hazardous and toxic materials. In most cases, Material Safety Data Sheets can be used to provide such information.

*K. Regulatory Flexibility Analysis*

*Comment:* Two respondents stated that the rule will have significant impact on small entities.

*DoD Response:* As mentioned above, since the rule was modified such that plating and anodizing are not covered by the rule, capital costs for conversions are *de minimis.* For the most part, compliance with the rule will only require switching to non-chromate paints and primers. As noted and described more thoroughly in section II.C. of this preamble, based on conversations with industry and small businesses, DoD believes that the rule will have a positive impact on industry and small business profits and at worst, be revenue neutral over time. A number of small businesses have developed non-chromate processes but have been hindered in their ability to market these processes to DoD by existing DoD specifications. The rule will also help make businesses more competitive in the world market. Non-hexavalent chromium processes should be less costly over the lifecycle of the process due to the use of less hazardous materials and related control and disposal costs.

*Comment:* Four respondents stated that the rule will increase lifecycle cost due to less corrosion protection.

*DoD Response:* The rule does not necessarily require the use of substitutes for hexavalent chromium if lifecycle costs are higher or if performance requirements for corrosion control are not met. As described in Section II.E of this preamble, the DoD policy of April 8, 2009, contains factors for considering substitutes. These factors include lifecycle costs.

*L. Meeting With Industry and Stakeholders*

*Comment:* Two respondents recommended that DoD should meet with industry and stakeholders prior to proceeding with proposed rule.

*DoD Response:* The DoD Strategic Environmental Research and Development Program (SERDP) has held and participated in several workshops with industry related to the use of hexavalent chromium and substitutes. The results of these workshops and related research are available on the SERDP Web site at *http://www.serdp.org* and *asetsdefense.org*). In addition, DoD representatives briefed attendees at the 2010 meeting of the National Association for Surface Finishing (NASF). DoD also provided a worldwide briefing concerning the rule on a Web-cast hosted by the NASF. During the Webcast, no negative comments were received (A transcript of the Webcast is available at a cost at *http://www.nasf.org/staticcontent/Dec14Recording.pdf*).

## III. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. This rule is not a major rule under 5 U.S.C. 804.

## IV. Regulatory Flexibility Act

DoD certifies that this rule will not have a significant economic impact on a substantial number of small entities

within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

The rule has been revised to minimize effects on small businesses in particular. The rule only affects deliverables that contain greater than 0.1% hexavalent chromium, not in-plant hexavalent chromium processes or deliverables containing the metal chromium. The rule is primarily aimed at coatings. Consequently, the rule has no effect on—

- Conversion coatings;
- Hard chrome plating;
- Chromic acid anodizing;
- Most chromated metallic ceramics; and
- Chromate washes, etches, pickling, etc.

The primary coatings used by DoD affected by the rule are—

- Chromated primers (for aircraft skins);
- Chromated primers (for components);
- Aircraft fuel tank internal coatings;
- Wet install fastener sealants (used on Naval aircraft);
- Other chromated sealants (used to seal panels, covers, electronics, etc.); and
- Chromated metallic-ceramic paints used in turbine engines.

With respect to deliverables provided to DoD, the above materials are used primarily by the large aerospace companies such as—

- Airframe manufacturers;
- Engine manufacturers; and
- Missile and spacecraft manufacturers.

The suppliers to these large manufacturers will be affected primarily by the requirement to supply components painted with non-chrome primers and chrome-free sealants. Some of these suppliers are large corporations but many are small businesses. However, the substitution of non-chromated products does not require a capital investment but rather a substitution of one coating formulation for another. For the most part, the same coating application equipment can be used and, as stated earlier, the rule will be positive for many of the small businesses that have developed non-hexavalent products.

Some commercial aerospace companies have already adopted chromate-free finish systems. This is being accomplished to meet commercial client desires for more sustainable products, but it also results in a reduction in operating costs. A Boeing press release on the initial testing of non-chromate primers on commercial aircraft states:

"In addition to simplified health and safety monitoring requirements, a chrome-free primer reduces the environmental impact of the paint and stripping process. Removing chrome from the paint and primer eliminates the need for special handling of paint waste, clean up and designated offsite disposal areas."

(Reference *http://www.boeing.com/apachenews/2009/issue_01/news_s7_p2.html*).

In one military example, significant cost avoidance was achieved by eliminating the extensive chromate control requirements involved in bonding attach points for wiring on the production line. Meeting the federal Permissible Exposure Level (PEL) requirements when using chromated primers requires blocking off the area during sanding operations, which interferes with all other work and reduces the efficiency of the production process.

The examples below provide evidence that in most cases, companies will achieve savings when replacing hexavalent chromium with an alternative.

At one maintenance facility, a side-by-side cost comparison was developed for a hexavalent chromium process and a non-hexavalent chromium process developed by a small business. The report shows that—

- The non-chromate process replaced three steps which dramatically reduced labor costs and also eliminated the need to purchase three other chemicals;
- The non-chromate process used ⅔ less rinse water resulting in water and wastewater cost savings and environmental benefit;
- There was a significant reduction in hazardous waste disposal costs;
- The equipment used for the non-chromate product was the same as the standard process (with hexavalent chromium); therefore there were no capital costs for the conversion; and
- Less personal protection equipment (PPE) was required when converting to the non-chromate process (e.g., full mask, hazardous materials suit, respirator cartridges, etc.).

At another facility, there was a savings of $6,000 per aircraft with $1.3 million in documented operational savings at the time of the report due to switching to a non-chromate process. The process also eliminated 500,000 gallons of wastewater per year.

A large maintenance facility in Ohio switched to a non-chromate process and significantly reduced pollutant discharges, improved worker safety, cut process time, and reported savings in excess of $200,000 just due to reduction in state and federal compliance requirements.

Another facility reported a savings of approximately $120,000 per year in water consumption and treatment costs alone and reduced production times by 4,400 man-hours per year.

Fact sheets and detailed cost and performance reports for numerous non-hexavalent chromium processes can be found by searching for "hexavalent chromium" at *http://www.serdp-estcp.org*.

## V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

## List of Subjects in 48 CFR Parts 223 and 252

Government procurement.

**Mary Overstreet,**

*Editor, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 223 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 223 and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

# PART 223—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

■ 2. Add subpart 223.73 to read as follows:

### Subpart 223.73—Minimizing the Use of Materials Containing Hexavalent Chromium

Sec.
223.7300 Definition.
223.7301 Policy.
223.7302 Authorities.
223.7303 Prohibition.
223.7304 Exceptions.
223.7305 Authorization and approval.
223.7306 Contract clause.

## Subpart 223.73—Minimizing the Use of Materials Containing Hexavalent Chromium

### 223.7300 Definition.

*Legacy system,* as used in this subpart, means any program that has passed Milestone A in the defense acquisition management system, as defined in DoD Instruction 5000.02.

### 223.7301 Policy.

It is DoD policy to minimize hexavalent chromium (an anti-corrosive) in items acquired by DoD

(deliverables and construction material), due to the serious human health and environmental risks related to its use. Executive Order 13423, section 3, paragraph (a) requires that the heads of agencies reduce or eliminate the acquisition and use of toxic or hazardous chemicals. Executive Order 13514 requires that the heads of agencies are responsible for "reducing and minimizing the quantity of toxic and hazardous chemicals and materials acquired, used, or disposed of."

**223.7302 Authorities.**

(a) Executive Order 13423 of January 24, 2007, Strengthening Federal Environmental, Energy, and Transportation Management.

(b) Executive Order 13514 of October 5, 2009, Federal Leadership in Environmental, Energy, and Economic Performance.

**223.7303 Prohibition.**

(a) Except as provided in 223.7304 and 223.7305, no contract may include a specification or standard that results in a deliverable or construction material containing more than 0.1 percent hexavalent chromium by weight in any homogeneous material in the deliverable or construction material where proven substitutes are available that provide acceptable performance for the application.

(b) This prohibition is in addition to any imposed by the Clean Air Act regardless of the place of performance.

**223.7304 Exceptions.**

The prohibition in 223.7303 does not apply to—

(a) Legacy systems and their related parts, subsystems, and components that already contain hexavalent chromium. However, alternatives to hexavalent chromium shall be considered by the appropriate official during system modifications, follow-on procurements of legacy systems, or maintenance procedure updates; and

(b) Additional sustainment related contracts (e.g., parts, services) for a system in which use of hexavalent chromium was previously approved.

**223.7305 Authorization and approval.**

(a) The prohibition in 223.7303 does not apply to critical defense applications if no substitute can meet performance requirements. The DoD policy of April 8, 2009, "Minimizing the Use of Hexavalent Chromium," contains requirements for weighing hexavalent chromium versus substitutes. DoD Program Managers must consider the following factors—

(1) Cost effectiveness of alternative materials or processes;

(2) Technical feasibility of alternative materials or processes;

(3) Environment, safety, and occupational health risks associated with the use of the hexavalent chromium or substitute materials in each specific application;

(4) Achieving a DoD Manufacturing Readiness Level of at least eight for any qualified alternative;

(5) Materiel availability of hexavalent chromium and the proposed alternatives over the projected life span of the system; and

(6) Corrosion performance difference of alternative materials or processes as determined by agency corrosion subject matter experts.

(b) However, unless an exception in 223.7304 applies, the incorporation of hexavalent chromium in items acquired by DoD shall be specifically authorized at a level no lower than a general or flag officer or a member of the Senior Executive Service from the Program Executive Office or equivalent level, in coordination with the component Corrosion Control and Prevention Executive. Follow the procedures in PGI 223.7305.

**223.7306 Contract clause.**

Unless an exception in 223.7304 applies, or use has been authorized in accordance with 223.7305, use the clause at 252.223–7008, Prohibition of Hexavalent Chromium, in solicitations and contracts for supplies, maintenance and repair services, or construction.

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Add section 252.223–7008 as follows:

**252.223–7008 Prohibition of Hexavalent Chromium.**

As prescribed in 223.7306, use the following clause:

**Prohibition of Hexavalent Chromium (MAY 2011)**

(a) *Definitions.* As used in this clause—

*Homogeneous material* means a material that cannot be mechanically disjointed into different materials and is of uniform composition throughout.

(1) Examples of homogeneous materials include individual types of plastics, ceramics, glass, metals, alloys, paper, board, resins, and surface coatings.

(2) Homogeneous material does not include conversion coatings that chemically modify the substrate. *Mechanically disjointed* means that the materials can, in principle, be separated by mechanical actions such as unscrewing, cutting, crushing, grinding, and abrasive processes.

(b) *Prohibition.* (1) Unless otherwise specified by the Contracting Officer, the Contractor shall not provide any deliverable or construction material under this contract that—

(i) Contains hexavalent chromium in a concentration greater than 0.1 percent by weight in any homogenous material; or

(ii) Requires the removal or reapplication of hexavalent chromium materials during subsequent sustainment phases of the deliverable or construction material.

(2) This prohibition does not apply to hexavalent chromium produced as a by-product of manufacturing processes.

(c) If authorization for incorporation of hexavalent chromium in a deliverable or construction material is required, the Contractor shall submit a request to the Contracting Officer.

(d) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts for supplies, maintenance and repair services, or construction materials.

(End of clause)

[FR Doc. 2011–10882 Filed 5–4–11; 8:45 am]

BILLING CODE 5001–08–P

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

### 49 CFR Part 195

**[Docket PHMSA–2008–0186; Amdt. 195–96]**

**RIN 2137–AE36**

## Pipeline Safety: Applying Safety Regulations to All Rural Onshore Hazardous Liquid Low-Stress Lines

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** PHMSA is amending its pipeline safety regulations to apply safety regulation to rural low-stress hazardous liquid pipelines that were not covered previously by safety regulations. This change complies with a mandate in the Pipeline Inspection, Protection, Enforcement, and Safety Act of 2006 (PIPES Act).

**DATES:** This final rule takes effect October 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** For technical contents of the final rule contact Mike Israni by phone at 202–366–4571 or by e-mail at *Mike.Israni@dot.gov.* For all other information contact Tewabe Asebe by phone at 202–366–4595 or by e-mail at *tewabe.asebe@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

Until 2008, a hazardous liquid pipeline operating at low-stress in a rural area was not regulated under Federal pipeline safety regulations in 49 CFR part 195 unless it crossed a commercially navigable waterway. Section 195.2 defines a "rural area" as one outside the limits of any incorporated or unincorporated city, town, village, or any other designated residential or commercial area, such as a subdivision, a business or shopping center, or community development.

The PIPES Act was signed into law on December 29, 2006, (Pub. L. 109–468). Section four of the PIPES Act (codified at 49 U.S.C. 60102(k)) required PHMSA to "issue regulations subjecting low-stress hazardous liquid pipelines to the same standards and regulations as other hazardous liquid pipelines." The PIPES Act also stated that the new regulations could be issued in phases.

**Implementation of the PIPES Act Mandate**

PHMSA decided to implement the PIPES Act mandate in phases, in part because PHMSA did not have complete data on the extent of rural low-stress pipelines that would be covered by the statutory mandate. Phase one, through a final rule published on June 3, 2008, (73 FR 31634), applied full Part 195 regulation to higher-risk, larger-diameter rural low-stress pipelines (i.e., those low-stress pipelines with a diameter of 8 ⅝ inches or greater located in or within one-half mile of an unusually sensitive area (USA)). (These requirements are in 49 CFR 195.12.) These are the rural low-stress pipelines that have more potential to cause harm to USAs. These were also the rural low-stress pipelines on which PHMSA had the most information to prepare a regulatory cost/benefit evaluation. PHMSA planned to regulate all remaining rural low-stress pipelines (i.e., smaller-diameter—less than 8 ⅝ inches diameter—rural low-stress pipelines located in or within one-half mile of a USA and all rural low-stress pipelines, of any diameter, located outside the one-half mile USA buffer) once PHMSA had more complete information on the extent of these unregulated rural low-stress pipelines. Phase one also applied reporting requirements in Subpart B of Part 195 to all rural low-stress pipelines (§ 195.48). This data was necessary for PHMSA to complete the regulatory evaluation for the extension of all safety requirements to the remaining rural low-stress pipelines in phase two.

**Surveys**

Because PHMSA did not have adequate information on the number of operators with rural low-stress pipelines, or on the total mileage of these lines in service, we initiated the following actions:

(1) We revised the Pipeline Safety Regulations to require operators of any low-stress line (including those rural low-stress lines not brought under safety regulations) to comply with the annual reporting requirements and the incident reporting requirements of Part 195. This was part of phase one, as discussed above.

(2) On July 31, 2008, (73 FR 44800) OMB Control Number 2137–0623, PHMSA published in the **Federal Register** a notice of OMB-approved survey asking each operator of a rural low-stress hazardous liquid pipeline for voluntary information concerning the mileage and characteristics of these pipelines to assess the costs of subjecting rural low-stress pipeline mileage to Part 195 regulation.

(3) Based on the information received in response to the notice, PHMSA conducted two follow-up inquiries: (1) A request for information from operators who operate rural low-stress lines to determine the potential operating costs they were likely to incur to bring these unregulated lines into compliance with Part 195 regulation; and (2) a request to states with the majority of rural low-stress lines to identify any incident data the state may have collected through the years.

**Phase Two—Notice of Proposed Rulemaking**

With the information PHMSA gathered, we moved to phase two to complete the requirement of the PIPES Act and to apply Part 195 safety requirements to all rural low-stress pipelines not included in the phase one rule. A Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** on June 22, 2010, (75 FR 35366) that proposed to extend Part 195 safety requirements to rural low-stress pipelines of any diameter located more than one-half mile from a USA and those less than 8⅝ inches in diameter located in or within one-half mile of a USA.

The phase one rule established compliance deadlines for the rural low-stress pipelines that it addressed. The phase two NPRM proposed no changes to these phase one deadlines, but proposed new compliance deadlines to apply the requirements to the phase two rural low-stress pipelines proposed for regulation. In addition, PHMSA proposed to define the scope of the "could affect" buffer for application of the integrity management (IM) requirements in § 195.452 to the phase two pipelines. To codify the compliance dates and requirements, we proposed to define three "categories" of rural low-stress pipelines subject to the requirements of § 195.12. These were as follows:

- Category 1: Those rural low-stress pipelines that were covered under the phase one rule;
- Category 2: Rural low-stress pipelines of smaller diameter (less than 8⅝ inches diameter) located in or within one-half mile of a USA (which would be subject to all Part 195 requirements including IM requirements); and
- Category 3: All other rural low-stress pipelines that were not included in phase one. Category 3 lines would fall outside the defined "could affect" buffer for application of IM requirements.

**Integrity Management**

Section 195.452 addresses IM requirements for hazardous liquid pipelines. Under the requirements of that section, operators must take additional actions for each pipeline segment that could affect a high consequence area (HCA). PHMSA has defined HCAs as populated areas, commercially navigable waterways and USAs. HCAs are identified and displayed on maps available from the NPMS.

To comply with IM requirements, pipeline operators must first determine which segments of their pipeline could affect an HCA. To do this, an operator needs to compare its pipeline's location to the locations of HCAs and determine which segments of the pipeline could affect an HCA if there was a product release from the segment. These comparisons have proven to be considerably more burdensome in practice than PHMSA believed when IM rules were initially established. They involve more than just comparison of maps of pipeline location to maps of HCAs. Operators have had to consider the topography and nature of ground cover around their pipelines to estimate the direction and distance that released product might flow. Operators have also had to consider the potential transport of released product via nearby waterways, including such factors as seasonal variations in flow, the effect of stream turbulence, and their ability to respond to a release and contain further transport of spilled product.

During the phase one rulemaking for rural low-stress pipelines, PHMSA

concluded it would be unnecessarily burdensome to require operators of these pipelines to perform a complete "could affect" analysis to determine which rural low-stress pipeline segments would be subject to IM requirements. Rather, PHMSA adopted a one-half mile buffer around USAs [1] as the "could affect" area (i.e., any rural low-stress pipeline segment covered by the phase one rule within the one-half mile buffer would be subject to IM requirements). PHMSA found it unlikely a "could affect" analysis on a rural low-stress pipeline would result in a larger area than the one-half mile buffer for application of IM requirements. Available data showed that the largest spill on land from a low-stress line covered two acres. An acre is 43,560 square feet. If this spill had been limited to a corridor 35 feet wide over its entire length, it still would not have traveled one-half mile. This data, coupled with the relatively lower pressure of low-stress pipelines, led PHMSA to conclude that a one-half mile buffer was more than adequate for application of IM requirements. In the NPRM, PHMSA proposed to continue to use the one-half mile buffer for phase two because PHMSA believed it would be an adequate "could affect" area that identifies the vast majority (if not all) of rural low-stress pipelines that could affect a USA.

As in phase one, PHMSA also proposed to include an option for pipeline operators to use "could affect" analyses in lieu of the one-half mile buffer to determine which of their smaller-diameter low-stress pipelines would be subject to IM requirements. PHMSA recognized that operators could use this option in circumstances where it is likely the "could affect" analysis would determine that a pipeline segment cannot affect a USA (e.g., where the USA is uphill from the pipeline). Nevertheless, PHMSA concluded it would be unreasonable to exclude this option for rural low-stress pipelines since it can identify instances in which application of IM requirements would be unnecessary.

**Economic Burden**

The phase one rule allowed operators of pipelines meeting specified criteria to notify PHMSA if they would incur an excessive economic burden in complying with IM assessment requirements. The criteria were designed for rural pipelines that carry oil from a production facility (e.g., well) and where the pipeline would be abandoned or shut down as a result of the economic burden associated with IM assessments. The phase one rule provided that PHMSA would stay compliance with the IM assessment requirements while it reviews the notification. Based on the outcome of the review, PHMSA may grant the operator a special permit imposing alternative safety requirements in lieu of IM assessments.

For phase two, PHMSA considered extending the economic compliance burden provision to Category 2 pipelines—those smaller diameter rural low-stress pipelines located in or within one-half mile of a USA that would be subject to IM assessment requirements. (Category 3 low-stress pipelines would not be subject to the IM requirements under the NPRM, as described above). PHMSA concluded that this was not necessary because no Category 2 low-stress pipeline would meet the criteria in the economic burden compliance provision (§ 195.12(c)) and concerns about preserving oil production or minimizing risk of alternative transport of crude oil from wells would not apply to these pipelines. Accordingly, we did not propose to extend the economic burden compliance provision to these pipelines in the NPRM.

**Pipelines Subject to USCG Regulation**

Section 195.1(b)(3) states that Part 195 requirements do not apply to pipelines subject to safety regulations of the United States Coast Guard (USCG). The NPRM noted that this exception had previously applied only to low-stress pipelines subject to USCG regulation and through a drafting error in the phase one final rule, was inadvertently expanded to all pipelines subject to USCG requirements. PHMSA proposed to correct this error.

**Public Comments**

PHMSA received comments from three trade associations (two of which filed joint comments), one government agency (National Transportation Safety Board, NTSB), one pipeline consultant, and one individual. None of the comments objected to the changes proposed in the NPRM. The American Petroleum Institute (API) and the Association of Oil Pipelines (AOPL), in joint comments, explicitly noted that they did not oppose application of the baseline requirements of Part 195 to all low-stress pipelines and a requirement that rural low-stress pipelines within one-half mile of a USA also be subject to the IM requirements of Part 195. NTSB supported regulating all low-stress pipelines with requirements graded according to risk. All those commenting suggested some changes, however.

Several comments addressed the scope of the proposed rule. API–AOPL requested that PHMSA clarify that the proposed rule did not apply to gathering or production pipelines or to pipelines excluded from regulation in § 195.1(b). The Independent Petroleum Association of America similarly requested clarification that the proposed requirements do not apply to gathering pipelines. NTSB suggested that the change should include all rural gathering lines and gathering lines in inlets of the Gulf of Mexico. Tracy S. Dahl, who commented on behalf of herself, suggested that the scope should include low-stress gas pipelines such as those associated with coal bed methane gas production.

With the exception of correcting a drafting error associated with low-stress pipelines subject to regulation by the USCG (discussed above), the NPRM proposed no changes to the exclusions listed in § 195.1(b). This section lists the types of pipelines excluded from the requirements of Part 195. The NPRM did not propose any new requirements for gathering pipelines, and thus no requirements applicable to those pipelines may be included in this final rule. Regulation of rural gathering pipelines is governed by § 195.11, which is not affected by this rulemaking. Further, PHMSA notes that Section 4 of the PIPES Act explicitly states, "[t]he regulations issued under this paragraph shall not apply to gathering lines." [2] Gas pipelines were not included in the scope of the NPRM and thus no new requirements can be applied to gas pipelines as part of this rulemaking.

API–AOPL specifically requested that PHMSA clarify the exclusion in paragraph (4) of § 195.1(b) applying to "[a] low-stress pipeline that serves refining, manufacturing, or truck, rail, or vessel terminal facilities, if the pipeline is less than one mile long (measured outside facility grounds) and does not cross an offshore area or a waterway currently used for commercial navigation." API–AOPL noted that PHMSA field personnel have recently informed certain pipeline operators that these segments are part of a larger, non-low-stress pipeline and are thus subject to Part 195, which the associations believe is contrary to the plain language of the regulation. As noted above, the exclusions of § 195.1(b) are not changed

[1] The other component of HCAs (i.e., populated areas) was not affected by the phase one rulemaking and was not included in the phase two NPRM since pipelines in populated areas are not, by definition, in "rural areas" and are already regulated.

[2] 49 U.S.C. 60102(k)(1), as amended by PIPES Act Section 4.

by this rulemaking, and low-stress inter-facility pipelines meeting these criteria are excluded from regulation under Part 195. However, PHMSA notes that § 195.2 and the PIPES Act both define a low-stress hazardous liquid pipeline to be one "that is operated *in its entirety* at a stress level of 20 percent or less of the specified minimum yield strength of the line pipe" (emphasis added). Inter-facility pipelines operating at less than 20% SMYS that is part of a larger pipeline (i.e., some of which operates at higher stress levels) would not fall under this exclusion. Such inter-facility pipelines would be subject to Part 195. Determining whether particular inter-facility piping is part of a larger pipeline depends on the characteristics of individual installations and the applicability of Part 195 requirements to specific inter-facility lines.

API–AOPL objected to the proposed change to the exception in § 195.1(b)(3) for pipelines subject to regulation by the USCG. API–AOPL contended that this was not an error because the change was included in the phase one NPRM and final rule, had been subject to notice and comment and thus cannot simply be "corrected." PHMSA disagrees. The entire rulemaking record clearly demonstrates that this was an error in the regulatory language in the phase one rule. API–AOPL is correct that the re-write of the regulatory language of § 195.1(b) in the phase one NPRM failed to limit this exception to low-stress pipelines and that this omission was repeated in the regulatory language in the final phase one rule. The remainder of the record makes it clear, however, that this change was not intended. The NPRM for the phase one rule stated that PHMSA had

> * * * also clarified the language in several of the exceptions from part 195's coverage. *We have not changed the intent or scope of any of these.* We have simply cleaned up some of the language to make the exceptions easier to read [3] (emphasis added).

The NPRM stated elsewhere that, "[t]his proposal will not affect other *exempt low-stress lines,* specifically pipelines subject to the safety regulations of the USCG * * *" [4] (emphasis added). The exception applicable to lines subject to USCG regulation prior to the effective date of the phase one final rule clearly applied only to low-stress pipelines. Further, the PIPES Act required that PHMSA continue to except from part 195 those "low-stress hazardous liquid pipelines" that were subject to USCG safety regulations. Therefore, PHMSA concludes that the record demonstrates the regulatory language in the phase one final rule concerning the exemption for low-stress pipelines subject to USCG regulation was an inadvertent error and that error has been corrected in this final rule.

API–AOPL and the Independent Petroleum Association of America suggested that PHMSA exclude low-stress carbon dioxide ($CO_2$) pipelines involved in enhanced oil recovery and/or carbon capture and storage. The associations noted that these pipelines pose different risks from petroleum pipelines, that releases from low-stress $CO_2$ pipelines would not require the cleanup that would be associated with releases from crude oil or refined petroleum product pipelines, and that new requirements on $CO_2$ lines could have a chilling effect on future investment in such pipelines. PHMSA notes that these factors were not raised in comments on the phase one rule even though the phase one rule applies to rural low-stress $CO_2$ pipelines. PHMSA never proposed such an exclusion and also considers it inappropriate to exclude some rural low-stress $CO_2$ pipelines from safety regulation while regulating others (i.e., those subject to the phase one final rule), and has not incorporated the suggested exclusion in this final rule.

API–AOPL also objected to the proposed requirement that a pipeline segment subject to IM requirements must remain subject to those requirements if subsequent changes to USA boundaries result in it being more than one-half mile from a USA. They contended this requirement is inappropriate and unsupported. They stated:

> "[i]f future analyses demonstrate that a segment could affect a USA that it previously could not affect, an operator is appropriately required to apply IMP requirements to that segment. Likewise, if a segment no longer could affect a USA, it is only equitable that an operator need not apply the additional protection of such plans to the segment."

PHMSA would agree if the operator of a rural low-stress pipeline were, indeed, required to analyze its pipelines to determine which segments could affect a USA. They are not. This final rule uses a one-half mile buffer as a surrogate for these expensive and complex analyses, as did the phase one rule. While PHMSA considers this a reasonable surrogate, it is possible, though unlikely, that a pipeline segment slightly less than one-half mile from a USA could not affect that USA and it is similarly possible that a pipeline segment slightly more than one-half mile distant could affect a USA. Thus, eliminating IM requirements that already apply solely because the distance to a USA has increased above one-half mile is not appropriate. Operators always have the option to perform an analysis to demonstrate that any pipeline segment could not affect a USA, in which case IM requirements need not apply regardless of the distance from a USA. Operators who experience a change in USA boundaries could exercise this option to remove a pipeline segment from IM scope. If the change in USA boundaries is significant (e.g., the USA ceases to exist), demonstrating that a segment could not affect a USA could be a simple analysis. PHMSA has retained in this final rule the requirement that a pipeline segment determined to be subject to IM requirements due to proximity to a USA must remain subject to those requirements if boundary changes result in more than one-half mile separation, absent a demonstration that the segment could not affect a USA.

Thomas Lael Services, L.P., a pipeline consultant, suggested changes to the regulatory language to improve clarity. Specifically, Lael suggested that proposed §§ 195.12(c)(2)(i) and 195.12(c)(3)(i) be modified to refer specifically to the criteria defining the pipeline segments for which identification is required. PHMSA agrees that this change would improve the clarity of the regulatory language and has revised the final rule accordingly.

Lael also suggested that the provision allowing the operator of a Category 1 rural low-stress pipeline to notify PHMSA of undue economic burden should be extended to operators of Category 2 rural low-stress pipelines. Lael noted that revenue is less for these smaller-diameter pipelines while costs are the same, increasing the importance of considering economic burden. Lael cites costs associated with patrolling the pipeline and performing pipe-to-soil potential readings as examples. These requirements, however, are outside the scope of the economic burden provision. That provision allows an operator of a Category 1 rural low-stress pipeline to notify PHMSA if the economic burden of complying with IM assessment requirements, not other provisions as cited by Lael, would be sufficient to cause the operator to shut down its pipeline. The provision is applicable only to pipelines carrying crude oil from a production facility (among other criteria). Pipelines of 8⅝ inches or less nominal outside diameter—the size that would

[3] **Federal Register**, September 6, 2006, 71 FR 52511.

[4] **Federal Register**, September 6, 2006, 71 FR 52505.

categorize a rural low-stress pipeline as Category 2—and that carry crude oil from a production facility are, by definition, gathering pipelines. Gathering pipelines, as noted above, are not subject to the provisions of § 195.12 and are not subject to IM requirements. Thus, PHMSA concludes that no change to the economic burden provision is needed.

Lael also suggested that the time allowed for operators to identify Category 2 and 3 rural low-stress pipelines be extended to 12 months from the proposed nine months. Lael noted that this would correct an apparent inconsistency with discussion in the NPRM preamble noting the proposed timeframes were the same as those required in phase one; therefore, 12-month timeframes were being proposed for operators of Category 2 and 3 rural low-stress pipelines in instances where 12 months was required of operators of Category 1 rural low-stress pipelines. There is no inconsistency. The NPRM preamble discussion cited by Lael clearly uses 12 months only as an example. The phase one rule required operators of Category 1 rural low-stress pipelines to identify pipeline segments meeting the criteria in the rule before nine months after the effective date of the phase 1 rule. Nine months is also required for Category 2 and 3 rural low-stress pipelines in this final rule, thus affording the consistency discussed in the NPRM.

Lael also questioned the logic of a statement in the phase two NPRM that available data showed that the largest spill on land from a low-stress pipeline traveled two acres and that this justified a one-half mile buffer as a surrogate for analyses of whether a pipeline segment could affect a USA. Lael noted that an acre is a measure of area rather than a measure of distance. PHMSA agrees that the NPRM statement was unclear about the assumptions we used to conclude that this data demonstrated a one-half mile buffer was adequate. PHMSA considered that a spill covering two acres would need to be limited to 35 feet in width over its entire length if it were to extend one-half mile from the pipeline. We concluded that it was unlikely that a spill would behave in this manner and that based on the data we could conclude that a one-half mile buffer was adequate. PHMSA has revised the discussion in the preamble of this final rule to better explain its reasoning.

API–AOPL raised a number of concerns regarding the draft regulatory analysis and regulatory flexibility (i.e., small business) analysis supporting the NPRM. These included use of data from parent companies rather than distinct operating subsidiaries in determining whether small businesses could be affected and use of inappropriate data to estimate costs. These comments have been addressed in the final regulatory analysis that is included in the rulemaking docket.

Finally, NTSB suggested that PHMSA should be given sole jurisdiction over offshore pipelines on the outer continental shelf. NTSB noted, in making this suggestion, that regulation of offshore pipelines was outside the scope of this NPRM. PHMSA agrees that changes in PHMSA jurisdiction over offshore pipelines are beyond the scope of this proceeding.

**Consideration by Technical Hazardous Liquid Pipeline Safety Standards Committee**

On December 3, 2010, PHMSA discussed the proposed rule with the Technical Hazardous Liquid Pipeline Safety Standards Committee (THLPSSC). The THLPSSC is a statutorily mandated advisory committee that advises PHMSA about the technical feasibility, reasonableness and cost-effectiveness of its proposed regulations. PHMSA discussed the comments received in response to the NPRM (e.g., concerns over effect on pipelines excluded from regulation and on rural gathering pipelines). These comments have been previously discussed in this document.

After careful consideration, the THLPSSC voted unanimously to find the NPRM and supporting regulatory evaluation technically feasible, reasonable, practicable, and cost effective. A transcript of the meeting is available in the docket for this rulemaking.

**Final Rule**

This final rule revises 49 CFR part 195 to cover: (1) Rural onshore low-stress pipelines with a diameter smaller than 8⅝ inches located in or within one-half mile of a USA and (2) rural onshore low-stress pipelines of any diameter located more than one-half mile from a USA. With the publication of this final rule, and with limited exceptions, all low-stress pipelines regardless of location or size are now subject to the pipeline safety regulations. The final rule continues in place the one-half mile buffer to be used as the "could affect" area for application of IM requirements.

Our phased approach resulted in several distinct groups of rural low-stress pipelines:

- Rural low-stress pipelines that cross navigable waterways. These have historically been subject to the safety requirements of Part 195. These pipelines were not affected by phase one and are not affected by this rulemaking.
- Rural low-stress pipelines 8⅝ inches or greater in diameter that are located in or within one-half mile of a USA. The requirements of Part 195 were made applicable to these rural pipelines in the phase one rule.
- Rural low-stress pipelines less than 8⅝ inches in diameter that are located in or within one-half mile of a USA. These pipelines are made subject to the safety requirements of Part 195, including the IM requirements in § 195.452, by this final rule.
- Rural low-stress pipelines of any diameter that are located more than one-half mile from a USA. These pipelines are also made subject to the safety requirements of Part 195, excluding the IM requirements in § 195.452, by this final rule.

The phase one rule established a number of compliance deadlines for the rural pipelines it addressed, now referred to as Category 1 rural low-stress pipelines. These deadlines varied from relatively near term (e.g., identifying all pipeline segments subject to the phase one rule by April 3, 2009) to long term (e.g., completing baseline IM assessments by July 3, 2015). This final rule retains the compliance deadlines established in phase one for Category 1 rural low-stress pipelines. This rule subjects Category 2 rural low-stress pipelines to the same Part 195 requirements as those made applicable to Category 1 pipelines in phase one but with different compliance deadlines. Finally, this rule applies all requirements of Part 195 to Category 3 rural low-stress pipelines except for the IM requirements of § 195.452. Consistent with the phase one rule, pipeline segments will have to be identified within nine months of publication of this final rule, baseline IM assessments will have to be completed within five years of publication of the final rule, compliance with the requirements of subpart H of Part 195, Corrosion Control, will have to occur within three years and compliance with all other applicable requirements will have to occur with 12 months of publication of the final rule.

This final rule includes, as did the phase one rule, an option for operators to determine which pipeline segments are subject to IM requirements by performing analyses to determine whether pipeline segments could affect a USA in lieu of using the one-half-mile buffer.

This rule includes, as did the phase one rule, a provision addressing newly

identified USAs. Such new USAs could result in additional pipeline segments meeting criteria for Category 1 or 2 rural low-stress pipelines and thus become subject to IM requirements. This final rule requires that pipeline segments identified as Category 1 or 2 continue to meet the requirements applicable to those Categories even if the boundaries of a USA are redefined so that the pipeline segment (or portion thereof) is no longer within one-half mile of the USA unless the operator determines that the segment could not affect the USA. This provision adds no additional burden because pipeline operators may simply continue to treat their pipelines as they would have without the redefinition of USA boundaries.

**Section-by-Section Analysis**

*Section 195.1*

Which pipelines are covered by this Part?

Section 195.1 has been revised numerous times over the years to include changes to the pipelines covered or excluded from the scope of Part 195. Section 195.1 was revised in the phase one rule to provide more clarity and to include the phase one rural low-stress pipelines within the scope of Part 195. This final rule revises Sections 195.1(a) and (b) to include the rural low-stress pipelines brought under Part 195 regulations in phase two. The changes to this section do not affect any of the other covered or excluded pipelines previously identified in § 195.1.

This final rule also corrects an inadvertent error to § 195.1 that was introduced by the changes made under the phase one rule. The error concerns the long-standing exception for low-stress pipelines subject to the regulations of the USCG. Under the phase one rule, § 195.1 was incorrectly revised to state that Part 195 does not apply to any pipeline subject to the safety regulations of the USCG. In this final rule, we are correcting § 195.1 to state again that Part 195 does not apply to any low-stress pipeline subject to the safety regulations of the USCG.

*Section 195.12*

What requirements apply to low-stress pipelines in rural areas?

This Section is being revised to clarify that all previously unregulated low-stress pipelines in rural areas are now covered under Part 195 regulation. This Section does not apply to rural low-stress pipelines that cross a waterway used for commercial navigation because they have been regulated under Part 195 before either of the rulemakings addressing rural low-stress pipelines.

This section has been revised to define three categories of rural low-stress pipelines (Section 195.12(b)):

- Category 1 lines are those that were regulated in phase one (i.e., rural low-stress pipelines with a diameter of 8⅝ inches or more located in or within one-half mile of a USA).
- Category 2 pipelines are those rural low-stress pipelines of smaller diameter (less than 8⅝ inches) located in or within one-half mile of a USA.
- Category 3 are all remaining rural low-stress pipelines except for those that cross navigable waterways (which are already regulated under § 195.1 and are not addressed in § 195.12).

Section 195.12(c) also sets forth the required deadlines for compliance with various portions of Part 195. The compliance deadlines established by the phase one final rule for Category 1 rural low-stress pipelines remain unchanged. Except for the compliance deadlines for the completion of baseline IM assessments, this final rule establishes deadlines for Category 2 and Category 3 rural low-stress pipelines in the same manner as was done for Category 1 pipelines. For example, operators of Category 1 rural low-stress pipelines were required to identify these pipelines within nine months of the effective date of the phase one final rule and this final rule requires the same nine-month time frame for an operator of a Category 2 or Category 3 rural low-stress pipeline. In phase one, PHMSA adopted a compliance deadline of three and one-half years for completing 50% of baseline IM assessments and seven years for completing all baseline assessments. PHMSA concluded that it was appropriate to reduce the compliance deadlines for these requirements for the pipelines covered by this final rule considering the amount of time that has transpired since the passage of the PIPES Act and the relatively small number of miles that would be subject to these requirements. Thus, this final rule requires that operators of Category 2 pipelines complete all baseline IM assessments within five years of the effective date of the final rule and that at least 50 percent of the assessments be completed within two and one-half years.

As discussed above, PHMSA did not change the provision allowing operators of some Category 1 rural low-stress pipelines to notify PHMSA if they conclude that implementing the IM assessment requirements would pose such an economic burden that they would abandon their pipelines. This provision continues to be limited to Category 1 rural low-stress pipelines carrying crude oil from production facilities and where shutdown of the pipeline would cause loss of oil supply or a transition to truck transportation. PHMSA (with assistance from DOE, as appropriate) will review notifications and, if justified, may grant the operator a special permit to allow continued operation of the pipeline subject to alternative safety requirements.

PHMSA's reasoning for not extending the provision to Category 2 pipelines is based on the definition of "gathering line" in § 195.2. That Section defines any "pipeline 219.1 mm (8⅝ inch) or less nominal outside diameter that transports petroleum from a production facility" as a gathering line. Gathering lines are not subject to the provisions of § 195.12. Instead, requirements applicable to regulated rural gathering lines are found in § 195.11, and do not include IM requirements. As a result, no rural low-stress pipeline of 8⅝ inch or less nominal diameter that carries crude oil from a production facility is subject to IM requirements, and it is not necessary to provide an economic burden provision for these pipelines to ameliorate unintended impacts on production.

*Section 195.48 Scope*

This Section was added in the phase one final rule. There had not previously been a scope Section in Subpart B because all pipelines subject to Part 195 were subject to all the reporting requirements in Subpart B. This Section was added in phase one because the reporting requirements of Subpart B were made applicable to all rural low-stress pipelines, even those not subject to the safety requirements of the phase one rule. Operators of those rural low-stress pipelines not subject to the technical requirements of Part 195 under phase one were not required to complete those portions of the annual report form that relate to IM requirements and inspections.

With this final rule, all rural low-stress pipelines are now subject to all requirements of Part 195, except that Category 3 pipelines are not subject to the IM requirements in § 195.452. The exclusion of portions of the annual report form related to IM has therefore been modified to apply only to operators of Category 3 pipelines.

**Regulatory Analyses and Notices**

*Executive Order 12866 and DOT Policies and Procedures*

PHMSA considers this final rule a non-significant regulatory action under Section 3(f) of Executive Order 12866

(58 FR 51735; Oct. 4, 1993). The rule is also non-significant under DOT regulatory policies and procedures (44 FR 11034: February 26, 1979). PHMSA prepared a Regulatory Evaluation, a copy of which has been placed in the docket.

This final rule affects those rural low-stress pipelines of any diameter that are more than one-half mile outside a USA and rural low-stress pipelines less than 8⅝ inches in diameter that are located in or within one-half mile of a USA. The following table presents the estimates for the mileage affected by this rulemaking:

• Phase Two Eligible Mileage

| Pipeline diameter | Miles inside USA | Miles outside USA |
|---|---|---|
| < 8⅝″ ..... | 100.5 | 443.2 |
| ≥ 8⅝″ ..... | NA | 840.6 |

Four sources of mileage data that provide varying levels of detail were analyzed to derive these final mileage estimates:

• The Regulatory Analysis for the low-stress phase 1 final rule by PHMSA published in August 2006.

• A survey of operators of low-stress pipelines.

• The annual mileage data pipeline operators report to PHMSA.

• Mileage estimates reported to the NPMS.

PHMSA concluded that the estimate of 5,624 miles of rural low-stress pipeline made in the phase one regulatory analysis was a high-end estimate. The results of the survey PHMSA conducted identified 1,575 miles and the NPMS reports 1,672.9 miles, with the NPMS data excluding both intra-plant miles and lines regulated in phase one. The PHMSA annual report database includes 1,536 newly-reported low-stress rural miles. Since the data collected in the survey includes a variety of other information used in this analysis, including characteristics of the reported mileage, it was used for phase two rural low-stress pipeline mileage estimates. Distribution percentages and assumptions relating to the three phase two rural low-stress pipeline segments result in a slightly lower estimate of total miles than the original estimate that resulted from the survey data. This final estimate is approximately 1,384 miles of eligible rural low-stress pipeline.

**Costs of the Regulation**

PHMSA estimates the 30-year net present values [5] of compliance costs for this final rule to be $104.9 million. The operators of the pipelines affected by the regulatory changes included in the final rule are expected to incur costs attributable to those changes. The costs of the rulemaking will be those associated with bringing the affected pipelines into compliance with Part 195, which has the following eight Subparts:

• Subpart A—General
• Subpart B—Annual, Accident, and Safety-Related Condition Reporting
• Subpart C—Design Requirements
• Subpart D—Construction
• Subpart E—Pressure Testing
• Subpart F—Operation and Maintenance
• Subpart G—Qualification of Pipeline Personnel
• Subpart H—Corrosion Control

In addition, operators of the low-stress pipelines brought under Part 195 would also need to comply with 49 CFR part 199, the alcohol and drug testing requirements.

**Benefits of the Regulation**

The 30-year net present value of benefits of this final rule is $326.5 million. PHMSA expects the regulatory changes to reduce the number of incidents and the incident costs and consequences. The ability of the final rule to reduce or avoid these costs is considered to be the primary benefit of the regulation and is referred to as traditional benefits. Data on incident costs for rural low-stress pipelines are generally not available because PHMSA has not regulated these pipelines in the past. Moreover, the reduction in costs that the regulation would cause is also unknown. The final 30-year net present values of benefits of this final rule are $326.5 million.

This final rule also may produce benefits by preventing disruptions in the fuel supply caused by pipeline failures. Any interruption in the fuel supply impacts the U.S. economy by putting upward pressure on the prices paid by businesses and consumers, as incidents on Alaskan low-stress pipelines feeding major petroleum trunk lines have illustrated. Supply disruptions also have national security implications because they increase dependence on foreign sources of oil.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980, as amended, requires Federal agencies to conduct a separate analysis of the economic impact of rules on small entities. The Regulatory Flexibility Act requires that Federal agencies take small entities' concerns into account when developing, writing, publicizing, promulgating, and enforcing regulations.

**Need for Final Rule**

This final rule covers certain rural onshore low-stress hazardous liquid pipelines. Beginning in 1991, Congress paid greater attention to the risks that hazardous liquid and natural gas pipelines pose to the environment. In the Pipeline Safety Act of 1992 (Pub. L. 102–508), Congress gave DOT greater authority to protect the environment from risks posed by pipelines. Congress continued to emphasize the need to better protect the environment from the risks pipelines pose in the Accountable Pipeline Safety and Partnership Act of 1996 (Pub. L. 104–304). With the PIPES Act of 2006 (Pub. L. 109–468), Congress went further and instructed DOT to apply all Part 195 requirements to unregulated rural low-stress pipelines.

PHMSA decided to apply Part 195 requirements to rural low-stress pipelines as a two-phase process. The phase one rulemaking covered large diameter pipe (greater than or equal to 8⅝ inches in diameter) located in or within one-half mile of a USA. These were the higher-risk rural low-stress pipelines. This final rule addresses the remaining unregulated rural low-stress pipelines.

**Description of Actions**

PHMSA is bringing the remaining rural onshore low-stress pipelines not regulated by phase one under the safety regulations of 49 CFR part 195. These lines include rural low-stress pipelines with a diameter of less than 8⅝ inches that are within one-half mile of a USA and rural low-stress pipelines of any size diameter that are outside of the one-half mile USA buffer.

**Related Federal Rules and Regulations**

There are currently no related rules or regulations issued by other departments or agencies of the Federal Government.

**Identification of Potentially Affected Small Entities**

In accordance with size standards published by the Small Business Administration, a pipeline transportation business with 1,500 or fewer employees is considered a small entity.[6] Depending on the products being transported, low-stress pipeline operators belong to the North American Industry Classification System Code (NAICS) 486110, Pipeline Transportation of Crude Oil, or NAICS 486910, Pipeline Transportation of Refined Petroleum Products. For both NAICS codes, a business with 1,500 or

fewer employees is considered a small entity.

PHMSA made an extensive effort to identify small and other operators of rural low-stress lines. PHMSA surveyed these operators to get better information about the number of miles and compliance costs of rural hazardous liquid low-stress pipelines.

To ensure that the response rate was maximized, PHMSA publicized its plans to conduct the survey in (1) a 60-day **Federal Register** (FR) notice published on September 6, 2006, (71 FR 52504) and (2) a 30-day FR notice published on September 7, 2007, (72 FR 51489). No comments were submitted to either notice. PHMSA then announced the availability of the survey in a FR notice published on July 31, 2008, (73 FR 44800).

PHMSA delivered the survey and a letter explaining the importance of the study via three methods:

1. A version of the survey that allowed operators to directly input responses was posted on the PHMSA OPS Online Data Entry Web site (ODES). An e-mail announcing the survey was sent to the contact person responsible for each company's most recent annual report submission.

2. Respondents were also able to print an electronic version of the survey directly from the e-mail received and mail or fax a completed hard copy to the Volpe National Transportation Systems Center (Volpe Center).

3. Finally, in an effort to reach companies that currently operate unregulated pipelines exclusively, PHMSA and the Volpe Center worked with the American Petroleum Institute, the Association of Oil Pipelines and the Independent Petroleum Association of America to announce and distribute the survey to their members via their email newsletters.

Of the 112 operators that responded, 20 reported rural low-stress pipeline mileage. PHMSA then conducted additional follow-up discussions with these operators. Only 12 of the 20 operators were identified as actually having rural low-stress pipeline mileage that would be addressed by the phase two rulemaking. Two of the 12 relevant operators are owned by the same parent company. Therefore, there are 11 businesses that may be potentially affected by this rule.

In order assess the potential business compliance impact, information on the size of the ultimate parent companies for the potentially affected pipeline operators was collected from a compilation of Dun & Bradstreet data, online company profiles, and direct phone calls. This use of data for the ultimate parent enterprise is consistent with the Regulatory Flexibility Act which directs Federal agencies to use the U.S. Small Business Administration's (SBA) definition of a small business. The SBA's definition of a small business considers a firm's parent company and all affiliates to be a single entity. The enterprise name, number of employees, revenues, profits, compliance costs and affected mileage are listed in the following table.

## Ultimate Parent Company Profiles for Low-Stress Pipeline Operators

| Operator Enterprise | Number of Employees | Revenue (millions) | Profits (millions) | Affected Mileage | Compliance Costs | | | Data Source |
|---|---|---|---|---|---|---|---|---|
| | | | | | Initial | Recurring | | |
| | | | | | | Every one year | Every five year | |
| ExxonMobil US Production | 107,000 | $ 372,824 | $ 40,610 | 2.7 | $ 179,000 | $ 2,000 | $ - | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/387.html |
| ConocoPhillips | 32,600 | $ 178,558 | $ 11,891 | 56.8 | $ 15,000 | $ 3,000 | $ - | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/327.html |
| Holly Energy Partners | 1,381 | $ 5,867 | **N/A** | 30.3 | $ - | $ - | $ - | LinkedIn, http://www.linkedin.com/companies/holly-corporation |
| BP | 97,600 | $ 291,438 | $ 20,845 | 2.8 | $ - | $ - | $ - | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/6327.html |
| Marathon Pipe Line LLC | 30,360 | $ 77,193 | $ 3,528 | 82.9 | $ 645,000 | $ - | $ 268,000 | Marathon Fact Book (2008), http://www.marathon.com/content/documents/investor_center/fact_books/2008_factbook_final.pdf |
| Sunoco Pipeline LP | 14,200 | $ 42,101 | $ 891 | 45.0 | $ 500,000 | $ - | $ 500,000 | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/396.html |
| Plains All American Pipeline, L.P. | 2,000 | $ 31,177 | $ 217 | 178.7 | $ 13,632,100 | $ 564,500 | $ 5,691,200 | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/11014.html |
| McCain Pipeline Company | 2 | **N/A** | **N/A** | 4.0 | $ 475,000 | $ - | $ 100,000 | Operator Phone Call |
| MarkWest Energy Partners | 471 | $ 1,338 | **N/A** | 100.0 | $ - | $ - | $ - | Dun&Bradsheet |
| Westlake Petrochemicals | 2,955 | $ 2,290 | $ 69 | 6.3 | $ 121,500 | $ - | $ 100,000 | Yahoo Financial Profile, http://finance.yahoo.com/q/pr?s=WLK |
| Chevron Pipe Line Company | 65,035 | $ 210,783 | $ 18,688 | 37.0 | $ - | $ - | $ - | CNN Financial Profile, http://money.cnn.com/magazines/fortune/global500/2008/snapshots/385.html |

The table above shows that three of the 11 enterprises employ less than 1,500 persons and are thus considered small entities. The cost estimation analysis, described in the Regulatory Analysis, concluded that the rural low-

stress mileage held by two of these operators is already in compliance with Part 195. Therefore, these two small entities will not be adversely affected by the rulemaking. The other small entity, which has four miles of affected rural low- stress mileage, reports an initial compliance cost of $475,000 and recurring costs of $100,000 every five years.

**Alternate Proposals for Small Businesses**

The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where it is possible to do so, and still meet the objectives of applicable regulatory statutes.

The phase two Regulatory Analysis analyzes six regulatory alternatives. They are as follows:

*Alternative 1:* Apply all Part 195 requirements to all eligible rural low-stress pipelines.

*Alternative 2:* Apply all Part 195 requirements to small diameter rural low-stress pipelines located in or within one-half mile of a USA.

*Alternative 3:* Apply all Part 195 requirements to rural low-stress pipelines equal to or greater than 8⅝ inches in diameter located farther than one-half mile from a USA.

*Alternative 4:* Apply all Part 195 requirements to rural low-stress pipelines less than 8⅝ inches in diameter outside one-half mile of a USA.

*Alternative 5:* Apply all Part 195 requirements except Subpart H (Corrosion Control) to all rural low-stress pipelines not currently regulated.

*Alternative 6:* Apply all Part 195 requirements except the IM Program to all rural low-stress pipelines not currently regulated.

Alternative 1 is the alternative that PHMSA has selected. This alternative not only complies with the statutory requirement but also increases the level of safety and environmental protection associated with the transportation of hazardous liquids through low-stress pipelines to a level commensurate with other pipelines that are already subject to the pipeline safety regulations.

**Conclusion**

From the information we have gathered, this final rule will have an economic impact on one known small entity. Therefore, under Section 605 of the Regulatory Flexibility Act, this final rule will not have a significant impact on a substantial number of small entities.

*Executive Order 13175*

PHMSA has analyzed this final rule according to the principles and criteria in Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Because this final rule would not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13175 do not apply.

*Paperwork Reduction Act*

Pursuant to 5 CFR 1320.8(d), PHMSA used the NPRM to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. PHMSA identified four information collections that would bear some impact as a result of this rulemaking. No comments were received. Upon review of the burden impacts on the identified information collection requests, PHMSA believes that the minimal impact to these information collections do not warrant revisions to the currently approved information collections.

The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) type of request; (4) abstract of the information collection activity; (5) description of affected public; (6) estimate of total annual reporting and recordkeeping burden; and (7) frequency of collection. PHMSA estimates that based on the requirements in this rule, the current information collection burden for the following information collections will remain as follows:

*Title of information Collection:* Transportation of Hazardous Liquids by Pipeline: Recordkeeping and Accident Reporting.

*OMB Control Number:* 2137–0047.

*Type of Request:* Revision of a currently approved information collection.

*Abstract:* Hazardous liquid pipeline operators must keep records to ensure that their pipelines are operated safely. Operators must also report accidents.

*Type of Respondents:* Hazardous Liquid Operators.

*Total Annual Responses:* 847.

*Total Annual Burden Hours:* 51,329 hours.

*Frequency of Collection:* On occasion.

*Title of information Collection:* National Pipeline Mapping Program.

*OMB Control Number:* 2137–0596.

*Type of Request:* Revision of a currently approved information collection.

*Abstract:* The operator of a pipeline facility (except distribution lines and gathering lines) provides information to PHMSA on the characteristics of its pipeline system. The submitted information includes updates to annual mapping information for each mile of pipeline.

*Type of Respondents:* Pipeline Facility Operators (except distribution lines and gathering lines).

*Total Annual Responses:* 894.

*Total Annual Burden Hours:* 16,312 hours.

*Frequency of Collection:* Annual.

*Title of information Collection:* Pipeline Integrity Management in High Consequence Areas (Operators with less than 500 Miles of Hazardous Liquid Pipelines).

*OMB Control Number:* 2137–0605.

*Type of Request:* Revision of a currently approved information collection.

*Abstract:* Hazardous Liquid Operators with less than 500 miles of Pipelines are required to continually assess and evaluate the integrity of their pipeline through inspection or testing. Such operators must also implement remedial, preventive, and mitigative actions on these pipelines.

*Type of Respondents:* Hazardous Liquid Operators (with less than 500 miles of pipelines).

*Total Annual Responses:* 132.

*Total Annual Burden Hours:* 267,960 hours.

*Frequency of Collection:* On occasion.

*Title of information Collection:* Public Awareness Program.

*OMB Control Number:* 2137–0622.

*Type of Request:* Revision of a currently approved information collection.

*Abstract:* Current regulations require pipeline operators to develop and implement public awareness programs. Public awareness and understanding of pipeline operations is vital to the continued safe operation of pipelines. Upon request, operators must submit their completed programs to PHMSA or, in the case of an intrastate pipeline facility operator, the appropriate state agency.

*Type of Respondents:* Pipeline Operators.

*Total Annual Responses:* 22,500.

*Total Annual Burden Hours:* 517,480 hours.

*Frequency of Collection:* On occasion.

Any questions regarding these information collections should be directed to Cameron Satterthwaite, Office of Pipeline Safety (PHP–30), Pipeline and Hazardous Materials Safety Administration (PHMSA), 2nd Floor,

1200 New Jersey Avenue, SE., Washington, DC 20590–0001, SW., Washington, DC 20590–0001, Telephone 202–366–8553.

*Unfunded Mandates Reform Act of 1995*

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $141.3 million or more to either state, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the regulatory action.

*National Environmental Policy Act*

The National Environmental Policy Act requires Federal agencies to integrate environmental values into their decision making processes by considering the environmental impacts of their proposed actions and reasonable alternatives to those actions. PHMSA conducted an environmental assessment of the application of phase two safety regulations to rural onshore hazardous liquid pipelines. This environmental assessment examined the environmental impacts of the requirements proposed in the NPRM, and reasonable alternatives to those actions, on the environment.

The environmental assessment found that the NPRM requirements would not significantly affect the quality of the environment. Only limited physical modification or other work that would disturb pipelines would be required, such as identifying segments of pipelines meeting the regulatory definitions, inspection and testing, installing and maintaining line markers, implementing corrosion controls, pipeline cleaning, and establishing integrity assessment programs. The environmental assessment preliminarily concluded the expected reductions in hazardous liquid spills are a minor to moderate positive environmental impact offsetting the negligible negative environmental impacts associated with implementing the rulemaking. The full final environmental assessment is available for review in the public docket. We did not receive any comment on the assessment or preliminary conclusion. Therefore, we conclude that this rulemaking will not result in any significant negative or positive environmental impacts affecting the quality of the human environment.

*Executive Order 13132*

PHMSA has analyzed this final rule according to the principles and criteria contained in Executive Order 13132 ("Federalism"). This final rule would not (1) have substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government; (2) impose substantial direct compliance costs on state and local governments; or (3) preempt state law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

*Executive Order 13211*

This final rule is not a "significant energy action" under Executive Order 13211. It is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Furthermore, this final rule has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

**List of Subjects in 49 CFR Part 195**

Regulated rural gathering, Rural low-stress pipelines.

For the reasons provided in the preamble, PHMSA amends 49 CFR Part 195 as follows:

## PART 195—TRANSPORTATION OF HAZARDOUS LIQUIDS BY PIPELINE

■ 1. The authority citation for Part 195 continues to read as follows:

**Authority:** 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60118; and 49 CFR 1.53.

■ 2. Section 195.1 is revised to read as follows:

### § 195.1 Which pipelines are covered by this Part?

(a) *Covered.* Except for the pipelines listed in paragraph (b) of this Section, this Part applies to pipeline facilities and the transportation of hazardous liquids or carbon dioxide associated with those facilities in or affecting interstate or foreign commerce, including pipeline facilities on the Outer Continental Shelf (OCS). Covered pipelines include, but are not limited to:

(1) Any pipeline that transports a highly volatile liquid;

(2) Any pipeline segment that crosses a waterway currently used for commercial navigation;

(3) Except for a gathering line not covered by paragraph (a)(4) of this Section, any pipeline located in a rural or non-rural area of any diameter regardless of operating pressure;

(4) Any of the following onshore gathering lines used for transportation of petroleum:

(i) A pipeline located in a non-rural area;

(ii) A regulated rural gathering line as provided in § 195.11; or

(iii) A pipeline located in an inlet of the Gulf of Mexico as provided in § 195.413.

(b) *Excepted.* This Part does not apply to any of the following:

(1) Transportation of a hazardous liquid transported in a gaseous state;

(2) Transportation of a hazardous liquid through a pipeline by gravity;

(3) Transportation of a hazardous liquid through any of the following low-stress pipelines:

(i) A pipeline subject to safety regulations of the U.S. Coast Guard; or

(ii) A pipeline that serves refining, manufacturing, or truck, rail, or vessel terminal facilities, if the pipeline is less than one mile long (measured outside facility grounds) and does not cross an offshore area or a waterway currently used for commercial navigation;

(4) Transportation of petroleum through an onshore rural gathering line that does not meet the definition of a "regulated rural gathering line" as provided in § 195.11. This exception does not apply to gathering lines in the inlets of the Gulf of Mexico subject to § 195.413;

(5) Transportation of hazardous liquid or carbon dioxide in an offshore pipeline in state waters where the pipeline is located upstream from the outlet flange of the following farthest downstream facility: The facility where hydrocarbons or carbon dioxide are produced or the facility where produced hydrocarbons or carbon dioxide are first separated, dehydrated, or otherwise processed;

(6) Transportation of hazardous liquid or carbon dioxide in a pipeline on the OCS where the pipeline is located upstream of the point at which operating responsibility transfers from a producing operator to a transporting operator;

(7) A pipeline segment upstream (generally seaward) of the last valve on the last production facility on the OCS where a pipeline on the OCS is producer-operated and crosses into state waters without first connecting to a transporting operator's facility on the OCS. Safety equipment protecting PHMSA-regulated pipeline segments is not excluded. A producing operator of a segment falling within this exception may petition the Administrator, under § 190.9 of this chapter, for approval to operate under PHMSA regulations governing pipeline design, construction, operation, and maintenance;

(8) Transportation of hazardous liquid or carbon dioxide through onshore production (including flow lines), refining, or manufacturing facilities or storage or in-plant piping systems associated with such facilities;

(9) Transportation of hazardous liquid or carbon dioxide:

(i) By vessel, aircraft, tank truck, tank car, or other non-pipeline mode of transportation; or

(ii) Through facilities located on the grounds of a materials transportation terminal if the facilities are used exclusively to transfer hazardous liquid or carbon dioxide between non-pipeline modes of transportation or between a non-pipeline mode and a pipeline. These facilities do not include any device and associated piping that are necessary to control pressure in the pipeline under § 195.406(b); or

(10) Transportation of carbon dioxide downstream from the applicable following point:

(i) The inlet of a compressor used in the injection of carbon dioxide for oil recovery operations, or the point where recycled carbon dioxide enters the injection system, whichever is farther upstream; or

(ii) The connection of the first branch pipeline in the production field where the pipeline transports carbon dioxide to an injection well or to a header or manifold from which a pipeline branches to an injection well.

(c) *Breakout tanks.* Breakout tanks subject to this Part must comply with requirements that apply specifically to breakout tanks and, to the extent applicable, with requirements that apply to pipeline systems and pipeline facilities. If a conflict exists between a requirement that applies specifically to breakout tanks and a requirement that applies to pipeline systems or pipeline facilities, the requirement that applies specifically to breakout tanks prevails. Anhydrous ammonia breakout tanks need not comply with §§ 195.132(b), 195.205(b), 195.242(c) and (d), 195.264(b) and (e), 195.307, 195.428(c) and (d), and 195.432(b) and (c).

■ 3. Section 195.12 is revised to read as follows:

**§ 195.12 What requirements apply to low-stress pipelines in rural areas?**

(a) *General.* This Section sets forth the requirements for each category of low-stress pipeline in a rural area set forth in paragraph (b) of this Section. This Section does not apply to a rural low-stress pipeline regulated under this Part as a low-stress pipeline that crosses a waterway currently used for commercial navigation; these pipelines are regulated pursuant to § 195.1(a)(2).

(b) *Categories.* An operator of a rural low-stress pipeline must meet the applicable requirements and compliance deadlines for the category of pipeline set forth in paragraph (c) of this Section. For purposes of this Section, a rural low-stress pipeline is a Category 1, 2, or 3 pipeline based on the following criteria:

(1) A Category 1 rural low-stress pipeline:

(i) Has a nominal diameter of 8⅝ inches (219.1 mm) or more;

(ii) Is located in or within one-half mile (.80 km) of an unusually sensitive area (USA) as defined in § 195.6; and

(iii) Operates at a maximum pressure established under § 195.406 corresponding to:

(A) A stress level equal to or less than 20-percent of the specified minimum yield strength of the line pipe; or

(B) If the stress level is unknown or the pipeline is not constructed with steel pipe, a pressure equal to or less than 125 psi (861 kPa) gauge.

(2) A Category 2 rural pipeline:

(i) Has a nominal diameter of less than 8⅝ inches (219.1mm);

(ii) Is located in or within one-half mile (.80 km) of an unusually sensitive area (USA) as defined in § 195.6; and

(iii) Operates at a maximum pressure established under § 195.406 corresponding to:

(A) A stress level equal to or less than 20-percent of the specified minimum yield strength of the line pipe; or

(B) If the stress level is unknown or the pipeline is not constructed with steel pipe, a pressure equal to or less than 125 psi (861 kPa) gage.

(3) A Category 3 rural low-stress pipeline:

(i) Has a nominal diameter of any size and is not located in or within one-half mile (.80 km) of an unusually sensitive area (USA) as defined in § 195.6; and

(ii) Operates at a maximum pressure established under § 195.406 corresponding to a stress level equal to or less than 20-percent of the specified minimum yield strength of the line pipe; or

(iii) If the stress level is unknown or the pipeline is not constructed with steel pipe, a pressure equal to or less than 125 psi (861 kPa) gage.

(c) *Applicable requirements and deadlines for compliance.* An operator must comply with the following compliance dates depending on the category of pipeline determined by the criteria in paragraph (b):

(1) An operator of a Category 1 pipeline must:

(i) Identify all segments of pipeline meeting the criteria in paragraph (b)(1) of this Section before April 3, 2009.

(ii) Beginning no later than January 3, 2009, comply with the reporting requirements of Subpart B for the identified segments.

(iii) IM requirements—

(A) Establish a written program that complies with § 195.452 before July 3, 2009, to assure the integrity of the pipeline segments. Continue to carry out such program in compliance with § 195.452.

(B) An operator may conduct a determination per § 195.452(a) in lieu of the one-half mile buffer.

(C) Complete the baseline assessment of all segments in accordance with § 195.452(c) before July 3, 2015, and complete at least 50-percent of the assessments, beginning with the highest risk pipe, before January 3, 2012.

(iv) Comply with all other safety requirements of this Part, except Subpart H, before July 3, 2009. Comply with the requirements of Subpart H before July 3, 2011.

(2) An operator of a Category 2 pipeline must:

(i) Identify all segments of pipeline meeting the criteria in paragraph (b)(2) of this Section before July 1, 2012.

(ii) Beginning no later than January 3, 2009, comply with the reporting requirements of Subpart B for the identified segments.

(iii) IM—

(A) Establish a written IM program that complies with § 195.452 before October 1, 2012 to assure the integrity of the pipeline segments. Continue to carry out such program in compliance with § 195.452.

(B) An operator may conduct a determination per § 195.452(a) in lieu of the one-half mile buffer.

(C) Complete the baseline assessment of all segments in accordance with § 195.452(c) before October 1, 2016 and complete at least 50-percent of the assessments, beginning with the highest risk pipe, before April 1, 2014.

(iv) Comply with all other safety requirements of this Part, except Subpart H, before October 1, 2012. Comply with Subpart H of this Part before October 1, 2014.

(3) An operator of a Category 3 pipeline must:

(i) Identify all segments of pipeline meeting the criteria in paragraph (b)(3) of this Section before July 1, 2011.

(ii) Beginning no later than January 3, 2009, comply with the reporting requirements of Subpart B for the identified segments.

(A)(iii) Comply with all safety requirements of this Part, except the requirements in § 195.452, Subpart B, and the requirements in Subpart H, before October 1, 2012. Comply with Subpart H of this Part before October 1, 2014.

(d) *Economic compliance burden.*

(1) An operator may notify PHMSA in accordance with § 195.452(m) of a situation meeting the following criteria:

(i) The pipeline is a Category 1 rural low-stress pipeline;

(ii) The pipeline carries crude oil from a production facility;

(iii) The pipeline, when in operation, operates at a flow rate less than or equal to 14,000 barrels per day; and

(iv) The operator determines it would abandon or shut-down the pipeline as a result of the economic burden to comply with the assessment requirements in § 195.452(d) or 195.452(j).

(2) A notification submitted under this provision must include, at minimum, the following information about the pipeline: its operating, maintenance and leak history; the estimated cost to comply with the integrity assessment requirements (with a brief description of the basis for the estimate); the estimated amount of production from affected wells per year, whether wells will be shut in or alternate transportation used, and if alternate transportation will be used, the estimated cost to do so.

(3) When an operator notifies PHMSA in accordance with paragraph (d)(1) of this Section, PHMSA will stay compliance with §§ 195.452(d) and 195.452(j)(3) until it has completed an analysis of the notification. PHMSA will consult the Department of Energy, as appropriate, to help analyze the potential energy impact of loss of the pipeline. Based on the analysis, PHMSA may grant the operator a special permit to allow continued operation of the pipeline subject to alternative safety requirements.

(e) *Changes in unusually sensitive areas.*

(1) If, after June 3, 2008, for Category 1 rural low-stress pipelines or October 1, 2011 for Category 2 rural low-stress pipelines, an operator identifies a new USA that causes a segment of pipeline to meet the criteria in paragraph (b) of this Section as a Category 1 or Category 2 rural low-stress pipeline, the operator must:

(i) Comply with the IM program requirement in paragraph (c)(1)(iii)(A) or (c)(2)(iii)(A) of this Section, as appropriate, within 12 months following the date the area is identified regardless of the prior categorization of the pipeline; and

(ii) Complete the baseline assessment required by paragraph (c)(1)(iii)(C) or (c)(2)(iii)(C) of this Section, as appropriate, according to the schedule in § 195.452(d)(3).

(2) If a change to the boundaries of a USA causes a Category 1 or Category 2 pipeline segment to no longer be within one-half mile of a USA, an operator must continue to comply with paragraph (c)(1)(iii) or paragraph (c)(2)(iii) of this section, as applicable, with respect to that segment unless the operator determines that a release from the pipeline could not affect the USA.

(f) *Record Retention.* An operator must maintain records demonstrating compliance with each requirement applicable to the category of pipeline according to the following schedule.

(1) An operator must maintain the segment identification records required in paragraph (c)(1)(i), (c)(2)(i) or (c)(3)(i) of this Section for the life of the pipe.

(2) Except for the segment identification records, an operator must maintain the records necessary to demonstrate compliance with each applicable requirement set forth in paragraph (c) of this Section according to the record retention requirements of the referenced Section or Subpart.

■ 4. Section 195.48 is revised to read as follows:

**§ 195.48 Scope.**

This Subpart prescribes requirements for periodic reporting and for reporting of accidents and safety-related conditions. This Subpart applies to all pipelines subject to this Part. An operator of a Category 3 rural low-stress pipeline meeting the criteria in § 195.12 is not required to complete those parts of the hazardous liquid annual report form PHMSA F 7000–1.1 associated with IM or high consequence areas.

Issued in Washington, DC, on April 28, 2011.

**Cynthia L. Quarterman,**

*Administrator.*

[FR Doc. 2011–10778 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–60–P**

---

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

### 49 CFR Part 395

**[Docket ID. FMCSA–2010–0032]**

**RIN 2126–AB36**

## Hours of Service Exception for Railroad Signal Employees

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Final rule.

**SUMMARY:** The Federal Motor Carrier Safety Administration (FMCSA) amends its hours-of-service (HOS) regulations to adopt regulatory language consistent with the statutory exemption for certain railroad signal employees operating commercial motor vehicles (CMVs) in connection with railroad signal work. This is in accordance with the Rail Safety Improvement Act of 2008 (RSIA of 2008), which took effect July 16, 2009. This action will ensure that Federal, State and local motor carrier enforcement officials are aware of the statutory exemption applicable to signal employees and eliminate the potential for issuance of improper citations.

**DATES:** This action is effective on May 5, 2011.

Docket: For access to the docket to read background documents identified by docket number FMCSA–2010–0032 or RIN 2126–AB36 go to *Federal eRulemaking Portal: http://www.regulations.gov* at any time, or visit the U.S. Department of Transportation's Docket Management Facility at West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Thomas Yager, Chief, Driver and Carrier Operations Division, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, (202) 366–4325.

**SUPPLEMENTARY INFORMATION:**

### I. Background/Overview

This exception to FMCSA's hours-of-service (HOS) regulations is mandated by the RSIA of 2008. This law provides that "signal employees" who operate motor vehicles and who are regulated under 49 U.S.C. 21101, *et seq.,* are not subject to HOS rules promulgated by any other Federal authority, including FMCSA. *See* 49 U.S.C. 21104(e). Thus, FMCSA amends its regulations to state that FMCSA's HOS regulations do not apply to a signal employee who is regulated under 49 U.S.C. 21101–21109. This amendment will clarify the current exception applicable to signal employees for industry and for Federal, State and local law enforcement and eliminate the potential for issuance of improper citations.

FMCSA is also amending the authority citation for 49 CFR part 395 to add appropriate statutory references and eliminate references that are either erroneous or unnecessary.

### II. Legal Basis for the Rulemaking

This final rule is based on FMCSA's authority to implement statutory directives enacted by several provisions of the RSIA of 2008, Public Law 110–432, 122 Stat. 4848, 49 U.S.C. 21101, *et seq.* Section 108 of the RSIA of 2008 substantively amends the law applicable to employees engaged in signal work for

railroad operations, effective July 16, 2009. Section 108(a) amends the definition of "signal employee" to eliminate the words "employed by a railroad carrier." *See* 49 U.S.C. 21101(4). As a result, employees of railroad contractors and subcontractors who are engaged in installing, repairing, or maintaining signal systems (the functions within the definition of signal employee) will also be covered by the HOS laws administered by the Federal Railroad Administration (FRA). Section 108(c) modifies the HOS restrictions applicable to covered employees. *See* 49 U.S.C. 21104(a)–(d).

Finally, section 108(c) provides that the HOS, duty hours, and rest periods of signal employees are governed exclusively by the HOS laws administered by FRA. It also provides that signal employees operating applicable motor vehicles are not subject to other HOS, duty hours, or rest period rules besides the FRA's requirements. *See* 49 U.S.C. 21104(e).

The statutory provision may be incorporated in regulations adopted by FMCSA under the authority of the Motor Carrier Act of 1935 (49 U.S.C. 31502(b)) and the Motor Carrier Safety Act of 1984 (49 U.S.C. 31136). FMCSA is authorized to implement these statutory provisions by delegation from the Secretary of Transportation in 49 CFR part 1.73.

Congress gave the Agency no discretion with respect to implementation of these RSIA of 2008 provisions. While the Administrative Procedure Act (APA) ordinarily requires the issuance of a notice of proposed rulemaking (NPRM) and opportunity for public comment, the APA provides an exception when an "agency for good cause finds * * * that notice and public procedure * * * are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(B). Because this rule is technical and simply conforms FMCSA rules with current statutory provisions, the Agency deems notice and comment procedures "unnecessary" under 5 U.S.C. 553(b)(B). The promulgation of this final rule is a nondiscretionary ministerial act required by a statute. It is also contrary to the public interest to delay clarification of this requirement and FMCSA's lack of authority to enforce regulations in light of the FRA's authority of this area. Thus, the Agency finds that this rule may be adopted without issuing an NPRM and receiving public comment.

Similarly, the Agency finds the normal 30-day delayed effective date following publication of a rule does not apply. 5 U.S.C. 553(d). The APA exempts from the delayed effective date requirement "a substantive rule which grants or recognizes an exemption or relieves a restriction." 5 U.S.C. 553(d)(1). Pursuant to the RSIA of 2008, persons covered by the statutory provision have not been subject to FMCSA's HOS requirements since the enactment of the legislation. This rule simply makes FMCSA rules consistent with the statute. Therefore, a 30-day delay in the effective date would serve no purpose as the Agency amends its rule to eliminate confusion among enforcement officials. The Agency further finds good cause for this rule to take effect upon publication under 5 U.S.C. 553(d)(3) because, given that the rule results in no substantive change in the law, there is no need for the affected industry to prepare for its implementation.

Although the RSIA of 2008 uses the term "exemption" to cover signal employees, in order to avoid confusion with the process that FMCSA uses to grant time-limited exemptions under 49 CFR part 381, today's final rule creates an "exception." This exception, unlike an exemption, is permanent in nature, subject to our legal authority.

## III. RSIA of 2008 Provisions Implemented by the Final Rule

We implement section 108(c) of the RSIA of 2008 by adding paragraph (r) to § 395.1, exempting signal employees who operate CMVs, but who are covered by laws applicable to railroad operations, from FMCSA HOS regulations.

### *Executive Orders 13563 and 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures*

FMCSA has determined that this action does not meet the criteria for a "significant regulatory action" either as specified in Executive Order (E.O.) 12866 as supplemented by E.O. 13563 issued by the President on January 18, 2011 (76 FR 3821), or within the meaning of the Department of Transportation regulatory policies and procedures (44 FR 11034, Feb. 26, 1979). Therefore, this rule has not been reviewed by the Office of Management and Budget (OMB). There is no economic impact to this rule that would necessitate conducting a full regulatory evaluation. The rule simply codifies the elimination of FMCSA jurisdiction over railroad signal employees, pursuant to the RSIA of 2008. The RSIA of 2008 section 108(c) delegates the jurisdiction over the HOS, duty hours, and rest periods of signal employees exclusively to the FRA. *See* 49 U.S.C. 21104(a)–(e).

### *Regulatory Flexibility Act*

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FMCSA is not required to prepare a final regulatory flexibility analysis under 5 U.S.C. 604(a) for this final rule because the Agency has not issued an NPRM prior to this action. This final rule also complies with the President's memorandum of January 18, 2011, entitled *Regulatory Flexibility, Small Business, and Job Creation* (76 FR 3827). As discussed above, promulgation of this final rule is a nondiscretionary ministerial act required by a statute and it creates a regulatory exception.

### *Unfunded Mandates Reform Act of 1995*

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. However, as noted above, this is a non-discretionary action mandated by statute, and such actions do not require preparation of a statement under 2 U.S.C. 1532. In addition, FMCSA is not required to prepare a statement for this final rule because the Agency has not issued an NPRM prior to this action. 2 U.S.C. 1532.

### Executive Order 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this action.

### Paperwork Reduction Act

The rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Given FRA's authority under the RSIA of 2008 to regulate the HOS for certain carriers previously regulated by FMCSA under 49 CFR part 395, FMCSA expects the population of affected entities subject to its HOS paperwork burden may be reduced slightly. However, due to the total number of entities covered, the impact to the burden from this change is expected to be *de minimis.* Therefore, FMCSA has not modified its burden estimate based on this final rule. FMCSA will consider this impact during its next planned update to the associated Information Collection Request.

### National Environmental Policy Act

The Agency analyzed this final rule in accordance with all statutory and regulatory policies under the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and

determined under FMCSA environmental procedures Order 5610.1, published March 1, 2004 (69 FR 9680), that the provision of this rule is categorically excluded (CE) based on Appendix 2, section 6(b) of the FMCSA order. This is a technical amendment needed to conform the regulations to a statutory mandate. In addition to the NEPA requirements to examine impacts on air quality, the Clean Air Act (CAA) as amended (42 U.S.C. 7401 *et seq.*) also requires FMCSA to analyze the potential impact of its actions on air quality and to ensure that FMCSA actions conform to State and local air quality implementation plans. The additional contributions to air emissions from this action are expected to fall within the CAA *de minimis* standards and are not expected to be subject to the Environmental Protection Agency's General Conformity Rule (40 CFR parts 51 and 93).

*Executive Order 12988 (Civil Justice Reform)*

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

*Executive Order 13045 (Protection of Children)*

FMCSA has analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. We determined that this final rule does not pose an environmental risk to health or safety that may disproportionately affect children.

*Executive Order 12630 (Taking of Private Property)*

This final rule does not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

*Executive Order 13132 (Federalism Assessment)*

This action has been analyzed in accordance with the principles and criteria contained in E.O. 13132, Federalism Assessment, and it has been determined that this rulemaking does not have a substantial direct effect or sufficient federalism implications for States that would limit the policymaking discretion of the States. Nothing in this document directly preempts any State law or regulation. This final rule does not impose additional costs or burdens on the States.

*Executive Order 13211 (Energy Effects)*

FMCSA has analyzed this final rule under E.O. 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 Executive Order because it would not be likely to have an adverse effect on the supply, distribution, or use of energy.

**List of Subjects in 49 CFR Part 395**

Highway safety, Motor carriers, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Federal Motor Carrier Safety Administration amends 49 CFR part 395 as follows:

## PART 395—HOURS OF SERVICE OF DRIVERS

■ 1. The authority citation for part 395 is revised to read as follows:

**Authority:** 49 U.S.C. 504, 31133, 31136, 31137, and 31502; sec. 113, Pub. L. 103–311, 108 Stat. 1673, 1676; sec. 229, Pub. L. 106–159 (as transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743, 1744); sec. 4133, Pub. L. 109–59, 119 Stat. 1144, 1744; sec. 108, Pub. L. 110–432. 122 Stat. 4860–4866; and 49 CFR 1.73.

■ 2. Amend § 395.1 to revise paragraph (a)(1) and add paragraph (r) to read as follows:

**§ 395.1 Scope of the rules in this part.**

(a) * * *

(1) The rules in this part apply to all motor carriers and drivers, except as provided in paragraphs (b) through (r) of this section.

* * * * *

(r) *Railroad signal employees.* The provisions of this part shall not apply to a signal employee, as defined in § 395.2, who operates a commercial motor vehicle, is engaged in installing, repairing, or maintaining signal systems, is employed by a railroad carrier or a contractor or subcontractor to a railroad carrier, while regulated by the Federal Railroad Administration.

■ 3. Amend § 395.2 by adding the definition "signal employee" in alphabetical order to read as follows:

**§ 395.2 Definitions.**

* * * * *

*Signal employee,* as defined in 49 U.S.C. 21101(4), means an individual who is engaged in installing, repairing, or maintaining signal systems.

* * * * *

Issued on: May 2, 2011.

**Anne S. Ferro,**

*Administrator.*

[FR Doc. 2011–11018 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**[Docket No. FWS–R6–ES–2011–0032; 92220–1113–0000; ABC Code: C6]**

**RIN 1018–AX81**

## Endangered and Threatened Wildlife and Plants; Reissuance of Final Rule To Identify the Northern Rocky Mountain Population of Gray Wolf as a Distinct Population Segment and To Revise the List of Endangered and Threatened Wildlife

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** On April 15, 2011, President Obama signed the Department of Defense and Full-Year Appropriations Act, 2011. A section of that Appropriations Act directs the Secretary of the Interior to reissue within 60 days of enactment the final rule published on April 2, 2009, that identified the Northern Rocky Mountain population of gray wolf (*Canis lupus*) as a distinct population segment (DPS) and to revise the List of Endangered and Threatened Wildlife by removing most of the gray wolves in the DPS. This rule complies with that directive.

**DATES:** This action is effective May 5, 2011.

**ADDRESSES:** This final rule is available on the Internet at *http://www.regulations.gov.* It will also be available for inspection, by appointment, during normal business hours at U.S. Fish and Wildlife Service, Montana Ecological Services Field Office, 585 Shepard Way, Helena, MT 59601; telephone (406) 449–5225.

**FOR FURTHER INFORMATION CONTACT:** For information on wolves in the northern Rocky Mountains, see *http://www.fws.gov/mountain-prairie/species/mammals/wolf/,* or contact U.S. Fish and Wildlife Service, Montana Ecological Services Field Office (see **ADDRESSES**) or telephone (406) 449–5225. Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

**SUPPLEMENTARY INFORMATION:**

## Background

On April 2, 2009, we, the U.S. Fish and Wildlife Service (Service), published a final rule to remove protections of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), from most of the concurrently designated northern Rocky Mountain (NRM) gray wolf Distinct Population Segment (DPS) (74 FR 15123). Additional background information on the NRM gray wolf population, including previous Federal actions, can be found in our April 2, 2009, final rule. The complete text of the April 2, 2009, publication in the **Federal Register** can be viewed online as part of the docket for this rulemaking at *http://www.regulations.gov.*

Lawsuits challenging our April 2, 2009, final rule were filed in U.S. District Court for the District of Montana and U.S. District Court for the District of Wyoming. On August 5, 2010, the U.S. District Court for the District of Montana vacated and set aside our 2009 delisting rule (*Defenders of Wildlife et al.* v. *Salazar et al.,* (729 F. Supp. 2d 1207 (D. Mont.).

On April 15, 2011, President Obama signed Public Law 112–10—The Department of Defense and Full-Year Continuing Appropriations Act, 2011. Section 1713 of Public Law 112–10 requires: "Before the end of the 60-day period beginning on the date of enactment of this Act, the Secretary of the Interior shall reissue the final rule published on April 2, 2009 (74 FR 15123 *et seq.*), without regard to any other provision of statute or regulation that applies to issuance of such rule. Such reissuance (including this section) shall not be subject to judicial review and shall not abrogate or otherwise have any effect on the order and judgment issued by the United States District Court for the District of Wyoming in Case Number 09–CV–118J and 09–CV–138J on November 18, 2010."

This final rule implements that directive. The regulatory text of this final rule differs from that of the April 2, 2009, final regulation only to reflect the withdrawal of the April 2, 2009, delisting of the western Great Lakes distinct population segment of gray wolves (74 FR 15070) pursuant to terms of a settlement agreement approved by the District Court for the District of Columbia in *Humane Society of the United States* v. *Salazar,* 1:09–CV–1092–PLF (D.DC), on July 1, 2009. The preamble to the 2009 final NRM rule was explicit that the regulatory language pertaining to the western Great Lakes DPS was not attributable to the NRM rule:

"Elsewhere in today's **Federal Register**, we also identify the Western Great Lakes (WGL) DPS and removed the gray wolves in that DPS from the List of Endangered and Threatened Wildlife. As the Service is taking these regulatory actions with respect to the NRM DPS and WGL DPS at the same time, this final rule includes regulatory revisions under § 17.11(h) that reflect the removal of the protections of the Act for both the WGL DPS and most of the NRM DPS, and reflect that gray wolves in Wyoming, an SPR of the NRM DPS range, continue to be listed as an experimental population. However, only that portion of the revised gray wolf listing in § 17.11(h) that pertains to the NRM DPS is attributable to this final rule." [74 FR at 15184]

## Effects of the Rule

Gray wolves in Montana and Idaho, as well as portions of eastern Oregon, eastern Washington, and north-central Utah, are removed from the List of Endangered and Threatened Wildlife. Gray wolves in Wyoming remain on the List of Endangered and Threatened Wildlife and continue to be subject to the provisions of our experimental population regulations codified at 50 CFR 17.84(i) and (n).

Outside Wyoming, this rule will not affect the status of the gray wolf in the NRM under State laws or suspend any other legal protections provided by State law. This rule will not affect the gray wolf's Appendix II status under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

## Concurrent Proposed Rule

In the Proposed Rules section of today's **Federal Register**, we are also publishing a proposed rule that reevaluates the listing of the western Great Lakes population of gray wolves (*Canis lupus*) and proposes to revise it to conform to current statutory and policy requirements. The rule portions for 50 CFR 17.11(h) of this final rule and the proposed western Great Lakes rule are different because the final rule depicts the listing for the gray wolf as it stands today, based on the long history of rulemaking for this species, various judicial decisions, and the recent congressional action. The rule portion of the western Great Lakes rule reflects the listing for the gray wolf as we envision it should be unless public comments on the proposed rule provide information that persuades us that the listing should be presented differently.

## Effective Date

This rule is effective upon publication in the **Federal Register**. Section 1713 of Public Law 112–10, directs us to reissue, within 60 days of enactment, the final NRM rule published on April 2, 2009. Section 1713 also expressly provides that such reissuance is not subject to any other statute or regulation that applies to such a rule.

## Administrative Procedure

This rulemaking implements section 1713 of Public Law 112–10, which expressly provides that the reissuance of this rule is not subject to any other provision of statute or regulation that applies to issuance of such a rule.

## List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

## Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the CFR, 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. Amend § 17.11(h) by revising the entry for "Wolf, gray" under MAMMALS in the List of Endangered and Threatened Wildlife to read as follows:

**§ 17.11 [Amended]**

* * * * *

(h) * * *

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| MAMMALS | | | | | | | |

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| * | * | * | * | * | * | | * |
| Wolf, gray | *Canis lupus* | Holarctic | U.S.A., conterminous (lower 48) States, except: (1) Where listed as an experimental population below; (2) Minnesota; (3) MT, ID, WY (however, see experimental population designation below), eastern WA (that portion of WA east of the centerline of Highway 97 and Highway 17 north of Mesa and that portion of WA east of the centerline of Highway 395 south of Mesa), eastern OR (portion of OR east of the centerline of Highway 395 and Highway 78 north of Burns Junction and that portion of OR east of the centerline of Highway 95 south of Burns Junction), and north central UT (that portion of UT east of the centerline of Highway 84 and north of Highway 80). Mexico. | E | 1, 6, 13, 15, 35 | 17.95(a) | N/A |
| Do | do | do | U.S.A. (MN) | T | 35 | 17.95(a) | 17.40(d) |
| Do | do | do | U.S.A. (portions of AZ, NM, and TX—see § 17.84(k)). | XN | 631 | N/A | 17.84(k) |
| Wolf, gray [Northern Rocky Mountain DPS]. | *Canis lupus* | U.S.A. (MT, ID, WY, eastern WA, eastern OR, and north central UT). | U.S.A. (WY—see § 17.84(i) and (n)). | XN | 561, 562 | N/A | 17.84(i) 17.84(n) |
| * | * | * | * | * | * | | * |

■ 3. Amend § 17.84 by:

■ a. Revising paragraphs (i)(7)(i) and (ii) and removing paragraph (i)(7)(iii);

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

■ c. Revising paragraphs (n)(9)(1) and (ii) and removing paragraph (n)(9)(iii).

The revisions read as follows:

**§ 17.84 Special rules—vertebrates.**

* * * * *

(i) * * *

(7) * * *

(i) The nonessential experimental population area includes all of Wyoming.

(ii) All wolves found in the wild within the boundaries of this paragraph (i)(7) will be considered nonessential experimental animals. In the conterminous United States, a wolf that is outside an experimental area (as defined in paragraph (i)(7) of this section) would take on the status for wolves in the area in which it is found unless it is marked or otherwise known to be an experimental animal; such a wolf may be captured for examination and genetic testing by the Service or Service-designated agency. Disposition of the captured animal may take any of the following courses:

(A) If the animal was not involved in conflicts with humans and is determined likely to be an experimental wolf, it may be returned to the reintroduction area.

(B) If the animal is determined likely to be an experimental wolf and was involved in conflicts with humans as identified in the management plan for the closest experimental area, it may be relocated, placed in captivity, or killed.

(C) If the animal is determined not likely to be an experimental animal, it will be managed according to any Service-approved plans for that area or will be marked and released near its point of capture.

(D) If the animal is determined not to be a wild gray wolf or if the Service or agencies designated by the Service determine the animal shows physical or behavioral evidence of hybridization with other canids, such as domestic dogs or coyotes, or of being an animal raised in captivity, it may be returned to captivity or killed.

* * * * *

(n) * * *

(1) The gray wolves (wolf) identified in paragraph (n)(9)(i) of this section are a nonessential experimental population.

* * *

* * * * *

(9) * * *

(i) The nonessential experimental population area includes all of Wyoming.

(ii) All wolves found in the wild within the boundaries of this experimental area are considered nonessential experimental animals.

* * * * *

Dated: April 26, 2011.

**Daniel M. Ashe,**

*Acting Director, Fish and Wildlife Service.*

[FR Doc. 2011–10860 Filed 5–4–11; 8:45 am]

**BILLING CODE 4310–55–P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**[Docket No. FWS–R2–ES–2009–0077; 92220–1113–0000; ABC Code: C3]**

**RIN 1018–AW63**

# Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population of Sonoran Pronghorn in Southwestern Arizona

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), are reestablishing the Sonoran pronghorn, a federally listed endangered mammal, in its historical habitat in King Valley, Kofa National Wildlife Refuge, in Yuma County, and the Barry M. Goldwater Range—East, Maricopa County, in southwestern Arizona. We are reestablishing the Sonoran pronghorn under section 10(j) of the Endangered Species Act of 1973, as amended, and classify that reestablished population as a nonessential experimental population (NEP). The NEP is located in southwestern Arizona in an area north of Interstate 8 and south of Interstate 10, bounded by the Colorado River on the west and Interstate 10 on the east; and an area south of Interstate 8, bounded by Highway 85 on the west, Interstates 10 and 19 on the east, and the United States-Mexico border on the south.

This action is one of the recovery actions that the Service, Federal and State agencies, and other partners are conducting throughout the historical range of the species. This final rule establishes the NEP and provides for limited allowable legal taking of Sonoran pronghorn within the defined NEP area. An Environmental Assessment and Finding of No Significant Impact have been prepared for this action (see **ADDRESSES** section below).

**DATES:** The effective date of this rule is June 6, 2011.

**ADDRESSES:** This final rule, along with the public comments, Environmental Assessment (EA) and Finding of No Significant Impact (FONSI), is available on the Internet at *http://www.regulations.gov* and *http://www.fws.gov/southwest/es/arizona/.* Supporting documentation is also available for public inspection, by appointment, during normal business hours, at the U.S. Fish and Wildlife Service's Arizona Ecological Services Office at 2321 W. Royal Palm Road, Suite 103, Phoenix, AZ 85021.

**FOR FURTHER INFORMATION CONTACT:** Steve Spangle, Field Supervisor, Arizona Ecological Services Office, 2321 W. Royal Palm Road, Suite 103, Phoenix, AZ 85021 (telephone 602–242–0210, facsimile 602–242–2513). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

## Background

It is our intent to discuss only those topics directly relevant to this final rule establishing a Sonoran pronghorn nonessential experimental population (NEP). For more information on the Sonoran pronghorn, refer to the February 4, 2010, proposed rule (75 FR 5732) and the 1998 Revised Sonoran Pronghorn Recovery Plan (Service 1998: *http://ecos.fws.gov/docs/recovery_plan/981203.pdf*) and its amendments (Service 2002: *http://ecos.fws.gov/docs/recovery_plan/031126.pdf*).

### *Regulatory Background*

We listed the Sonoran pronghorn subspecies (*Antilocapra americana sonoriensis*) as endangered throughout its range on March 11, 1967 (32 FR 4001), under the Endangered Species Preservation Act of October 15, 1966, without critical habitat. This subspecies was included as an endangered species when the Endangered Species Act was signed into law in 1973 (Act; 16 U.S.C. 1531 *et seq.*). The Act provides that species listed as endangered are afforded protection primarily through the prohibitions of section 9 and the requirements of section 7. Section 9 of the Act, among other things, prohibits the take of endangered wildlife. "Take" is defined by the Act as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. Service regulations (50 CFR 17.31) generally extend the prohibitions of take to threatened wildlife. Section 7 of the Act outlines the procedures for Federal interagency cooperation to conserve federally listed species and protect designated critical habitat. It mandates that all Federal agencies use their existing authorities to further the purposes of the Act by carrying out programs for the conservation of listed species. It also states that Federal agencies will, in consultation with the Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 of the Act does not affect activities undertaken on private or other non-Federal land unless they are authorized, funded, or carried out by a Federal agency.

Under section 10(j) of the Act, the Secretary of the Department of the Interior can reestablish populations outside the species' current range and designate them as "experimental." With the experimental population designation, the relevant population is treated as threatened for purposes of section 9 of the Act, regardless of the species' designation elsewhere in its range. Threatened designation allows us discretion in devising management programs and special regulations for such a population. Section 10(j) of the Act allows us to adopt whatever regulations are necessary and advisable to provide for the conservation of a NEP. In these situations, the general regulations that extend most section 9 prohibitions to threatened species do not apply to that species, and the 10(j) rule contains the prohibitions and exemptions necessary and appropriate to conserve that species.

For the purposes of section 7 of the Act, we treat an NEP as a threatened species when the NEP is located within a National Wildlife Refuge or unit of the National Park Service, and section 7(a)(1) and the consultation requirements of section 7(a)(2) of the Act apply. Section 7(a)(1) requires all Federal agencies to use their authorities to carry out programs for the conservation of listed species. Section 7(a)(2) requires that Federal agencies, in consultation with the Service, ensure that any action authorized, funded, or carried out is not likely to jeopardize the continued existence of a listed species. When NEPs are located outside a National Wildlife Refuge or National Park Service unit, then for the purposes of section 7, we treat the population as proposed for listing, and only two provisions of section 7 apply—section 7(a)(1) and section 7(a)(4).

In these instances, NEPs provide additional flexibility because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(4) requires Federal agencies to confer (rather than consult) with the Service on actions that are likely to jeopardize the continued existence of a species proposed to be listed. The results of a conference are in the form of conservation recommendations that are optional as the agencies carry out, fund, or authorize activities. Because the NEP is, by definition, not essential to the continued existence of the species

(see below) then the effects of proposed actions on the NEP will generally not rise to the level of jeopardizing the continued existence of the species. As a result, a formal conference will likely never be required for Sonoran pronghorn established within the NEP area. Nonetheless, some agencies (e.g., Bureau of Land Management (BLM)) voluntarily confer with the Service on actions that may affect a proposed species. Section 10(j)(2)(c)(ii) precludes the designation of critical habitat for nonessential populations. Activities that are not carried out, funded, or authorized by Federal agencies are not subject to provisions or requirements in section 7.

Based on the best scientific and commercial data available, we must determine whether the experimental population is *essential* or *nonessential* to the continued existence of the species. The regulations (50 CFR 17.80(b)) state that an experimental population is considered essential if its loss would be likely to appreciably reduce the likelihood of survival of that species in the wild. All other populations are considered nonessential. We have determined that this experimental population is not essential to the continued existence of the species in the wild (see *Status of Reestablished Populations* section below). Therefore, the Service is designating a nonessential experimental population for the species in this area.

Sonoran pronghorn used to establish the experimental population will come from a captive-rearing pen on Cabeza Prieta National Wildlife Refuge (NWR), as long as appropriate permits are issued in accordance with our regulations (50 CFR 17.22) prior to the animals' removal. The donor population is a captive-bred population derived primarily from wild stock at Cabeza Prieta NWR and from a wild Sonoran pronghorn population in northwestern Sonora, Mexico. The purpose of the captive population is to provide stock for augmenting existing U.S. and Mexican populations of Sonoran pronghorn, as well as supplying founder animals for establishment of an additional U.S. herd(s), in accordance with recovery actions 2.1–2.4 of the Sonoran Pronghorn Recovery Plan (Service 2002, pp. 47–48). The proposed population establishment will involve two phases: (1) Construction and operation of a captive-breeding pen at Kofa NWR, with subsequent releases to establish a new herd; and (2) relocation of excess Sonoran pronghorn from the existing breeding pen at Cabeza Prieta NWR to the eastern portion of the BMGR–E, east of Highway 85 and south of Interstate 8, with the intent of establishing another herd.

*Biological Information*

The Sonoran pronghorn was first described by Goldman (1945, pp. 3–4) and is small in terms of cranial measurements compared to the measurements of other subspecies of pronghorn (Nowak and Paradiso 1971, p. 857). Historically, the Sonoran pronghorn ranged in the United States from approximately the Santa Cruz River, Arizona, in the east, to the Gila Bend and Kofa Mountains, Arizona, to the north, and to Imperial Valley, California, to the west (Service 1998, pp. 4–6). In northwestern Sonora, Mexico, the subspecies is thought to have occurred historically as far south as Bahia Kino and east to Santa Ana and Nogales. In Baja California, Mexico, the subspecies occurred in the northeast from the United States border south to the vicinity of Punta Estrella (Phelps and Webb 1981, pp. 20–21; Service 2002, Fig. 2). Currently, three populations of the Sonoran pronghorn are extant: (1) A U.S. population in southwestern Arizona, south of Interstate 8, west of Highway 85, and east of the Copper and Cabeza Prieta mountains (80–90 wild pronghorn); (2) a population in the El Pinacate Region of northwestern Sonora (101 pronghorn); and (3) a population south and east of Mexico Highway 8 and west and north of Caborca, Sonora (381 pronghorn). The three populations are geographically isolated due to barriers such as roads and fences (Service 2002, pp. 4–10, Fig. 1). The current range of the Sonoran pronghorn in the United States is defined by the boundaries described in number (1) above. Section 10(j)(2)(A) of the Act states that, "The Secretary may authorize the release (and the related transportation) of any population (including eggs, propagules, or individuals) of an endangered species or a threatened species outside the current range of such species * * *" Consistent with years of survey data, we are confident that no Sonoran pronghorn population occurs outside of the current range (Phelps 1981, pp. 23–24; Service 2002, pp. 16 and 47).

Threats to the Sonoran pronghorn include:

(1) Highways, fences, railroads, developed areas, and irrigation canals that block access to essential forage or water resources;

(2) a variety of human activities that disturb pronghorn or degrade habitat, including livestock grazing in the United States and Mexico; military activities; recreation; poaching and hunting; clearing of desert scrub and planting of buffelgrass (*Pennisetum ciliare*), particularly in Sonora; gold mining southeast of Sonoyta, Sonora; dewatering and development along the Gila River and Río Sonoyta; and high levels of undocumented immigration and drug trafficking across the international border, and associated law enforcement response in the United States;

(3) wildfire, fueled by nonnative perennial and ephemeral plants that have increased fine fuels and allowed fire to become a much more frequent event in the Sonoran Desert;

(4) drought and associated limited food and water; and

(5) small population size and random changes in demographics.

Populations at low levels may experience random variations in sex ratios, age distributions, and birth and death rates among individuals, which can cause fluctuations in population size and possibly extinction (Service 2002, pp. 14–35; Primack 2002, pp. 196–197). In very sparse populations, males may have trouble finding females, causing an unequal sex-ratio, which may lead to a reduction in productivity (Primack 2002, pp. 310–311). In 2002, a severe drought was the primary cause of a major die off of Sonoran pronghorn. The U.S. population declined in 2002 by 83 percent, to 21 animals (Bright and Hervert 2005, p. 46). The Mexican populations declined at the same time, but not to the same degree. The population southeast of Highway 8 declined by 18 percent, while the El Pinacate population declined by 26 percent. The differences between the rates of decline north and south of the border may be due to high levels of human disturbance on the U.S. side, due primarily to heightened levels of illegal immigration, smuggling, and law enforcement response (Service 2008, p. 55).

*Recovery Efforts*

Restoring an endangered or threatened species to the point where it is recovered is a primary goal of the endangered species program. Thus, in 1982 we published the Sonoran Pronghorn Recovery Plan (Plan) (Service 1982), which was produced by a Recovery Team comprised of representatives from the Arizona Game and Fish Department (AGFD), Cabeza Prieta NWR, BLM, and Organ Pipe Cactus National Monument (OPCNM). The Plan was subsequently revised in 1994, 1998, and 2002. Major recovery actions include:

(1) Enhance present populations of Sonoran pronghorn by providing supplemental forage and/or water;

(2) Determine habitat needs and protect present range;

(3) Investigate and address potential barriers to expansion of presently used range, and investigate, evaluate, and prioritize present and potential future reintroduction sites within the historical range;

(4) Establish and monitor a new, separate herd(s) to guard against catastrophes decimating the core population;

(5) Continue monitoring populations and maintain a protocol for a repeatable and comparable survey techniques; and

(6) Examine additional specimen evidence to assist in verification of taxonomic status (Service 1998, pp. iii–iv).

The 2002 Supplement did not include delisting criteria; however, eight short-term recovery actions were identified as necessary to downlist the species to threatened. The supplement goes on to say that accomplishing these actions would provide the information necessary to determine delisting criteria. One of the short-term recovery actions was "evaluating potential transplant locations, establishing methodology and protocols, developing interagency agreements (including with Mexico as required), acquiring funding, and initiating reestablishment projects" (Service 2002, p. 38).

After the catastrophic die off of Sonoran pronghorn in 2002, the Service and its partners embarked on a number of aggressive recovery actions to ensure the species' continued existence and to begin to rebuild populations. The cornerstone of these actions was a semi captive breeding facility, constructed in Childs Valley of Cabeza Prieta NWR in 2003, and stocked with wild Sonoran pronghorn in 2004. In 2009, as of May, 69 Sonoran pronghorn resided in the pen. To date, 44 Sonoran pronghorn have been released into the wild population. The goal of the facility is to produce at least 20 fawns each year for release to the current U.S. population, to newly established population(s) in the United States, and to augment Mexican populations.

A number of other projects are under way to increase availability of green forage and water during dry periods and seasons, offsetting to some extent the effects of drought and barriers that prevent Sonoran pronghorn from accessing greenbelts and water, such as the Gila River and Río Sonoyta. Nine emergency water sources (six on Cabeza Prieta NWR, one on OPCNM, and two on BMGR–West) have been constructed in recent years throughout the range of the U.S. population. Four forage enhancement plots, each consisting of a well, pump, pipelines, and irrigation lines, have been developed to irrigate the desert and produce forage for pronghorn. Another plot is nearing completion, and two additional plots will be installed over the next 5 years. These crucial projects, intended to pull the U.S. population back from the brink of extinction, have been cooperative efforts among the Service, AGFD, Marine Corps Air Station—Yuma, Luke Air Force Base, BLM, and OPCNM, with volunteer efforts from the Arizona Desert Bighorn Sheep Society, Arizona Antelope Foundation, and the Yuma Rod and Gun Club.

The U.S. wild population of Sonoran pronghorn has rebounded from 21 in 2002 to 80–90 in 2010; this increase has been facilitated by the collaborative recovery efforts for this species. However, at 80–90 animals currently, the U.S. population is far from being secure. We have begun to work with our Mexican partners on recovery of the Sonoran pronghorn in Sonora. Although the number of pronghorn in Sonora (482 animals) is significantly greater than in the United States, the safety net of water sources and forage plots is not in place there, and a severe drought could decimate those populations.

*Reestablishment Areas*

O'Brien *et al.* (2005) used landscape-level classification and modeling to assess potential Sonoran pronghorn habitat in southwestern Arizona, including current and historical range, as a means of beginning the process of identifying potential locations for establishing a second U.S. Sonoran pronghorn herd. Both models identified greater than 4,632 square miles (sq. mi) (greater than 12,000 square kilometers (sq. km)) of potential habitat (O'Brien *et al.* 2005, pp. 28–30). The largest blocks of potential habitat outside of the current range were the Ranegras and Harquahala plains, King Valley at Kofa NWR north of Interstate 8; Sentinel Plain and other areas to the west between Interstate 8 and the Gila River; and areas not currently occupied south of Interstate 8 and immediately west of Highway 85. The models also identified a large land area east of Highway 85 and south of Interstate 8 as potential habitat. The authors did not evaluate potential habitats in the far eastern portions of the historical range of the Sonoran pronghorn in Arizona (O'Brien *et al.* 2005, Figs. 3 and 4). O'Brien *et al.* (2005, p. 32) further explained that their models were an initial step toward identifying and evaluating potential translocation sites. They recommended soliciting public input, and reviewing predator presence and density, fencing, and the presence of preferred forage and water as additional steps in the evaluation process (O'Brien *et al.* 2005, p. 32).

An Interdisciplinary Team (IDT), comprising members of the Sonoran Pronghorn Recovery Team, the Tohono O'odham Nation, and representatives from land management agencies located in southwestern Arizona, was convened in 2008 to address these and other issues and considerations, and to recommend specific areas for establishing an additional U.S. herd or herds. Development of alternatives for population establishment entailed consideration of three key variables: (1) Geographical areas for establishing populations outside of the current range; (2) potential establishment techniques; and (3) legal status of established populations under the Act. Each of these three key variables had a range of options. The IDT evaluated the three key variables to arrive at the most effective combinations of geographical areas, establishment techniques, and legal status options.

The IDT conducted a mapping exercise to identify areas within the historical range of Sonoran pronghorn in the United States that were under Federal or State ownership and that contained suitable habitat for the species. The result of this exercise was identification of seven potential reestablishment areas, designated Areas A through G. The seven areas were then ranked by the IDT, using seven selection criteria, to determine the best areas for translocation. Area A (King Valley at Kofa NWR, and adjacent portions of primarily Yuma Proving Grounds and BLM lands) and Area D (primarily portions of the BMGR–E, BLM lands, and a portion of the Tohono O'odham Nation, all east of Highway 85) were ranked 1 and 2, respectively.

Public scoping for the Sonoran pronghorn population establishment project included three open houses held in November 2008 on successive evenings at Yuma, Tucson, and Phoenix, Arizona. After consideration of public input, two alternatives were carried forward in the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) process, including establishment of Sonoran pronghorn in Areas A and D, which we will implement as per this final rule. Specific population establishment techniques are described for both areas (see *Release Procedures,* below), and we are establishing Sonoran pronghorn as a NEP in these areas under section 10(j) of the Act.

The NEP encompasses Areas A and D in Arizona, as well as all areas into

which Sonoran pronghorn are likely to disperse. The NEP is defined as follows: An area north of Interstate 8 and south of Interstate 10, bounded by the Colorado River on the west and Interstate 10 on the east; and an area south of Interstate 8, bounded by Highway 85 on the west, Interstates 10 and 19 on the east, and the United States-Mexico border on the south.

Section 10(j) of the Act requires that an experimental population be wholly separate geographically from other wild populations of the same species. The Colorado River; Interstates 8, 10, and 19; and Highway 85, which form the boundaries of the NEP, are barriers to movement. Interstate 8 separates Area A from the current U.S. population, and Highway 85 forms a boundary between Area D and the current U.S. population. We do not expect Sonoran pronghorn to cross these barriers. Brown and Ockenfels (2007, p. 29) found that high-speed highways with right-of-way fences, such as these, were virtually Sonoran pronghorn-proof due to comprehensive fencing and high-volume traffic, and that interstate highways are effectively impassable for the species. Only once, in 1973, has a Sonoran pronghorn been known to cross Interstate 8 (Phelps 1981, p. 27). In 2008, a Sonoran pronghorn crossed Highway 85 and its associated right-of-way fences into BMGR–E (Howard 2008, pers. comm.); this is the only confirmed case of a Sonoran pronghorn crossing Highway 85 and its right-of-way fences. However, in July 2010, an unconfirmed sighting of a pronghorn doe was reported well east of Highway 85 in BMGR–E. This animal was not collared or ear-tagged, so its origins are uncertain, but it presumably crossed Highway 85 into BMGR–E from the wild population. No other documented cases of Sonoran pronghorn crossing Highway 85 and its right-of-way fences are known.

Nonetheless, in the unlikely event that a Sonoran pronghorn moves outside the NEP, the individual or individuals would not constitute a population. Our regulations define "population" as a "group of fish or wildlife * * * in common spatial arrangement that interbreed when mature" (50 CFR 17.3) and thus determine that a "geographic separation" is any area outside the area in which a particular *population* sustains itself. See *Wyo. Farm Bureau Fed'n* v. *Babbitt*, 199 F. 3d 1224, 1234 (10th Cir. 2000). These definitions preclude the possibility of population overlap as a result of the presence of individual dispersing Sonoran pronghorn—by definition lone dispersers do not constitute a population or even part of a population, since they are not in "common spatial arrangement" sufficient to interbreed with other members of a population. The evidence suggests that the likelihood of a lone pronghorn crossing the NEP boundary is very low, so it follows that the probability of that lone disperser encountering another Sonoran pronghorn of the opposite sex and reproducing is even more remote.

The status, as endangered or as a member of the NEP, of any dispersing Sonoran pronghorn that manages to cross Highway 85, Interstate 8, or other barriers between the NEP and the current range is defined geographically. Any Sonoran pronghorn within the NEP area is considered a member of the nonessential experimental population (including any dispersing animals from within the current range that cross into the NEP area), whereas any Sonoran pronghorn outside of the NEP is fully protected under the Act as an endangered species.

The geographical extent of the NEP designation includes areas unlikely to be used by Sonoran pronghorn, as only portions of this proposed NEP area contain suitable habitat. In the NEP area, Sonoran pronghorn habitat is limited to undeveloped areas within valleys. Mountainous areas, such as the Kofa, Castle Dome, Palomas, and Gila Bend mountains, do not provide habitat for this species; nor do developed areas within the valleys, such as agricultural areas and towns and cities. However, the NEP area represents what we believe to be the maximum geographical extent to which Sonoran pronghorn could move if released in Areas A and D. Once released into these areas, we expect the Sonoran pronghorn population(s) to grow and expand into adjacent suitable habitats, potentially moving to the boundaries of the NEP. In the unlikely event that any of the released Sonoran pronghorn, or their offspring, move across interstate highways or other barriers (e.g., rivers or mountainous areas, developed agriculture areas, or urban areas) to outside the designated NEP area (but not into the area occupied by the wild population), then the Service will evaluate the need, in the context of the 10(j) requirements, to amend the 10(j) rule to enlarge the boundaries of the NEP area to include the area of the expanded population. As discussed above, the likelihood of Sonoran pronghorn moving from the NEP area into the current range is very low.

*Release Procedures*

The IDT developed the methods of release of Sonoran pronghorn into Areas A and D with the objective of maximizing the likelihood of success in establishing herds, while minimizing the impact to the source population (the animals in the captive breeding pen at Cabeza Prieta NWR) and limiting mortality or injury to translocated Sonoran pronghorn to the maximum extent possible. In King Valley, Kofa NWR (Area A), a rectangular-shaped, 0.5-square-mile (sq.-mi) (1.29-square-kilometer (sq.-km)) captive-breeding pen will be constructed. The pen will include water sources and irrigated areas to enhance forage production, as well as two observation towers from which the animals will be monitored. In December 2011/January 2012, we anticipate moving 11 Sonoran pronghorn (10 females and 1 male) to the pen from the captive-rearing pen at Cabeza Prieta NWR. These animals will be captured, either by use of a boma (a circular trap used inside the pen) or tranquilizer dart gun and moved one or two at a time by helicopter.

Prior to movement to Kofa NWR, Sonoran pronghorn will be screened for epizootic hemorrhagic disease (EHD) and bluetongue (BTV). Both diseases can infect bighorn sheep and mule deer, as well as Sonoran pronghorn. To ensure these diseases are not inadvertently moved to Kofa NWR, only Sonoran pronghorn not exhibiting clinical signs (active lesions) of EHD and BTV will be transported to the new captive breeding pen at Kofa NWR. Biennial rotation of the breeding male and death of any Sonoran pronghorn in the breeding pen at Kofa NWR would require additional flights to bring new animals from Cabeza Prieta NWR. Methods perfected at Cabeza Prieta NWR will be employed in these activities, which have been used successfully with minimal mortality of pronghorn.

Assuming successful captive-breeding at the Kofa NWR pen, up to 20 Sonoran pronghorn will be released annually into suitable habitats outside of but adjacent to the pen site at Kofa NWR, beginning as early as the winter of 2012 or 2013 and recurring each winter until 2020. Sonoran pronghorn in the pen, as well as animals released, will be closely monitored to determine success or need for adaptive management. Success criteria will be developed by the recovery team prior to the release of any animals, but the objective will be to continue releases until the population can sustain itself without augmentation. Concurrently, but only if excess animals are available from the captive-breeding pen at Cabeza Prieta NWR (not needed to augment existing herds or for the pen at Kofa NWR), these animals will be

captured from the pen, transported to a holding pen in Area D, held temporarily, and then released as a group. The holding pen in Area D is located in the Midway Well area near Hat Mountain (an area locally known as BMGR–E "Area B") in Maricopa County, Arizona. Ideally, the Sonoran pronghorn will be captured together and moved quickly to a holding pen, allowed to recover for a brief period, and released together.

Released animals in Area D will be monitored via aircraft and on-the-ground personnel to determine survival, reproduction, and other measures of success. Details of the monitoring plan will be developed prior to release and will include collection of enough data to quantitatively determine if we are meeting success criteria and, if not, what needs to be corrected to ensure success. Through adaptive management, release techniques and other management will be revised as needed to ensure success. Additional description of the release procedures and monitoring protocols can be found in the final EA (for copies of this document, see **ADDRESSES** above).

*Status of Reestablished Populations*

We have determined that these reestablished populations are nonessential, based on the following:

(a) Wild populations of the Sonoran pronghorn, totaling about 562 to 572 animals, currently exist at: (1) Cabeza Prieta NWR, OPCNM, BMGR, and adjacent BLM lands; (2) in the El Pinacate region of Sonora; and (3) south and east of Highway 8 in Sonora.

(b) A captive-breeding pen at Cabeza Prieta NWR maintains a captive population and provides stock to augment the wild populations in Arizona and Sonora. The pen has been highly successful. It was first stocked with Sonoran pronghorn in 2004; the original group of 11 animals has grown to 69 (May 2010), and another 44 Sonoran pronghorn have been released from the pen into the wild.

(c) The first priority for use of animals in the captive-breeding pen at Cabeza Prieta NWR is to augment herds within the boundaries of the current range of the species. Relocation of Sonoran pronghorn from the captive breeding pen to Kofa NWR will not appreciably inhibit the augmentation efforts for the herds within the boundaries of the current range of the species. Sonoran pronghorn produced at the Cabeza Prieta NWR pen that are not needed to augment herds within the current range or to populate the Kofa NWR pen will be used to establish a population in Area D.

(d) The possible failure of this action will not appreciably reduce the likelihood of survival of the species in the wild, because (1) the first priority for use of Sonoran pronghorn from the captive-breeding pen at Cabeza Prieta NWR is to augment the wild herd, and (2) recovery actions have been, and continue to be, implemented in the United States to reduce the effects of drought on the species (Service 2009, pp. 9, 18–19).

(e) Through programs of work endorsed by the Canada/Mexico/U.S. Trilateral Committee for Wildlife and Ecosystem Conservation and Management, the Service and AGFD coordinate with our Mexican partners on recovery actions for Sonoran pronghorn in Mexico, enhancing the likelihood of their survival and recovery.

We will ensure, through our section 10 permitting authority and the section 7 consultation process, that the use of Sonoran pronghorn from the donor population at Cabeza Prieta NWR for releases in Areas A or D is not likely to jeopardize the continued existence of the species in the wild. Establishment of additional Sonoran pronghorn populations within the species' historical range is a necessary step in recovery (Service 2002, p. 38).

The special rule that accompanies this 10(j) rule is designed to broadly exempt take of Sonoran pronghorn from the section 9 prohibitions outside of National Wildlife Refuge and National Park Service lands, as long as the take is incidental to otherwise lawful activities. We provide this exemption because we believe that incidental take of members of the NEP associated with otherwise lawful activities will not pose a substantial threat to the recovery of Sonoran pronghorn, as activities that currently occur or are anticipated in the NEP area are generally compatible with Sonoran pronghorn recovery. For example, in Area A, there are vast expanses of open valleys without major barriers to Sonoran pronghorn movement that provide suitable habitat. These valleys include King Valley at Kofa NWR, Palomas Plain, the southern end of the Ranegras Plain, and portions of the Yuma Proving Grounds. The La Posa Plain and Castle Dome Plain also provide habitat. Highway 95 runs north-south through those plains, and although it may somewhat inhibit movement to the west side of those plains, it is not a substantial barrier because it lacks right-of-way fences. In Area D, there is considerable habitat in the valleys among the Sauceda, Sand Tank, Batamote, and other mountains in that region.

There are existing military activities at Yuma Proving Grounds in Area A and BMGR–E in Area D, but pronghorn have coexisted with military activities for many years at the BMGR (deVos 1990, pp. 49–50; Krausman *et al.* 2004, pp. 29–33; Krausman *et al.* 2005, pp. 20–22); as a result, we believe they will persist with the similar activities conducted at Yuma Proving Grounds and in Area D. Although some forms of military activities could potentially result in incidental death or injury of individual pronghorn, no incidental take has ever been documented due to military activities, even before precautions were set in place as a result of section 7 consultations to minimize the likelihood of such take at the BMGR.

There is some likelihood of Sonoran pronghorn drowning in canals in Area A. Canals are present in agricultural areas on the southern, eastern, and northeastern portions of Area A; Sonoran pronghorn are known to drown in such canals (Rautenstrauch and Krausman 1986, p. 9). The major canal in Area A most likely to be accessed by Sonoran pronghorn is the Wellton Canal, located north of the Gila River and on the northern edge of the agricultural lands in the Gila Valley. It is equipped with ramps and steps designed to prevent ungulate drownings. In addition, a series of wildlife water sources exists to the north of the canal as alternative water sources. Most of the canals elsewhere in Area A are too small to result in Sonoran pronghorn entrapment, or are surrounded by agriculture or other developments and are unlikely to be accessed by Sonoran pronghorn. Other activities such as recreational hunting and camping, vehicle use, livestock grazing, and small-scale rural or agricultural development, are anticipated to either have minimal effects on Sonoran pronghorn or will be limited in extent (e.g., rural and agricultural development).

Under section 7(a)(1) of the Act, all Federal agencies are mandated to use their authorities to conserve listed species. In addition, the BLM has a policy of conferring with the Service, under section 7(a)(4), on their actions that may affect proposed species (BLM 6840 Manual). Some activities do have greater potential to compromise the success of the Sonoran pronghorn reestablishment than those described above. For instance, construction of new highways, particularly those with rights-of-way fencing, or new canals in the NEP could create barriers to movement and bisect important pronghorn habitats. There is also the potential for BLM to permit large-scale solar power

plants, which would be constructed in the valleys and could eliminate up to tens of thousands of acres of habitat. Other BLM-authorized projects, such as agricultural leases, could also potentially remove large blocks of habitat and perhaps compromise the success of this project. The potential for these projects to impact the reestablishment is probably greatest on BLM lands in the valleys to the east of Kofa NWR. The Service will have the opportunity through the section 7(a)(4) conference process to work with the BLM to minimize the potential adverse effects of solar plants, agricultural leases, highways, or other projects that may compromise Sonoran pronghorn recovery.

*Management*

The lands within the NEP area are managed and listed in descending order of acreage within areas A and D as follows: Area A—the Service (Kofa NWR), Department of the Army (Yuma Proving Grounds), BLM, Arizona State Lands Department, private landowners, and Colorado River Indian Tribes; Area D: Tohono O'odham Nation, BLM, Department of the Air Force (BMGR–E), private owners, and Arizona State Land Department. Outside of Areas A and D, but within the NEP, land ownership is similar, but also includes lands within the Gila River Indian Reservation, Ak-Chin Indian Reservation, Pascua Yaqui Indian Reservation, San Xavier Reservation, Buenos Aires NWR, Saguaro National Park, OPCNM, Tucson Mountain Park, and Coronado National Forest. Due to the management flexibility provided by the NEP designation and the special rule, we do not anticipate that establishment of Sonoran pronghorn in Areas A or D and subsequent dispersal of Sonoran pronghorn from the release sites will affect management on Tribal, BLM, National Forest, Department of Defense, State, or private lands.

Through section 7 consultations on NWR lands and National Park Service lands, some changes in management may occur to reduce adverse effects to Sonoran pronghorn, including minimizing the likelihood of incidental take. However, we believe few changes will be needed, because management of these lands already is broadly compatible with Sonoran pronghorn recovery. Other Federal agencies that propose actions on Kofa NWR or National Park Service lands will also be required to consult with us under section 7 of the Act, if such activities may affect Sonoran pronghorn. For instance, some activities conducted by Yuma Proving Grounds (e.g., overflights of Kofa NWR) will be subject to the consultation requirements. Some Federal agencies, such as BLM, that propose actions outside of Kofa NWR or National Park Service lands may elect to work with the Service voluntarily through the section 7(a)(4) conferring process to ensure that adverse effects of their actions on Sonoran pronghorn in the NEP area are minimized.

The Service (Cabeza Prieta NWR, Kofa NWR, and the Ecological Services office in AZ), AGFD, OPCNM, Luke Air Force Base, BLM, and other partners, in close coordination with the Sonoran Pronghorn Recovery Team, will plan and manage the establishment of new populations of Sonoran pronghorn. This group will closely coordinate on releases, monitoring, and coordination with landowners and land managers, among other tasks necessary to ensure successful population establishment. Management issues related to the Sonoran pronghorn NEP that have been considered include:

(a) *Mortality:* "Incidental take," as defined by regulation at 50 CFR 17.3, is take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity, such as agricultural activities and other rural development, ranching, military training and testing, camping, hiking, hunting, vehicle use of roads and highways, and other activities that are in accordance with Federal, Tribal, State, and local laws and regulations. With the finalization of this 10(j) rule, incidental take of Sonoran pronghorn within the NEP area outside of National Wildlife Refuge and National Park Service lands will not be prohibited, provided that the take is unintentional, not due to negligent conduct, and is in accordance with the special rule that is a part of this 10(j) rule. However, if there is evidence of intentional take, not authorized by the special rule or by a section 10 permit, of a Sonoran pronghorn within the NEP we will refer the matter to the appropriate law enforcement entities for investigation. We expect levels of incidental take to be low, because, as discussed in paragraph (d) under *Status of Reestablished Populations,* above, the establishment of new populations is compatible with most existing human use activities and practices for the area. In the current range of the Sonoran pronghorn in the United States, no incidental take has been documented from military activities, recreation, use of highways, and most other activities that occur both in the current range and in the NEP, the exception being canals, in which Sonoran pronghorn have drowned on several occasions. More specific information regarding take can be found in the Regulation Promulgation section of this final rule.

(b) *Special handling:* In accordance with 50 CFR 17.21(c)(3), "any employee or agent of the Service, any other Federal land management agency, the National Marine Fisheries Service, or a State conservation agency, who is designated by his agency for such purposes, may, when acting in the course of his official duties", handle Sonoran pronghorn to aid sick or injured Sonoran pronghorn, or to salvage dead Sonoran pronghorn. However, other personnel and their agents, not specifically named in these regulations, will need to acquire permits from the Service for these activities.

(c) *Coordination with landowners and land managers:* During the NEPA scoping process, the Service and cooperators identified issues and concerns associated with the proposed Sonoran pronghorn population establishment. The population establishment was also discussed with potentially affected State agencies, tribes, and private landowners. All land owners and managers also had an opportunity to review and comment on the draft EA and proposed rule. State and Federal land management agencies either supported or did not oppose the reestablishment of a Sonoran pronghorn herd and designation as a NEP; however, at least two private landowners in the NEP expressed opposition to the proposal. U.S. Customs and Border Protection strongly encouraged limiting reestablishment to Area A. See the section Summary of Public and Peer Review Comments and Recommendations below for summaries of those comments and how we addressed any concerns.

(d) *Monitoring and Adaptive Management:* A monitoring and adaptive management plan for the population establishment program will be implemented by the Service, AGFD, and other partners to determine if the program is successful, and to adjust management as needed to ensure success. Success criteria have not yet been finalized, but they will include the concept that the objective of the program is to establish Sonoran pronghorn herds that are self-sustaining without augmentation via releases from captive pens or holding facilities, thereby contributing to recovery goals. The monitoring will assess all aspects of the population establishment program, from capture and movement of the animals to the captive breeding pen (Area A) or holding area (Area D), monitoring of the animals in these captive facilities, and monitoring and

tracking released Sonoran pronghorn in the release areas, including Sonoran pronghorn water sources and any forage enhancement vegetation plots developed to support the established herds. Monitoring of released Sonoran pronghorn will be conducted to determine the following:

(1) Mortality and recruitment rates,

(2) causes of mortality among adult and juvenile Sonoran pronghorn,

(3) reliance on freestanding water sources,

(4) movement corridors and barriers to movements, and

(5) habitat preferences.

Each released animal will be fitted with an ear tag and radio collar. A limited number of Sonoran pronghorn will be fitted with Geographic Positioning System (GPS) platform telemetry collars. It is expected the GPS transmitters will function for up to 3 years. Telemetry flights with a fixed-wing aircraft will be conducted twice a month. Each Sonoran pronghorn will be observed from an altitude of 1,000 feet (ft.) above ground level with the aid of binoculars. Group size and composition (sex and age), habitat type, and terrain will be recorded. Additional monitoring of individual Sonoran pronghorn and herd movements will be done from the ground, particularly from high points where valley habitats of the Sonoran pronghorn can be viewed. All monitoring flights and on-the-ground surveillance will be closely coordinated with and approved by the tribal, military, and other land managers and owners where such monitoring will occur. As Sonoran pronghorn become established and breed in the establishment areas, the percentage of animals tagged or radio-collared will decline over time, and additional animals may need to be captured and radio collared to adequately monitor the herds. We will attempt to maintain radio collars on at least 10 percent of a population.

Monitoring data will be assessed regularly by the Recovery Team, and methods will be revised as needed to increase the likelihood of successful population establishment and to increase efficiency. A comprehensive review, assessment, and report of the reestablishment program by the Recovery Team will occur at a frequency of no less than once every 5 years. If at any point the program is not meeting its stated objective, or is falling short of meeting the success criteria, techniques and methods will be reviewed and revised as needed to correct problems and increase the likelihood of success. If revisions fall outside the scope of the action evaluated in the EA and FONSI, all necessary environmental compliance will be completed before those revised techniques or methods are implemented. Additional details of the monitoring and adaptive management plan, including quantifiable and measurable success criteria, will be finalized and posted on our Web site at *http://www.fws.gov/southwest/es/arizona/* prior to release of Sonoran pronghorn into Areas A or D.

(e) *Public awareness and cooperation:* Public scoping for the Sonoran pronghorn population establishment project was conducted in the fall of 2008. Actions included an October 30, 2008, scoping letter sent to approximately 6,000 recipients, a news release to local media sources, and a series of 3 open houses held in the Arizona cities of Yuma, Tucson, and Phoenix, during November 18–20, 2008. We accepted written public scoping comments until December 12, 2008. We received 44 written responses about the project. In our EA, we discussed issues identified in the responses. The IDT and the Service used these issues to refine the proposed action and alternatives in the EA, and to identify mitigation measures to avoid or reduce potential project effects. The IDT and the Service also used the public concerns to determine which resources would be the greatest focus of the EA analysis. The comments received during the scoping process are listed in the EA, and were considered in the formulation of alternatives considered in the NEPA process. The following section describes the public outreach we conducted and the responses received during the public and peer review comment periods on the proposed rule and draft EA.

*Section 7 Consultation*

A special rule under section 4(d) of the Act is included in this establishment of an experimental population under section 10(j) of the Act. A population designated as experimental is treated for the purposes of section 9 of the Act as threatened, regardless of the species' designation elsewhere in its range. The development of protective regulations for a threatened species is an inherent part of the section 4 listing process. The Service must make this determination considering only the "best scientific and commercial data available." A necessary part of this listing decision is also determining what protective regulations are "necessary and advisable to provide for the conservation of [the] species." Determining what prohibitions and authorizations are necessary to conserve the species, like a listing determination of whether the species meets the definition of threatened or endangered, is not a decision that Congress intended to undergo section 7 consultation.

Actions associated with the establishment of the experimental population, such as construction of pens or the movement of wild animals, will undergo section 7(a)(2) consultation, as appropriate.

**Summary of Public and Peer-Review Comments and Recommendations**

On February 4, 2010, we published our proposed rule to establish a NEP of Sonoran pronghorn in southwestern Arizona (75 FR 5732), and requested written comments from the public on the proposed rule and draft EA. We also contacted the appropriate Federal, State, and local agencies; tribes; scientific organizations; and other interested parties and invited them to comment on the proposed rule and draft EA. The initial comment period was open from February 4, 2010, to April 5, 2010. A second comment period was open from June 9, 2010, to July 9, 2010 (75 FR 32727). A public hearing was held in Gila Bend, Arizona, on February 23, 2010; however, no verbal or written comments were submitted at that hearing.

In accordance with our policy on peer review, published on July 1, 1994 (59 FR 34270), we solicited opinions from three expert biologists who are familiar with this species regarding pertinent scientific or commercial data and assumptions relating to supportive biological and ecological information for the proposed rule. Reviewers were asked to review the proposed rule for accuracy and validity of its biological information and assumptions. Two out of three peer reviewers provided comments. They were both supportive of the proposal to reestablish the Sonoran pronghorn in areas of southwestern Arizona, but suggested revisions or had some questions about the proposal. The remaining peer reviewer asked for additional information, but did not submit a final peer review. Their letter requesting additional information is counted as a response, with no position taken.

We reviewed all comments received from the peer reviewers, agencies, and the public for substantive issues and new information regarding the proposed NEP. Substantive comments received during the comment period have been addressed below and, where appropriate, incorporated directly into this final rule. The comments are grouped below as peer review and agency or public comments.

We received responses from 29 parties, comprising private individuals

(15), nongovernmental organizations (4), peer reviewers (3), state agencies (2), Federal agencies (3), university (1), and anonymous (1). Some commenters clearly supported (10), opposed (4), or took no position (7) on the proposal. In addition, two supported the reestablishment, but opposed the NEP. One supported population reestablishment, but conditioned their support of the NEP on continued strong commitment by the Department of Defense to Sonoran pronghorn conservation. One conditioned their support on implementation of predator control, acknowledgement of the importance of water sources, and no impacts to hunting. Two others opposed the proposal unless predator control was conducted. One supported the Kofa NWR reestablishment but not the BMGR–E reestablishment, and one supported the BMGR–E reestablishment, but opposed the NEP and establishment of a population at Kofa NWR.

The two peer reviewers who submitted comments agreed with the following determinations: (1) The proposed establishment of experimental, nonessential populations of Sonoran pronghorn is well considered and has great potential to enhance the status of Sonoran pronghorn in the United States, and (2) proposed survey, monitoring, and capture techniques, and operation of the captive breeding pen, are within accepted practices in wildlife management. However, one commenter asked that the details of the monitoring program and success criteria be more clearly stated.

*Peer-Review Comments*

(1) *Comment:* Continual improvement in capture methods should be pursued on non-endangered subspecies across the range of the pronghorn to increase efficiency in capturing and maintaining captive populations.

*Our Response:* Consistent with Adaptive Management in the EA and the recovery plan, we will continue to evaluate new information, including publications, reports, and personal communications with others working on Sonoran pronghorn throughout its range. We will also learn from our experiences with Sonoran pronghorn to fine tune and improve capture methodologies, with the goal of minimizing stress and the possibility of injury or mortality of captured animals, while increasing efficiency of capture operations.

(2) *Comment:* Although habitat modeling to identify habitat suitable for reestablished populations is adequate at the landscape scale, additional work is needed to pinpoint the adequacy of habitat prior to releases. Cholla is a key forage plant that is missing or scarce north of Interstate 8. Supplemental feeding may be necessary in that area during prolonged drought.

*Our Response:* As discussed under "*Reestablishment Areas*" above, an IDT was tasked with identifying and ranking possible reestablishment areas within the historical range of the Sonoran pronghorn. Areas A and D ranked first and second of seven areas identified. Potential locations for a captive pen at Kofa NWR are somewhat limited by extensive wilderness designation that precludes construction and operation of that facility. Hence a block of non-wilderness, large enough to accommodate the pen, was selected in northern King Valley. This is a good location, because the pen will be located off well-traveled roads, yet it is relatively close to Highway 95, the access route from Yuma, and its location in the northern part of the valley provides an opportunity for pronghorn released directly from the pen to spread out throughout King Valley before moving off-refuge to areas of Yuma Proving Grounds or BLM lands. The IDT considered the absence of chain fruit cholla on Kofa NWR in its rankings of the seven areas. One of the seven criteria used to rank the areas was forage quality. The absence of chain fruit cholla is a concern; however, the value of that plant in the diet of the Sonoran pronghorn is primarily as a source of preformed water; it provides little nutrition (Fox 1997, pp. 76, 79). As a result, if freestanding water is available or can be provided dependably, the importance of chain fruit cholla in the diet is much reduced. Five water sources outside of the pen at Kofa NWR will be built to provide dependable water for Sonoran pronghorn. Water sources and chain fruit cholla are available on BMGR–E in Area D near where the holding pen will be constructed, and, if needed, additional water sources will be constructed; hence, water for drinking is not anticipated to be a limiting factor at BMGR–E.

(3) *Comment:* The movement of released Sonoran pronghorn might be underestimated, particularly as the populations grow. In particular, there is a possibility of Sonoran pronghorn moving south in Area D into Organ Pipe Cactus NM east of Highway 85, and then west into the areas occupied by the wild population.

*Our Response:* Some of the young male Sonoran pronghorn released from the pen in Cabeza Prieta NWR have moved extraordinary distances, and across barriers including, on at least two occasions, the right-of-way fence along Highway 85, a vehicle barrier constructed on the U.S./Mexico border, and Highways 2 and 8 in Sonora, Mexico. Released Sonoran pronghorn that wander over large areas tend to continue these long-distance movements until they find and join an existing herd or another Sonoran pronghorn. Although such movements are expected to be unusual, we agree that as Sonoran pronghorn are released and as populations grow, individuals will periodically make long-distance movements and some animals could potentially move across Highway 85 from Area D into areas occupied by the wild herd. Similarly, Sonoran pronghorn released from the pen at Cabeza Prieta NWR may occasionally move across Highway 85 into Area D.

Although these movements could occur more frequently as populations on both sides of Highway 85 increase, we do not anticipate they will ever be more than rare events for the reasons discussed in "*Reestablishment Areas*" above, hence we do not anticipate overlap of the wild population and the NEP. Lone dispersers do not constitute a population or even part of a population, because they are not in "common spatial arrangement" sufficient to interbreed with other members of a population (see discussion under "*Reestablishment Areas*"). Furthermore, the likelihood of a Sonoran pronghorn moving from the release site on BMGR–E south to the area east of Highway 85 in OPCNM is remote, because a Sonoran pronghorn would have to traverse miles of rugged terrain from the holding pen at Midway Wash through the Batamote/Coffee Pot Mountain region to reach the Hickiwan Valley or Pozo Redondo Valley, and then move south and west from there across Highway 86 and through the Gunsight Hills, then down the western bajada of the Ajo Mountains. Years of surveys have shown that Sonoran Pronghorn do not use the rugged slopes and mountainous terrain characteristic of this area (Hervert *et al.* 2005, p. 12).

(4) *Comment:* One peer reviewer expressed concern that there is a remote possibility of a Sonoran pronghorn moving through Area D south and east to Buenos Aires NWR, where a population of Mexican pronghorn (*Antilocapra americana mexicana*) currently exists.

*Our Response:* Buenos Aires NWR is in the southeastern portion of the NEP area, and is within the historical range of the Sonoran pronghorn (Service 2002, p. 17). The NEP area includes all regions into which Sonoran pronghorn could

potentially move from release sites. Although over 90 miles southeast of the release site, we agree there is a small probability that Sonoran pronghorn could reach Buenos Aires NWR at some point in the future. The major barrier between the two areas is likely a complex of rugged terrain between the release site and Sonoran pronghorn habitat to the east and south, formed by the Batamote, Sauceda, Sand Tank, and other ranges. If a Sonoran pronghorn could get past that barrier, then potentially it could move through the valleys of the Tohono O'odham Nation, and then around the north end of the Quinlan Mountains, across Highway 86 and south through the Altar Valley to Buenos Aires NWR. Historically a more direct route probably existed south of the Baboquivari Mountains in Mexico, but a vehicle barrier and livestock fence on the United States/Mexico border now block that route.

In the unlikely event that a Sonoran pronghorn reached Buenos Aires NWR, the Service would be required to assess the effects of its actions at the refuge, including managing herds of Mexican pronghorn, and conduct intra-Service section 7 consultation if those activities may affect the Sonoran pronghorn. A decision on how to proceed would emerge from that process and would be based on the circumstances at the time.

(5) *Comment:* The proposed rule stated that success criteria would be developed by the recovery team prior to release of any Sonoran pronghorn into areas A or D. Success criteria drive the types of monitoring needed. Some parameter(s) of success need to be identified.

*Our Response:* Broadly defined, success will be measured by our ability to achieve the purpose of the program, which, as stated in the EA (p. 19) and our recovery plan (Service 2002, p. 38), is to contribute to recovery of the Sonoran pronghorn by establishing additional populations in suitable habitat within its historical range in Arizona. In accordance with 50 CFR 17.81(c)(4), a technical definition of what it means to establish a population of Sonoran pronghorn will, as the commenter notes, be forthcoming; however, it will almost certainly involve the presence of Sonoran pronghorn surviving and breeding in the wild to an extent that, at some point, release of additional animals to augment the population—either via the captive breeding pen at Kofa NWR or the holding pen in Area D— is no longer needed to sustain the population.

(6) *Comment:* If the reestablished populations cannot be sustained into the future without intensive management, this needs to be clearly stated.

*Our Response:* Some level of management will always be needed to maintain the reestablished herds. These management actions will be undertaken by the Service, in conjunction with our partners, including AGFD. The Sonoran pronghorn will need to be monitored to track their status, water sources will need to be maintained for them, and the lands they occupy must remain as habitat capable of supporting a viable herd. However, once a population is established to the degree that additional augmentation is no longer needed to sustain it, we anticipate that some intensive management actions, including the maintenance of a captive rearing pen, will no longer be necessary.

(7) *Comment:* Not enough information is presented to determine if the proposed monitoring will be adequate to determine whether the program is successful, and to better determine the role of water and forage enhancement plots in recovery, mortality, and recruitment rates; causes of mortality by age and sex, movements; and the role of habitat in the life history of the Sonoran pronghorn.

*Our Response:* The monitoring should not only allow us to determine whether the program is a success, but if it is failing to meet its objectives, the reason(s) why it is failing must emerge from the monitoring data. The latter is crucial for making appropriate changes in management to correct problems and ensure we achieve sustainable herds in Areas A and D. Although our monitoring plan is not yet complete, released animals in Area D will be monitored primarily via aircraft to determine survival, reproduction, and other measures of success. We acknowledge that all of the parameters noted by the commenter above are important in terms of tracking the status of Sonoran pronghorn populations. All of these factors will be carefully considered in the development of the monitoring program in Areas A and D.

*Public Comments*

(8) *Comment:* Establishment of additional herds of Sonoran pronghorn in the United States is not needed because the animals at Cabeza Prieta NWR are safe from extinction. Specifically, their continued existence is ensured because Sonoran pronghorn have been captively reared, resulting in a wild population of greater than 70 animals. An awareness of the population's precarious nature has been raised, their status will be closely watched, and animals from self-sustaining herds in Mexico can be brought to the United States if the current population crashes.

*Our Response:* The 1998 revision of the Sonoran Pronghorn Recovery Plan established downlisting criteria to reclassify the subspecies from endangered to threatened. Included in the downlisting criteria were stipulations that an estimated 300 adult Sonoran pronghorn occur in one U.S. population and a second separate population be established in the United States, or numbers are determined to be adequate to sustain the population through time (Service 1998, p. 37). At 80–90 wild Sonoran pronghorn, the current U.S. population is not safe from extinction. A 1996 population viability analysis concluded that at least 300 Sonoran pronghorn were needed in a population to achieve reasonable population persistence over time; however, to prevent loss of genetic diversity, 500 or more animals were needed (Defenders of Wildlife 1996, p. vii). The 2002 Supplement and Amendment to the Recovery Plan identified "evaluating potential transplant locations, establishing relocation methodology and protocols, developing interagency agreements (including with Mexico as required), acquiring funding, and initiating reestablishment projects" as one of eight priority, near-term actions needed to further recovery (Service 2002, p. 38.). In regard to bringing additional animals north from Sonora, Mexico, to augment the U.S. population, we cannot depend on the continued availability of Sonoran pronghorn from Sonora, both in terms of required international permits and the ability of Mexican populations to sustain additional harvest. In conclusion, establishing additional herds of Sonoran pronghorn in the United States is consistent with the recovery plan for the species and will further its recovery, consistent with Service mandates under section 4(f)(1) of the Act.

(9) *Comment:* Part of the funding for the population reestablishment is coming from the Department of Homeland Security (DHS) as mitigation for damage to Cabeza Prieta NWR, so the money should be spent at Cabeza Prieta NWR.

*Our Response:* Funding provided by DHS for the establishment of additional Sonoran pronghorn herds in the United States was closely negotiated, and the use of those funds was specifically defined for certain recovery actions. Mitigation funds for establishment of additional U.S. herds were secured to mitigate effects of vehicle barriers at Cabeza Prieta NWR and the BMGR, and the effects of the Ajo 1 SBInet Tower

Project. The purpose of this mitigation was to offset effects to Sonoran pronghorn from these projects, not to mitigate or repair damage to resources at Cabeza Prieta NWR. Consistent with the recovery plan, one of the greatest needs for recovering the Sonoran pronghorn is to establish additional herds, off of Cabeza Prieta NWR. The Service and DHS agreed that use of the mitigation funds to establish additional Sonoran pronghorn herds outside of the current range was an appropriate offsetting measure.

(10) *Comment:* The proposed reestablishment will fail unless predators of Sonoran pronghorn are controlled. Specifically, commenters mentioned the need to control mountain lions at Kofa NWR and coyotes.

*Our Response:* Coyote, mountain lion, and bobcats are known to prey on Sonoran pronghorn (Service 2002, p. 22). Predation generally has an insignificant effect except on small populations (Lee *et al.* 1998, p. 61). Coyotes are the most abundant large predator sympatric with Sonoran pronghorn. In 20 mortality investigations not related to capture operations, coyotes killed at least 5 Sonoran pronghorn and are suspected in the death of another. Of 23 Sonoran pronghorn released from the captive breeding pen at Cabeza Prieta NWR in December 2009, 4 were predated by coyotes within the first 3 weeks. Since that time, one other Sonoran pronghorn found dead from the original group of 23 was probably predated, although the type of predator is unknown (Atkinson 2010, pers. comm.). Coyotes are thought to prey heavily on Sonoran pronghorn fawns as well.

Steps will be taken to deter predators from entering the captive breeding pen at Kofa NWR, including a perimeter fence constructed of woven wire 5.5 ft. (1.7 m) tall and buried 1 ft. (0.3 m) into the ground. The interior of the fence will be lined with material that will create a visual blind for predators. In addition, two layers of electric fences will be installed just outside of the woven wire fence to deter predators. Monitors will check for presence of Sonoran pronghorn predators inside the pen and holding facility daily, and if any are found, they will be removed. The holding facility at BMGR–E will be equipped with 5.5-ft (1.7-m) tall woven wire, but it will not be buried and no electric fence will be installed. However, the potential for predation will be minimized because pronghorn will not be in the facility for more than a few days, and someone will be staying with them all the time until they are released.

No predator control is proposed outside the pen at Kofa NWR and the holding facility at BMGR–E, because predation types and levels are anticipated to be similar to those at Cabeza Prieta NWR, where up to this point, predator control has not been deemed necessary to recover the Sonoran pronghorn. We anticipate that predation of released animals in Area A and D is unlikely to affect the success of the reestablishments, and mortality of released animals due to predators is expected to be similar to that experienced at Cabeza Prieta NWR. We will monitor the success of the population reestablishments, and consistent with adaptive management and recovery actions 2.411 and 2.412 in the recovery plan, we will evaluate the monitoring data and propose additional actions, if deemed necessary. Those additional actions could include predator control outside of the captive breeding pen at Kofa NWR or the holding pen at BMGR–E. However, predator control outside the pens is not covered in the EA for establishing a NEP of Sonoran pronghorn at Kofa NWR or BMGR–E. Hence, if predator control were proposed, it would be closely coordinated with land managers and AGFD, and would only proceed after all required environmental compliance was completed.

(11) *Comment:* Development of additional water sources, such as wildlife drinkers or tanks, should be undertaken to support the population reestablishments. In addition, an "Adopt a Game Tank" program should be implemented for interested parties to monitor, maintain, and repair water tanks for wildlife and game species.

*Our Response:* At Kofa NWR, we propose to develop up to seven water sources for Sonoran pronghorn, including up to two inside of the pen and five outside of the pen, but none in the Kofa Wilderness. At BMGR–E and Area D, numerous developed wildlife water sources occur in paloverde-mixed cacti-mixed scrub vegetation on the bajadas that could potentially be used by Sonoran pronghorn. As a result, no new water sources are planned for Area D; however, the need for additional wildlife water sources will be evaluated and, if needed, new water sources will be installed to support the reestablished Sonoran pronghorn. Construction of any additional water sources in Area D would be preceded by cultural resource surveys and any necessary environmental compliance. The water sources at Kofa NWR were planned in anticipation of the needs of the Sonoran pronghorn. Additional water sources at Kofa NWR, beyond those mentioned above, are not anticipated; however, consistent with proposed adaptive management and recovery actions 2.411 and 2.412 in the recovery plan, we will evaluate the monitoring data and propose additional water sources if deemed necessary to support the reestablished populations. Any additional water sources proposed at Kofa NWR would be outside the current scope of the program and supporting environmental compliance; hence additional coordination with land managers and AGFD and all necessary environmental compliance would be completed prior to construction of any additional water sources.

(12) *Comment:* The five water sources outside of the captive pen at Kofa NWR should have their locations generally described and mapped. Some flexibility in locations is desirable, so precise locations are unnecessary. Cultural resource surveys should be conducted prior to construction, and water sources should be built with the minimum disturbance necessary and in the least visually obtrusive manner possible.

*Our Response:* The approximate locations of the five water sources outside the pen at Kofa NWR have been identified and mapped in the EA (p. 36). Cultural resource surveys shall be conducted prior to any ground-disturbance activities, and the water sources will be built with the minimum disturbance necessary and in the least visually obtrusive manner possible.

(13) *Comment:* The efficacy of additional water sources outside of the pens is questionable based on published studies. The effects of additional water sources on other species, as well as degradation of areas around water sources as a result of increased wildlife use, need to be fully evaluated.

*Our Response:* The benefits and costs of water developments for wildlife in the arid southwest have been debated for many years (see reviews in Rosenstock *et al.* 1999 and Krausman *et al.* 2006). Artificial water sources in the southwest are used by a variety of wildlife species, with nongame species far outnumbering game species (O'Brien *et al.* 2006, pp. 544–548). Some species will use freestanding water opportunistically, whereas others require it to occupy an area (Krausman *et al.* 2006, pp. 565–566). Water sources can affect the distribution of wildlife species and habitat use patterns of individuals, although in some cases the effect is small (Marshal *et al.* 2006a, pp. 616–617). There is no evidence that water catchments elevate predation rates on wildlife (O'Brien *et al.* 2006, p. 589), and plant communities and forage resources in washes with water sources

do not differ from washes without water, providing no evidence that water sources cause detrimental effects to Sonoran Desert plant communities via herbivory or trampling by animals attracted to the water (Marshal *et al.* 2006b, pp. 621–622). Construction of the five water sources outside the pen and up to two water sources inside the pen at Kofa NWR will have a disturbance footprint, but the acreage affected is small (about 0.5 acre in total), and most of the disturbance will be temporary. None of the water sources are proposed in wilderness.

Monson (1968, pp. 67–68) found there was no hard evidence that Sonoran pronghorn drink freestanding water; rather, he surmised they obtained all the water they need from the plants they consume. However, more recent work indicates they drink water, and that it is probably crucial for survival during seasonal and long-term drought periods (Fox *et al.* 2000; pp. 1–18; Morgart *et al.* 2005, pp. 57–58). Hervert *et al.* (2005, p. 14) found that placement of water sources in palo verde-mixed cacti associations, such as occur in King Valley of Kofa NWR, would likely functionally convert them to higher quality habitats, in some cases making them suitable for Sonoran pronghorn. This could be especially important at Kofa NWR, where chain fruit cholla is absent, but at Cabeza Prieta NWR, it is an important source of preformed or dietary water for Sonoran pronghorn (Fox *et al.* 2000, pp. 1–18). Currently existing developed and natural wildlife water sources within Area A are primarily located in habitats that are not likely to be used by Sonoran pronghorn or used only infrequently. For example, there are no developed wildlife water sources in potential Sonoran pronghorn habitat in King Valley. Creating new water sources for the reestablished Sonoran pronghorn herd in Area A is important to the success of the project. Sonoran pronghorn will benefit, with minimal impacts to plant communities, other wildlife, and wilderness values.

(14) *Comment:* One commenter suggested that if Sonoran pronghorn once inhabited the Chuckwalla Bench or East Mojave of California, then the Mojave National Preserve should be considered as a reestablishment site.

*Our Response:* Although the historical distribution of the Sonoran pronghorn is not entirely known, none of the reports or publications we have reviewed indicate the Sonoran pronghorn ranged into what is known today as the Mojave National Preserve in California. Phelps and Webb (1981, p. 21) show the historical distribution in California lying entirely south of Interstate 10. The 1982 version of the recovery plan (Service 1982, p. 2) adopted the distribution as interpreted by Hall and Kelson (1959, p. 1023), which did not show the subspecies occurring in California. However, Mearns (1907, p. 231) mentions observing pronghorn tracks near "Gardner's and Laguna stations" in 1894 in the Colorado Desert west of the Colorado River. Figure 2 in the 1998 recovery plan (Service 1998, p. 6) and in the 2002 revision (Service 2002, p. 17) show the historical distribution extending into California north to the vicinity of Blythe and westward into an area that includes the Chuckwalla Bench. Figure 1 of the 1998 plan extended the range north to the vicinity of Parker Dam. The southern boundary of the Mojave National Preserve is Interstate 40, which is no closer than 70 miles to Parker Dam.

We find no other reference suggesting Sonoran pronghorn occurred historically any closer to the Mojave National Preserve than Parker Dam. As a result, establishment of Sonoran pronghorn at the Preserve will be outside of its historical distribution as we understand it. Although section 10(j) of the Act does not limit experimental populations to a species' historical range, the suitability of habitats that are clearly outside of the historical range is questionable. Moreover, our analysis of potential reestablishment sites was limited to portions of the historical range in Arizona (O'Brien *et al.* 2005, p. 25); the suitability of the Mojave National Preserve as a potential establishment site has not been evaluated. As a result, pursuing an additional herd of Sonoran pronghorn at the Mojave National Preserve is not a desired action at this time.

(15) *Comment:* One commenter supported the reestablishment proposal, but believed it was inappropriate to allow hunting of Sonoran pronghorn.

*Our Response:* Hunting of Sonoran pronghorn is currently prohibited by section 9 of the Act. This designation of a NEP with a special rule will not change that prohibition.

(16) *Comment:* Designation as a NEP implies that the proposed release and subsequent establishment of an additional wild population can fail completely without adverse consequence to the continued existence of the species. This conclusion lacks scientific support; thus the population should be given full protection under the Act or designated as an experimental, essential population. Commenters also note that agency authorized take under 10(j) rules can be abused to the point of precluding recovery; a commenter cited the Mexican gray wolf NEP designation as a case in point. Another commenter offered the example of the NEP population of California condor in Arizona, which they asserted is being used as an excuse not to limit lead ammunition in the California condor recovery area.

*Our Response:* Because the establishment of a second Sonoran pronghorn herd is identified as a downlisting criterion in the recovery plan (Service 2002, p. 36), if such establishment failed, it would adversely affect recovery. However, we do not believe the loss of the experimental population would reduce appreciably the likelihood of the survival of the species in the wild, which is why we are designating the reestablished population as a nonessential experimental population. The Sonoran pronghorn occurs in three other populations, including two in Mexico and one in southern Arizona. Currently, the total in all three populations is approximately 562 to 572 animals in the wild. As described above under "Recovery Efforts," a variety of aggressive management actions have been to taken to avert catastrophic declines in the U.S. population in the event of a drought. The first priority for use of animals in the captive-breeding pen at Cabeza Prieta NWR is to augment herds within the boundaries of the current range of the species in the United States and Mexico; hence, any use of animals to establish herds in Areas A or D would only be carried out after the needs of the wild populations are met. For these reasons, and for further justification for why reestablished Sonoran pronghorn herds are not essential to the continued existence of the species, refer to the section "*Status of Reestablished Populations*."

In regard to authorized take precluding recovery, the Sonoran pronghorn population reestablishments are very different from that of the Mexican gray wolf or California condor. As detailed in the special rule, only take incidental to otherwise authorized activities plus intentional take as necessary for translocation, aiding sick Sonoran pronghorn, taking biological data, salvaging dead Sonoran pronghorn, or affixing, removing, or servicing radio transmitters will be allowed. As described in the sections "*Status of the Reestablished Populations*" and "Management," we anticipate very little mortality or injury associated with military, recreational, agricultural, and other uses in the NEP that could potentially result in incidental take.

(17) *Comment*: The survival and growth of the NEP hinges on the good faith and stewardship of the action agencies on whose land the NEP resides. If agency commitments to conservation are not fulfilled, the Service should reconsider the NEP designation and take whatever action is necessary to ensure the recovery of Sonoran pronghorn. Conferring under Section 7 is an opportunity to ensure the actions of Federal agencies are consistent with recovery of the Sonoran pronghorn.

*Our Response*: The Service is dedicated to achieving the recovery of the Sonoran pronghorn, which includes using all of our authorities to achieve success in regard to reestablished Sonoran pronghorn populations in Areas A and D. As we have discussed (see *Regulatory Background*), we will work with Federal action agencies through the section 7(a)(4) conference provisions of the Act in areas outside of National Park and Wildlife Refuge lands, and via the section 7(a)(2) consultation process where the NEP might be affected within Parks and Refuges. Luke Air Force Base, which manages BMGR–E lands in Area D, has been a consistent and strong partner in recovery of the Sonoran pronghorn and has contributed millions of dollars to recovery. We fully anticipate that they will continue to be a strong partner. Through the development of the NEP proposal, we were and continue to be in close contact with Yuma Proving Grounds, which manages lands in Area A and has agreed to cooperate with us on this project. The BLM has pledged its support, and furthermore has a policy of conferring with the Service on activities that may affect proposed species, including NEPs. Thus, their standard for conferring exceeds that in the regulations, which only require conferring if a Federal action is likely to jeopardize the continued existence of a proposed species or is likely to result in adverse modification or destruction of proposed critical habitat (50 CFR 402.10(a)).

Because of this support and cooperation, and as we anticipate Sonoran pronghorn recovery will be compatible with current and future activities within the NEP (see discussion under "*Management*"), we believe there will be no need to reconsider the NEP designation. However, if at any time in the future the status of the wild populations declines dramatically or other circumstances suggest that the loss of reestablished populations would be likely to appreciably reduce the likelihood of survival of the species in the wild, the Service will reevaluate the NEP designation in accordance with our policies and regulations. Furthermore, a comprehensive review, assessment, and report of the reestablishment program by the Recovery Team will occur at least every 5 years. If at any point the program is not meeting its stated objective, or is falling short of meeting the success criteria, all aspects of the program can be reevaluated and modified as needed to better meet the recovery needs of the species.

(18) *Comment*: Because the legal status of Sonoran pronghorn will be defined geographically (i.e., if they are in the NEP area they are part of the NEP population; if they are outside the NEP, they are fully protected under the Act), wild, endangered Sonoran pronghorn could lose the majority of their protections simply by natural movements. If it turns out that crossings by wild pronghorn into BMGR–E are occurring and/or increasing, the Service should assess and potentially reconsider the new populations' designation and requirements under section 10(j) of the Act.

*Our Response:* As we have earlier discussed (see discussion under "*Reestablishment Areas*"), we do not expect Sonoran pronghorn to cross over the substantial barriers that separate the NEP area from the wild herd. Only once or twice has a Sonoran pronghorn been known to cross Highway 85 and its associated right-of-way fences into BMGR–E. Released, pen-raised Sonoran pronghorn have a greater tendency to move than do wild Sonoran pronghorn. We have also seen Sonoran pronghorn make unusual movements in response to severe drought. However, the fact remains that such crossings are rare. As the wild population continues to recover and when a population becomes established in Area D, the likelihood of pronghorn crossing Highway 85, both into or out of the NEP, will probably increase. But because highways and their associated right-of-way fences are nearly impermeable barriers for Sonoran pronghorn (Brown and Ockenfels 2007, pg. 29), we do not anticipate more than occasional lone animals moving across the highway, and the occurrence of that will remain a rare event. However, if at any time in the future the wild population and the NEP begin to intermingle because of unexpected and common movement of Sonoran pronghorn across barriers between those populations, the Service will reevaluate the NEP designation in accordance with our policies and regulations.

(19) *Comment*: The wild and NEP populations should, at some point in the future, be allowed to intermingle in order to maximize genetic diversity and reduce possible effects from stochastic events. Linking these habits and populations may be crucial for long-term survival of the species.

*Our Response*: We acknowledge that allowing movement of Sonoran pronghorn among populations increases the viability of those populations and their likelihood of persistence over the long term. However, accomplishing that is problematic logistically and economically. The barriers that separate the NEP and wild populations are not temporary structures. Interstate 8, canals, and the agricultural and rural development that separate the current range from pronghorn habitat in Area A are probably insurmountable barriers. Overpasses or underpasses may be possible to allow movement of Sonoran pronghorn across Highway 85, which separates the wild population from the NEP in Area D; however, whether such a connection is feasible or likely to be sufficiently successful to affect our expectation of very infrequent intermingling is unknown at present.

(20) *Comment*: The assertion that U.S. Customs and Border Protection operations pose a threat to the survival and recovery of Sonoran pronghorn is inconsistent with the best scientific and commercial data.

*Our Response*: The proposed rule identified high levels of undocumented immigration and drug trafficking across the international border and associated law enforcement as a threat to the Sonoran pronghorn. The proposed rule went on to say that the "U.S. population declined in 2002 by 83 percent to 21 animals (Bright and Hervert 2005, p. 46). The Mexican populations declined at the same time, but not to the same degree. The population southeast of Highway 8 declined by 18 percent, while the El Pinacate population declined by 26 percent. The differences between the rates of decline north and south of the border may be due to high levels of human disturbance on the United States side primarily as a result of heightened levels of illegal immigration, smuggling, and law enforcement response (Service 2008, p. 55)" (75 FR 5735). Whether these activities pose a threat to the survival and recovery of the Sonoran pronghorn has not been thoroughly addressed. Recent analysis has shown there are about 8,000 miles of unauthorized routes on the approximately 1,000-sq.-mi refuge, mostly in designated wilderness. These are most likely attributable to both illegal cross-border traffic and associated law enforcement response by Border Patrol (McCasland 2010, pers. comm.). Furthermore, there is strong anecdotal evidence suggesting

Sonoran pronghorn are avoiding areas of high cross-border traffic and law enforcement response, including the Granite forage enhancement plot and the pass near Bates Well (Service 2009, pp. 47–48). Border Patrol presence deters illegal cross-border traffic, but that deterrence has a substantial impact on its own (Milstead and Barnes 2002, pp. 87–88; Neeley 2006, p. 9; Duncan *et al.* 2010, pp. 123–130). However, as Border Patrol achieves operational control of the border region, we anticipate that human disturbance will be reduced over time.

(21) *Comment*: Kofa NWR is much more likely to support a successful reintroduction of Sonoran pronghorn than the area east of Highway 85 (Area D), which is a high-traffic area for human and narcotics smuggling. Attempting a reestablishment in Area D is inconsistent with the recovery plan, which specifies that a second, but not a third, U.S. population is needed for downlisting.

*Our Response*: Although not ranked as high as Area A (which includes Kofa NWR), Area D (including the area east of Highway 85) was ranked second of the seven areas evaluated by the IDT as potential release sites. The IDT believes Area D has good potential to support Sonoran pronghorn, and the subspecies existed here historically, possibly into the late 1980s (Service 1998, p. 9). Degree of disturbance, including that caused by illegal cross-border traffic and Border Patrol, were taken into account in the rankings of each area. Further, as discussed in the above comment, we anticipate that both illegal immigration and Border Patrol operations will lessen over time. The recovery plan identifies establishment of a second U.S. herd as a criterion for downlisting (Service 2002, p. 36); however, it does not suggest population reestablishments should be limited to only one. Recovery action 2 in the 1998 recovery plan is to "establish and monitor new separate herd(s)" (Service 1998, p. 40). Replication of effort in regard to population reestablishment is prudent in the event that populations in Area A or Area D are not successful. The holding pen at Area D will also serve as an outlet for excess pronghorn produced at the captive rearing pen at Cabeza Prieta NWR. Production of animals for release is expected to be more than 20 Sonoran pronghorn per year from that pen (23 were released from the pen in December 2009). Once animals are established at the pen at Kofa NWR, and as the wild herds are bolstered by releases, fewer animals will be needed, allowing releases to Area D. In addition, conditions such as drought within the current range of the Sonoran pronghorn may make release of captively propagated Sonoran pronghorn into the wild herd undesirable in some years. Area D will provide another option for use of these excess animals. Also, the ultimate goal of the Act is to delist the species, so it no longer needs the protections of the Act. Additional populations beyond what is being proposed in this action may be needed to achieve full recovery.

(22) *Comment*: The full effects of the rulemaking are not evaluated, because the analysis in the EA is limited to Areas A and D, but the NEP area is much larger, encompassing 10 million acres. For example, U.S. Customs and Border Protection will be required to consult on its activities at OPCNM east of Highway 85. Because of the scope and cost of the effort, along with potential effects of a wide range of activities, the proposed action appears to be a major Federal action significantly affecting the human environment. The commenter encourages the Service to limit the NEP to areas west of Highway 85.

*Our Response*: NEPA implementing regulations at 40 CFR 1508.9 define an EA as: "a concise public document for which a Federal agency is responsible that serves to: (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a FONSI, (2) aid an agency's compliance with the Act when no environmental impact statement is necessary, and (3) facilitate preparation of an environmental impact statement when one is necessary. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted" (40 CFR 1508.9(b)).

Sonoran pronghorn pens, holding facilities, water sources, and releases will all occur in Areas A and D, and are consistent with the regulations cited above. Those are the areas on which the effects of the alternatives were focused in the EA. Over time, and as populations grow, Sonoran pronghorn could move outside of Areas A and D and potentially to the boundaries of the NEP. In the event that Sonoran pronghorn move to the boundaries of the NEP but not outside of it, the effects of Sonoran pronghorn presence in these areas would be minimal because of the NEP designation and the special rule that together broadly allow Federal actions to go forward without section 7 consultations, and private actions that may result in incidental take of the species will not require incidental take permits from the Service. In National Parks and Wildlife Refuges, for the purposes of section 7 only, the Sonoran pronghorn will be listed as a threatened species, requiring consultations for actions that may affect the species. However, we expect few if any changes would be needed in those lands to comply with the Act (see "*Management*"). Thus, based on our EA we find that in no case do the effects of the action within Areas A or D or within the NEP generally, rise to the level of significantly affecting the human environment. A "major Federal action" includes actions with effects that may be major and which are potentially subject to Federal control and responsibility (40 CFR 1508.18). Due in part to the regulatory relief provided by the NEP designation and special rule, the effects of the action are not major as documented in our FONSI.

The likelihood of Sonoran pronghorn moving into that portion of Area D east of Highway 85 on OPCNM is low. The few Sonoran pronghorn that have moved into that area have either died or not stayed there, likely because of poor habitat quality. In any case, it is probably more likely that wild Sonoran pronghorn would colonize that area from west of Highway 85 than from the release site in Area D (see our response to the third peer review comment). In that scenario, U.S. Customs and Border Protection would need to consult on their activities in that area affecting Sonoran pronghorn with or without the NEP designation.

(23) *Comment*: During pen construction at Kofa NWR, any desert tortoises or rosy boas found should be immediately translocated to a release site agreed upon by the AGFD, Service, and BMGR.

*Our Response*: In the event that State-sensitive species, such as rosy boas (*Lichanura trivirgata*) or desert tortoises (*Gopherus agassizii*) are found during any phase of construction at either the captive breeding pen at Kofa NWR or the holding pen at BMGR–E, they will be relocated no more than 0.5 mi (0.8 km) away in the direction of the most suitable and typical habitat for the species (rock outcrops or rocky hillsides, and in the case of the tortoise, dissected washes with caliche caves). If rosy boas are found during the day, they shall be held temporarily in a climate-controlled environment (e.g., a cooler) and released in the evening to prevent overheating.

(24) *Comment*: A commenter expressed concern that reestablishment at Kofa NWR would interfere with the

hunting opportunities for bighorn sheep (*Ovis canadensis*) or other species on the refuge. In particular, the commenter questions whether areas of the refuge would be closed to public use during the Sonoran pronghorn fawning season or whether areas currently open to bighorn sheep hunting would be closed on Kofa NWR to protect Sonoran pronghorn.

*Our Response*: An area extending 0.25 mi (0.40 km) out from the boundaries of the captive breeding pen at Kofa NWR will be closed to the public. The pen will be in King Valley, in an area not frequented by bighorn sheep, so it will have no impact on sheep hunting. No other closures are needed or will be implemented at Kofa NWR to support the Sonoran pronghorn reestablishment.

(25) *Comment:* A commenter inquired how a 10(j) designation could be established on the BMGR when there are still Sonoran pronghorn in that area.

*Our Response:* Areas west of Highway 85 and south of Interstate 8 on the BMGR are not within the NEP. The wild herd, with the full protections of the Act, occupies this area. Only those areas of BMGR–E east of Highway 85 are in the NEP. Those areas are not currently occupied by Sonoran pronghorn. Highway 85 and its right-of-way fence provide a physical barrier to Sonoran pronghorn movement between the wild population and the NEP (see discussion in "*Reestablishment Areas*").

(26) *Comment*: One commenter asked if the NEP area is clearly delineated from the area in which the wild, fully protected Sonoran pronghorn occur, and if there is a chance of confusion in areas that include both NEP and fully protected Sonoran pronghorn (e.g., BMGR). Furthermore, the commenter asked if a potential exists for incidental take of Sonoran pronghorn occurring in the current range due to its close proximity to the NEP.

*Our Response*: The boundaries of the NEP are clearly delineated by major highways, the Colorado River, and an international border. Where the NEP adjoins the area occupied by the wild population, the boundary between the two includes Interstate 8 (boundary with Area A) and Highway 85 (boundary with Area D). Because of those clear boundaries, the likelihood of confusing wild and NEP Sonoran pronghorn is low, because the status of each is determined geographically. Designation of the NEP adjacent to the current range alters neither the likelihood of incidental take, nor the activities that could result in incidental take of Sonoran pronghorn in the wild herd.

(27) *Comment*: No sufficient or verifiable evidence exists to show that Kofa NWR or any areas north of the Gila River are within the historical range of the Sonoran pronghorn. Hence, establishing a population of pronghorn at Kofa NWR is inappropriate.

*Our Response*: The commenter provides much supporting information that brings into question whether Sonoran pronghorn ever occupied King Valley or other portions of Kofa NWR. We acknowledge that delineating the historical range of the Sonoran pronghorn is problematic because of a lack of specimens in key areas; the anecdotal nature of sightings, of which some of the most relevant are very old; and taxonomic uncertainty—the Mexican pronghorn occurs elsewhere in southern Arizona. The uncertainty in defining historical range is reflected in the prior and current Sonoran pronghorn recovery plans. The 1982 plan, adopting the range as described by Hall and Kelson (1959, p. 1023), did not show the range of the Sonoran pronghorn north of Ajo, which is well south of the Gila River (Service 1982, p. 2). The 1998 and 2002 versions of the recovery plan adopted a more expansive view of historical range first exposed by Phelps and Webb (1981, p. 21); this later view included Kofa NWR. Phelps and Webb (1981, p. 22) provide evidence of Sonoran pronghorn on the Harquahala Plain in the 1850s, northeast of Kofa NWR, and along the Gila River in 1852, south of the Kofa NWR. As shown in the 2002 supplement and amendment to the recovery plan (Service 2002, p. 17), based on the best scientific and commercial information available, the Sonoran pronghorn recovery team and the Service believe Kofa NWR is within the historical range of the subspecies.

(28) *Comment*: Yuma Proving Grounds is not going to ignore their mission and cease firing if Sonoran pronghorn are in their artillery footprint. Yuma Proving Grounds could bomb herds of expensively reared Sonoran pronghorn, and military operations may alter behavior and physiology of the species. No protocols are in place at Yuma Proving Grounds to minimize death or injury of Sonoran pronghorn. This is a moral issue that must not be overlooked, as well as an additional financial loss of valuable animals.

*Our Response*: Specific capabilities at Yuma Proving Grounds include testing of artillery; mortars; mines; ground and aircraft weapons; target acquisition and fire control systems; wheeled and tracked vehicles; and air delivery material, equipment, and techniques. Primarily artillery and tank testing activities occur on the Kofa Range portion of Yuma Proving Grounds, which lies directly south of Kofa NWR and is the portion of Yuma Proving Grounds most likely to be colonized by Sonoran pronghorn. We acknowledge that military activities at Yuma Proving Grounds may result in some mortality and injury of Sonoran pronghorn (see discussion in "*Status of Proposed Population*"). However, similar to BMGR–E, the vast majority of the Kofa Range portion of Yuma Proving Grounds is relatively undisturbed. The likelihood of a Sonoran pronghorn being hit by an artillery shell or shrapnel, colliding with a vehicle, or encountering lethal or injurious hazards is very small. At BMGR–E, no Sonoran pronghorn have ever been documented to have been killed or injured by military activities. Luke Air Force Base implements protocols to ensure that Sonoran pronghorn are not harmed on the live fire Tactical Ranges, but even before those protocols were put in place in 1997, no Sonoran pronghorn were ever known to have been killed or injured on the BMGR as a result of military activities. There is no evidence to suggest, nor do we anticipate, that military activities at Yuma Proving Grounds will compromise the recovery efforts for the Sonoran pronghorn in Area A.

(29) *Comment*: One commenter questioned the timeline in the EA, which had the construction of the captive pen at Kofa NWR beginning in spring of 2010.

*Our Response*: Implementation of the action will not begin until after publication of this rule and the signing of the FONSI.

(30) *Comment*: Creating irrigated forage enhancement plots in King Valley at Kofa NWR will exacerbate nonnative, invasive plant problems. In particular, the nonnative Sahara mustard (*Brassica tournefourtii*) and Mediterranean grass (*Schismus* sp.) are likely to increase.

*Our Response:* We acknowledge that irrigating the desert will cause increased growth of plants, including nonnative species such as Sahara mustard and Mediterranean grass. We propose irrigated areas to enhance forage within the captive pen at Kofa NWR. No forage enhancement plots are proposed outside the captive pen. Although we have not surveyed the pen site for Sahara mustard or Mediterranean grass, both almost certainly occur there. Mediterranean grass is likely ubiquitous. Sahara mustard achieves its greatest densities in fine, sandy soils, but still occurs on bajadas and in gravelly soils such as occurs at the pen site. Both species thrive in disturbed

sites; hence, hoof action from Sonoran pronghorn may further enhance populations of these nonnatives. That said, these species have not increased noticeably in forage enhancement plots at Cabeza Prieta NWR, including inside the captive breeding pen. The plant communities and soils are similar between the forage plots at Cabeza Prieta and at the pen site in Kofa NWR, so we have no reason to believe these species will respond any differently at Kofa NWR. Furthermore, the fencing and visual screening on the perimeter of the pen at Kofa NWR will likely reduce spread of seed from Sahara mustard and Mediterranean grass to areas outside the pen. Consistent with our monitoring and adaptive management plan, if our actions create a nonnative invasive plant problem, we will evaluate that problem and take appropriate action to correct it.

(31) *Comment:* In comments provided on the Environmental Assessment, the U.S. Customs and Border Protection strongly encouraged limiting reestablishment to Area A (Kofa) due to concerns that the experimental population might impede border security operations.

*Our Response:* The Service and the Recovery Team believe that it is important to efforts to conserve the Sonoran pronghorn to have two population centers within the experimental area. Based on our evaluation of possible reintroduction sites, Kofa (Area A) and BMGR–East (Area D) have the best combination of size, forage availability, water availability, fragmentation, disturbance, logistics, and other factors and that is why we have chosen those two areas. Release of animals into BMGR–East would only occur after we have achieved strongly positive results from our efforts at Kofa and we have surplus animals from Cabeza Prieta and Kofa that could be placed in BMGR–East. We do not anticipate reaching that point for at least 5 years and probably longer. The Service is committed to coordinating closely with U.S. Customs and Border Protection and other partners before implementing release of Sonoran pronghorns into BMGR–East so as to limit any potentially adverse effects to operations and activities of U.S. Customs and Border Protection and our other partners. We have added language to the text of the regulation clarifying that incidental take caused by border security and enforcement carried out by Federal law enforcement officials (e.g., U.S. Customs and Border Protection) would not be prohibited.

**Finding**

We followed the procedures required by the Act, NEPA, and the Administrative Procedure Act during this Federal rulemaking process. Therefore, we solicited public and peer-review comments on the proposed NEP designation. As required by law, we have considered all comments received on the proposed rule and draft EA before making this final determination. Based on the above information, and using the best scientific and commercial data available (in accordance with 50 CFR 17.81), we find that creating an NEP of Sonoran pronghorn and releasing them into the NEP area in Kofa NWR of Area A and BMGR–E of Area D will further the conservation of the species.

**Administrative Change to 50 CFR 17.84**

We are making a nonsubstantive change to correct a paragraph designation error in 50 CFR 18.74(u), the nonessential experimental population rule for Rio Grande silvery minnow. In that rule, there are four subparagraphs, numbered (1) through (4). Paragraph (u)(4) is further broken down into three subparagraphs. According to the correct format for the Code of Federal Regulations, these subparagraphs should be designated as paragraphs (i) through (iii). However, they are erroneously designated as paragraphs (a) through (c). We are making this correction as part of this final rule.

**Required Determinations**

*Regulatory Planning and Review (E.O. 12866)*

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under Executive Order 12866 (E.O. 12866). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

*Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal 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). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We are certifying that this rule will not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale.

The area affected by this rule includes an area north of Interstate 8, east of the Colorado River, and west of Interstates 10 and 19; and an area south of Interstate 8, east of Highway 85, and west of Interstates 10 and 19. Because of the substantial regulatory relief provided by NEP designations, we do not expect this rule to have any significant effect on recreational, agricultural, ranching, military, or other activities within the NEP area. In addition, when NEPs are located outside a National Wildlife Refuge or unit of the National Park System, we treat the population as a species proposed for listing for the purposes of Section 7 and only two provisions apply: Section 7(a)(1) and section 7(a)(4). In these instances, NEPs provide additional flexibility because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(1) requires Federal agencies to use their authorities to carry out programs to further the conservation of listed species. Section 7(a)(4) requires Federal agencies to confer (rather than consult) with the Service on actions that are likely to jeopardize the continued existence of a proposed species.

The BLM has a policy (BLM 6840 Manual) of conferring on activities that may adversely affect proposed species. The results of a conference are advisory in nature and do not restrict agencies from carrying out, funding, or authorizing activities. The section

7(a)(2) requirements will apply if Sonoran pronghorn may be affected by Federal activities within National Wildlife Refuges and National Park Service units in the NEP; however, we do not anticipate any significant changes to management because these areas are already managed in a way that will promote recovery of the Sonoran pronghorn. The principal activities on private property in the NEP are agriculture, ranching, rural living, and recreation. We believe the presence of the Sonoran pronghorn will not affect the use of private or tribal lands for these purposes because there will be no new or additional economic or regulatory restrictions imposed upon States, non-Federal entities, or members of the public due to the presence of the Sonoran pronghorn.

This rule authorizes incidental take of Sonoran pronghorn within the NEP area outside of National Wildlife Refuges and National Park Service units. The regulations implementing the Act define "incidental take" as take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity such as military training, livestock grazing, recreation, and other activities that are in accordance with Federal, tribal, state, and local laws and regulations. Intentional take for purposes other than aiding sick, injured, or orphaned Sonoran pronghorn; collection of biological data; or other conservation purposes as described in the special rule at the end of this document are not authorized unless for research or educational purposes, which would require a recovery permit under section 10(a)(1)(a) of the Act.

*Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)*

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

a. On the basis of information contained in the "Regulatory Flexibility Act" section above, this rule will not "significantly or uniquely" affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. A Small Government Agency Plan is not required. As explained above, small governments will not be affected because the NEP designation will not place additional requirements on any city, county, or other local municipalities.

b. This rule will not produce a Federal mandate of $100 million or greater in any year (i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act). This NEP designation for the Sonoran pronghorn will not impose any additional management or protection requirements on the states or other entities.

*Takings (E.O. 12630)*

In accordance with Executive Order 12630, the rule does not have significant takings implications. When reestablished populations of federally listed species are designated as NEPs, the Act's regulatory requirements regarding the reestablished listed species within the NEP are significantly reduced. Section 10(j) of the Act and the accompanying special rule can provide regulatory relief with regard to the taking of reestablished species within an NEP area. For example, with the exception of actions on National Wildlife Refuge or National Park Service lands within the NEP, this rule allows for the taking of reestablished Sonoran pronghorn when such take is incidental to an otherwise legal activity, such as military training and testing, agriculture, rural and urban development, livestock grazing, camping, hiking, hunting, recreational vehicle use, sightseeing, nature or scientific study, rockhounding, and geocaching; or other activities that are in accordance with applicable tribal, Federal, State, and local laws and regulations. Because of the substantial regulatory relief provided by NEP designations, we do not believe the reestablishment of this species will conflict with existing or proposed human activities or hinder public use of lands within the NEP.

A takings implication assessment is not required because this rule (1) will not effectively compel a property owner to suffer a physical invasion of property and (2) will not deny all economically beneficial or productive use of the land or aquatic resources. This rule substantially advances a legitimate government interest (conservation and recovery of a listed species) and does not present a barrier to all reasonable and expected beneficial use of private property.

*Federalism (E.O. 13132)*

In accordance with Executive Order 13132, we have considered whether this rule has significant Federalism effects and have determined that a Federalism assessment is not required. This rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. In keeping with Department of the Interior policy, we requested information from and coordinated development of this rule with the affected resource agencies in Arizona. The AGFD has been a key participant in the recovery program for the Sonoran pronghorn, including serving on the IDP that helped develop the reestablishment proposal. Achieving the recovery goals for this species will contribute to its eventual delisting and its return to State management. No intrusion on State policy or administration is expected, roles or responsibilities of Federal or State governments will not change, and fiscal capacity will not be substantially or directly affected. The special rule operates to maintain the existing relationship between the State and the Federal Government and is being undertaken in coordination with the State of Arizona. Therefore, this rule does not have significant Federalism effects or implications to warrant the preparation of a Federalism Assessment under the provisions of Executive Order 13132.

*Civil Justice Reform (E.O. 12988)*

In accordance with Executive Order 12988 (February 7, 1996; 61 FR 4729), the Office of the Solicitor has determined that this rule will not unduly burden the judicial system and will meet the requirements of sections (3)(a) and (3)(b)(2) of the Order.

*Government-to-Government Relationship With Tribes*

In accordance with Secretarial Order 3206 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act) (June 5, 1997); the President's memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951); Executive Order 13175; and the Department of the Interior's requirement at 512 DM 2, we have notified the Native American Tribes within and adjacent to the NEP area about the proposed and final rule. They have been advised through written contact, including informational mailings from the Service, and were provided an opportunity to comment on the draft EA and proposed rule. No comments were received from Tribes on these documents. If future activities resulting from this rule may affect Tribal resources, the Service will communicate and consult on a Government-to-Government basis with any affected Native American Tribes in order to find a mutually agreeable solution.

*Paperwork Reduction Act*

Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. The Office of Management and Budget has approved our collection of information associated with reporting the taking of experimental populations and assigned control number 1018–0095. We may not collect or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

*National Environmental Policy Act*

We have prepared an EA and FONSI, as defined under the authority of NEPA. It is available from the Arizona Ecological Services Field Office, 2321 West Palm Royal Road, Suite 103, Phoenix, AZ 85021, or from our Web site at *http://www.fws.gov/southwest/es/arizona/* or on *www.regulations.gov* under Docket No. FWS–R2–ES–2009–0077.

*Energy Supply, Distribution or Use (E.O. 13211)*

On May 18, 2001, the President issued Executive Order 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. This rule is not expected to significantly affect energy supplies, distribution, and use. Because this action is not a significant energy action, no Statement of Energy Effects is required.

**References Cited**

A complete list of all references cited in this rule is available upon request from the Arizona Ecological Services Field Office (see **ADDRESSES** section).

**Authors**

The primary authors of this rule are staff of the Arizona Ecological Services Field Office (see **ADDRESSES** section).

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Final Regulation Promulgation**

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

## PART 17—[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. Amend § 17.11(h) by revising the entry for "Pronghorn, Sonoran" under "MAMMALS" in the List of Endangered and Threatened Wildlife to read as follows:

**§ 17.11 Endangered and threatened wildlife.**

* * * * *

(h) * * *

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| MAMMALS | | | | | | | |
| * | * | * | * | * | * | | * |
| Pronghorn, Sonoran | *Antilocapra americana sonoriensis.* | U.S.A. (AZ), Mexico | Entire, except where listed as an experimental population. | E | 1, 3 | NA | NA |
| Pronghorn, Sonoran | *Antilocapra americana sonoriensis.* | U.S.A. (AZ), Mexico | In Arizona, an area north of Interstate 8 and south of Interstate 10, bounded by the Colorado River on the west and Interstate 10 on the east; and an area south of Interstate 8, bounded by Highway 85 on the west, Interstates 10 and 19 on the east, and the U.S.-Mexico border on the south. | XN | 782 | NA | 17.84(v) |
| * | * | * | * | * | * | | * |

■ 3. Amend § 17.84 by redesigning paragraphs (u)(4)(a) through (u)(4)(c) as paragraphs (u)(4)(i) through (iii) and by adding a new paragraph (v) to read as follows:

**§ 17.84 Special rules—vertebrates.**

* * * * *

(v) Sonoran pronghorn (*Antilocapra americana sonoriensis*).

(1) The Sonoran pronghorn (*Antilocapra americana sonoriensis*) population identified in paragraph (v)(12) of this section is a nonessential experimental population (NEP).

(2) No person may take this species, except as provided in paragraphs (v)(3) through (v)(6) of this section.

(3) Any person with a valid permit issued by the U.S. Fish and Wildlife Service under § 17.32 may take pronghorn within the NEP area for scientific purposes, the enhancement of

propagation or survival of the species, and other conservation purposes consistent with the Endangered Species Act.

(4) A Sonoran pronghorn may be taken within the boundaries of Yuma Proving Grounds; Barry M. Goldwater Range; lands of the Arizona State Land Department; Bureau of Land Management lands; privately owned lands; and lands of the Tohono O'odham Nation, Colorado River Indian Tribes, Gila River Indian Reservation, Ak-Chin Indian Reservation, Pascua Yaqui Indian Reservation, and San Xavier Reservation within the NEP area, provided that such take is incidental to, and not the purpose of, carrying out any otherwise lawful activity; and provided that such taking is reported as soon as possible in accordance with paragraph (v)(6) of this section. Otherwise lawful activities are any activities in compliance with applicable land management regulations, hunting regulations, tribal law, and all other applicable law and regulations, and include, but are not limited to, military training and testing, border security and enforcement carried out by Federal law enforcement officials (e.g., U.S. Customs and Border Protection), agriculture, rural and urban development, livestock grazing, camping, hiking, hunting, recreational vehicle use, sightseeing, nature or scientific study, rockhounding, and geocaching, where such activities are permitted.

(5) Any employee or agent of the U.S. Fish and Wildlife Service, the Arizona Department of Game and Fish, and the tribes listed in paragraph (v)(4) of this section, who is designated for such purpose may, when acting in the course of official duties, take a Sonoran pronghorn if such action is necessary to:

(i) Aid a sick, injured, or orphaned Sonoran pronghorn, including rescuing such animals from canals;

(ii) Dispose of a dead Sonoran pronghorn specimen, or salvage a dead specimen that may be useful for scientific study;

(iii) Move a Sonoran pronghorn for genetic purposes or to improve the health of the population; or

(iv) Capture and release a Sonoran pronghorn for relocation, to collect biological data, or to attach, service, or detach radio-telemetry equipment.

(6) Any taking pursuant to paragraphs (v)(3) through (v)(5) of this section must be reported as soon as possible by calling the U.S. Fish and Wildlife Service, Arizona Ecological Services Office, 201 N Bonita Avenue, Suite 141, Tucson, AZ 85745 (520/670–6150), or the Cabeza Prieta National Wildlife Refuge, 1611 North Second Avenue, Ajo, AZ 85321 (520/387–6483). Upon contact, a determination will be made as to the disposition of any live or dead specimens.

(7) No person may possess, sell, deliver, carry, transport, ship, import, or export by any means whatsoever, any Sonoran pronghorn or Sonoran pronghorn parts taken in violation of these regulations.

(8) It is unlawful for any person to attempt to commit, solicit another to commit, or cause to be committed, any offense defined in paragraphs (v)(2) and (7) of this section.

(9) The boundaries of the designated NEP area are based on the maximum estimated range of pronghorn that are released in and become established within the NEP area. These boundaries are physical barriers to movements, including major freeways and highways, and the Colorado River. All release sites will be within the NEP area.

(i) All Sonoran pronghorn found in the wild within the boundaries of the NEP area will be considered members of the NEP. Any Sonoran pronghorn occurring outside of the NEP area are considered endangered under the Act.

(ii) The Service has designated the NEP area to accommodate the potential future movements of wild Sonoran pronghorn. All released Sonoran pronghorn and their progeny are expected to remain in the NEP area due to the geographical extent of the designation and substantial barriers to movement that form the boundaries of the NEP.

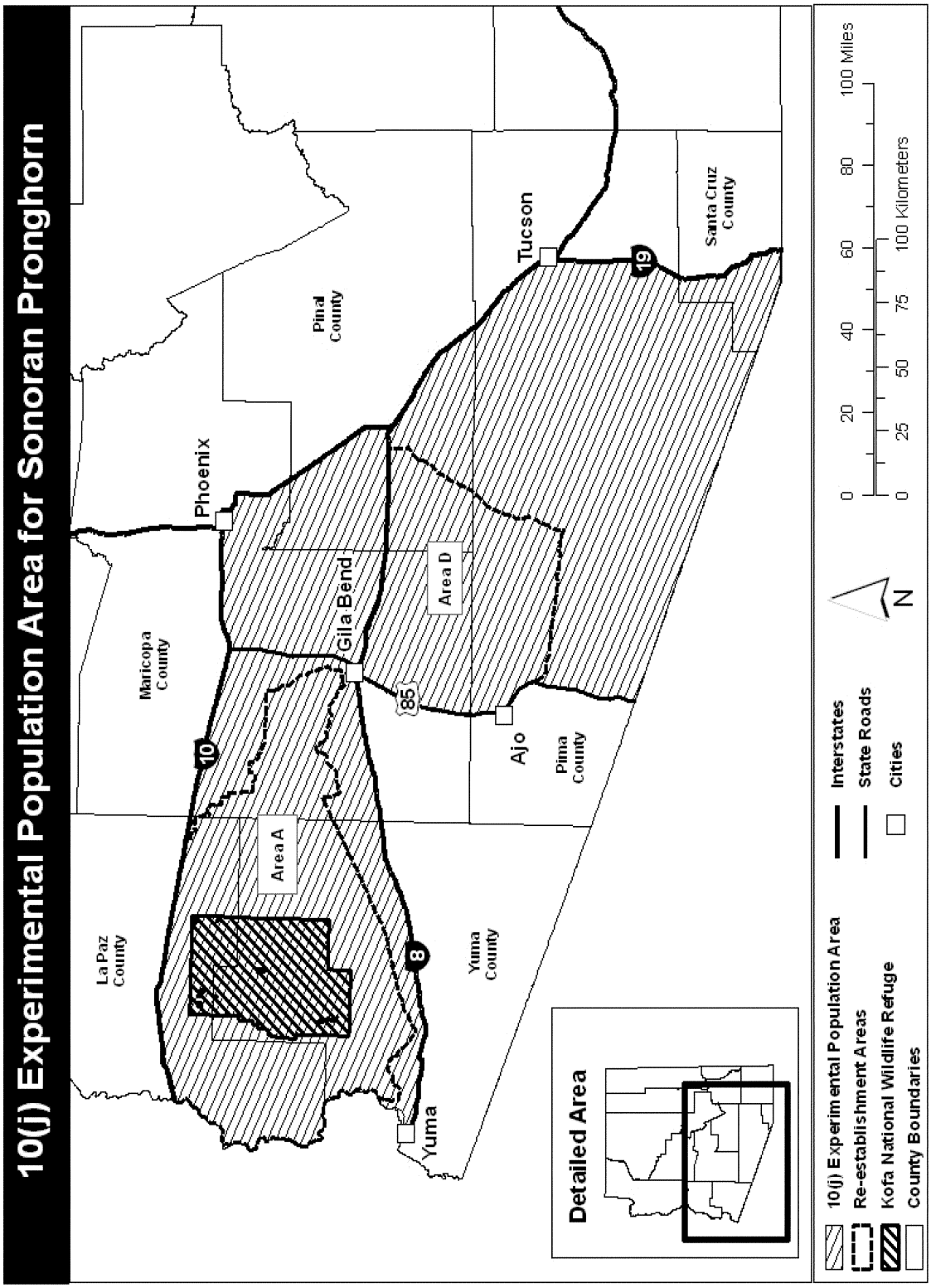
(10) The NEP will be monitored closely for the duration of the program. Any pronghorn that is determined to be sick, injured, or otherwise in need of special care will be recaptured to the extent possible by Service and/or State or Tribal wildlife personnel or their designated agent and given appropriate care. Such pronghorn will be released back to the wild as soon as possible, unless physical or behavioral problems make it necessary to return them to a captive-breeding facility.

(11) The Service plans to evaluate the status of the NEP every 5 years to determine future management status and needs, with the first evaluation occurring not more than 5 years after the first release of pronghorn into the NEP area. All reviews will take into account the reproductive success and movement patterns of individuals released, food habits, and overall health of the population. This evaluation will include a progress report.

(12) The areas covered by this proposed nonessential experimental population designation are in Arizona. They include the area north of Interstate 8 and south of Interstate 10, bounded by the Colorado River on the west and Interstate 10 on the east, and an area south of Interstate 8, bounded by Highway 85 on the west, Interstates 10 and 19 on the east, and the U.S.-Mexico border on the south.

(13) **Note:** Map of the NEP area for the Sonoran pronghorn in southwestern Arizona follows:

BILLING CODE 4310–55–P




BILLING CODE 4310–55–C

Dated April 19, 2011.

**Will Shafroth,**

*Acting Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2011–10467 Filed 5–4–11; 8:45 am]

BILLING CODE 4310–55–P

# Proposed Rules

Federal Register
Vol. 76, No. 87
Thursday, May 5, 2011

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

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 205

**[Document Number AMS–NOP–10–0078; NOP–09–03]**

**RIN 0581–AD05**

## National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances (Livestock)

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on June 20, 2008, and May 30, 2004. The recommendations addressed in this proposed rule pertain to establishing exemptions (uses) for two substances, fenbendazole and moxidectin, on the National List as parasiticides in organic livestock production. Consistent with the recommendations from the NOSB, this proposed rule would amend the National List to add these two substances, along with their restrictive annotations.

**DATES:** Comments must be received by July 5, 2011.

**ADDRESSES:** Interested persons may submit written comments on this proposed rule using one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2646–So., Ag Stop 0268, Washington, DC 20250–0268.

*Instructions:* All submissions received must include the docket number AMS–NOP–10–0078; NOP–09–03, and/or Regulatory Information Number (RIN) 0581–AD05 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for either or both of the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (*e.g.* scientific, environmental, manufacturing, industry, impact information, *etc.*). Only relevant material supporting your position should be submitted. All comments received will be posted without change to *http://www.regulations.gov.*

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments submitted in response to this proposed rule will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2646–South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

**FOR FURTHER INFORMATION CONTACT:** Melissa Bailey, PhD, Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

**SUPPLEMENTARY INFORMATION:**

### I. Background

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) (7 CFR part 205), the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*), (OFPA), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the NOP has published fourteen amendments to the National List: October 31, 2003, (68 FR 61987); November 3, 2003, (68 FR 62215); October 21, 2005, (70 FR 61217), June 7, 2006, (71 FR 32803); September 11, 2006, (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007, (72 FR 58469); December 10, 2007, (72 FR 70479); December 12, 2007, (72 FR 70479); September 18, 2008, (73 FR 59479); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919); and December 13, 2010 (75 FR 77521). Additionally, proposed amendments to the National List published on November 8, 2010, (75 FR 68505) are currently pending.

This proposed rule would amend the National List to reflect two recommendations submitted to the Secretary by the NOSB on June 20, 2008, and May 30, 2004. Based upon their evaluation of petitions submitted by industry participants and reviews prepared by Technical Advisory Panels, the NOSB recommended that the Secretary amend § 205.603 of the National List to add two substances (fenbendazole and moxidectin) for use as parasiticides in organic livestock production under the conditions specified in their respective annotations. The exemption for use of each substance in organic production was evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517–6518).

### II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to

designated sections of the National List regulations:

*Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production*

This proposed rule would amend § 205.603 of the National List Regulations by amending paragraph (a)(18) to move the name of the one listed substance (ivermectin) to a newly designated section (ii) and adding two new sections (i) and (iii) for the purpose of allowing the restricted use of the following substances in organic livestock production:

Fenbendazole (CAS #43210–67–9). Fenbendazole was petitioned for use in March 2007, as a parasiticide for the management of specific gastrointestinal worms and lungworms in organic livestock production.[1] Fenbendazole is a light brownish-gray, odorless crystalline powder which is insoluble in water and soluble in dimethyl sulfoxide. Fenbendazole is a member of the benzimidazole family of anthelmintics. It functions by blocking the polymerization of tubulin into microtubules in gastrointestinal worms and lungworms thereby disrupting the integrity and transport functions of the parasites' cells. Fenbendazole is most effective in ruminant animals because the rate of passage through the digestive system is slowed by the rumen or cecum.

When administered to livestock, fenbendazole and its metabolites can be released into the environment through the excretions of treated animals. Benzimidazole compounds demonstrate high chemical stability in the environment and fenbendazole binds tightly to soil particles, but rapidly degrades in sunlight.

In 1995, the Food and Drug Administration (FDA) issued a Finding of No Significant Impact (FONSI) based upon an environmental assessment of the use of fenbendazole suspension in dairy cattle.[2] The environmental assessment included studies on environmental fate of fenbendazole (*e.g.,* migration/adsorption in soil, photolysis, water solubility, biodegradation) and its potential toxicity in aquatic and terrestrial environments including toxicity to earthworms and dung beetles. In the FONSI, the FDA concluded that the introduction of fenbendazole as suspension, paste or premixes for treatment of dairy cattle, would not have a significant effect on the quality of the human environment. According to the Technical Advisory Panel (TAP) review prepared for the NOSB, there was no convincing evidence associating fenbendazole with serious chronic or acute effects upon human health.[3]

The FDA has approved forms of fenbendazole to treat parasites in cattle (including dairy cattle), goats, sheep, and swine (including pregnant swine), and turkeys. The FDA has approved four oral dosage forms of fenbendazole: suspension, powder, paste, and blocks, for various species of food animals, per 21 CFR 520.905(a)–(e). The FDA has also approved the use of fenbendazole in animal feeds for beef and dairy cattle, swine and turkeys, per 21 CFR 558.258. Table 1 shows the different forms of fenbendazole and the animals for which FDA has approved its use.[4]

TABLE 1—FDA APPROVED FENBENDAZOLE ORAL DOSAGE FORMS AND USES [4]

| Fenbendazole dosage form | Suspension | Paste | Powder | Blocks | Animal feed |
|---|---|---|---|---|---|
| 21 CFR reference | 21 CFR 520.905(a) | 21 CFR 520.905(c) | 21 CFR 520.905(d) | 21 CFR 520.905(e) | 21 CFR 558.258 |
| Animal species for which use is approved. | * Cattle—including dairy cattle of breeding age.<br>* Beef cattle.<br>* Non-lactating goats. | * Cattle ..... | * Swine ..... | * Cattle—excluding dairy cattle of breeding age. | * Turkeys.<br>* Swine.<br>* Dairy and beef cattle—not for use in veal calves. |

Per the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), the FDA established specific tolerances at 21 CFR 556.275 for residues of fenbendazole in animal tissues to be used as food. The acceptable daily intake (ADI) and tolerances are listed for liver, muscle and milk among the livestock species for which FDA has approved its use.

The NOP regulations at § 205.238(b)(1) permit the use of synthetic parasiticides if included on § 205.603 of the National List in breeder stock, excluding the last third of gestation and during lactation for progeny that will be sold, labeled or represented as organic. Section 205.2 of the NOP regulations defines breeder stock as "female livestock whose offspring may be incorporated into an organic operation at the time of their birth." Neither the NOP regulations nor the NOSB recommendation restrict the use of parasiticides to ruminant animals. In effect, this proposed action would allow the use of the applicable form of fenbendazole among breeder stock for beef and dairy cattle, goats, and swine, provided it is not administered during the last third of gestation and lactation for progeny that will be sold as organic. The action would also allow the use of the applicable form of fenbendzole for turkeys.

At its May 20–22, 2008, meeting in Washington, DC, the NOSB recommended revising the National List at § 205.603(a)(18) to permit the use of fenbendazole under the following conditions: "Only to be used upon written diagnosis of clinical infestation by a veterinarian; prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved

[1] The petition was submitted by Intervet Inc., and is retrievable from the NOP Web site in the Petitioned Substances Database, *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[2] Hoechst-Roussel Agri-Vet Company. May 1995. Environmental Assessment NADA 128–620 Fenbendazole Suspension 10% in Dairy Cattle of Breeding Age. Retrieved from FDA's Animal and Veterinary area via NADA number (the FONSI is also available via the link to the Environmental Assessment): *http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm072419.htm.*

[3] Technical Advisory Panel Review on Parasiticides (Fenbendazole, Ivermectin and Levamisole). November 25,1999. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[4] This table does not include the FDA mandated limitations and restrictions on use. That information can be found in the referenced section of the CFR. This table only includes livestock applicable to organic production and does not list other types of animals, such as horses not intended for food, dogs and zoo animals, for which certain forms of oral fenbendazole are approved.

preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock." Except for the provision, "only to be used upon written diagnosis of clinical infestation by a veterinarian," the recommended annotation is identical to the National List annotation for the parasiticide ivermectin at § 205.603. These common components reiterate the restrictions on the use of parasiticides in general, as set forth in §§ 205.238(b) and (c)(4)–(5).

During this open meeting, the NOSB evaluated the use of fenbendazole against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and received public comment. The record contains acknowledgement of the risks associated with chemical treatment of parasites, particularly to non-target organisms, human health and the food chain, residue accumulation and target organism resistance. However, the NOSB has considered the role of fenbendazole as part of an integrated system of animal health care, which includes the relief of pain and suffering that can be caused by parasitic infestation. The NOP regulations prohibit the routine use of synthetic parasiticides, per § 205.238(c)(4), and the infrequent use of fenbendazole in organic production is expected to mitigate its introduction to and persistence in the environment. The NOSB emphasized that the allowance of additional parasiticides should not be viewed as an indication that parasiticides will be approved with greater facility. The NOSB reiterated that organic livestock producers are first and foremost responsible for managing parasites through practices specified in their organic system plans, including selection of disease resistant breeds, rotational grazing and culling of susceptible animals. The NOSB concluded that fenbendazole had clear advantages over ivermectin which is the only parasiticide currently approved for use in organic production. In its discussion, the NOSB noted these comparative advantages of fenbendazole over ivermectin: (1) More targeted spectrum of activity; (2) notably benign to earthworms, plant life, microorganisms and particularly dung beetles, all of which are important in sustainable systems; (3) very few reports of anthelmintic resistance even in conventional livestock production; and, (4) very low toxicity.[5]

For the purpose of clarity, the Secretary is proposing that the shared elements of the annotation for ivermectin and proposed annotation for fenbendazole be placed as a separate paragraph at § 205.603(a)(18). The contents of that paragraph, which restate the requirements provided in §§ 205.238(b) and (c)(4)–(5), would apply to each parasiticide listed beneath including ivermectin and the new listings for fenbendazole and moxidectin as proposed below. The repetition of these requirements in § 205.603 of the National List ensures that the provisions which appear in another section of the regulations will not be overlooked.

The NOP engaged in consultations with the EPA and FDA. Concerning the use of fenbendazole, the EPA deferred to FDA as the appropriate regulatory body. The FDA informed the NOP that the proposed amendment to exempt fenbendazole for use in organic livestock is consistent with FDA regulations. The requirement that fenbendazole may only be used upon written diagnosis of clinical infestation by a veterinarian exceeds FDA requirements and is only applicable to the use of fenbendazole in organic livestock production.[6]

Therefore, after consultation with the EPA and FDA regarding the NOSB recommendation, the Secretary is proposing to accept the NOSB's recommendation and amend § 205.603(a) of the National List by removing ivermectin from (18) and placing ivermectin in new section (ii) and adding fenbendazole at new section (i) as follows: (a)(18) Parasiticides. Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210–67–9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288–86–7).

Moxidectin was petitioned in March 2003, for use as a topical medical treatment for controlling internal and external parasites in organic cattle production.[7] It is a white to pale yellow powder that is slightly soluble in water and is readily soluble in various organic solvents. Moxidectin belongs to the milbemycin group of macrolides. It is chemically synthesized from nemadectin, a fermentation product of *Streptomyces cyaneogriseus* subsp. *Noncyanogenus.* Moxidectin functions as an endectocide (a drug effective against both internal and external parasites) and activates glutamate-gated chloride channels and GABA-gated chloride channels, causing paralysis of certain arthropods and nematodes. Moxidectin is effective against a wide range of adult and larval internal and external parasites including gastrointestinal roundworms, lungworms, cattle grubs, mites, lice and horn flies.

Moxidectin and its active metabolites are primarily introduced into the environment through excretion of feces. In addition, a minute amount of topically applied moxidectin may wash off treated cattle when rainfall follows treatment.[8] Moxidectin is a lipophilic material that breaks down under sunlight and binds tightly to the soil, which mitigates the potential for contamination of water sources and effects on aquatic organisms. Under aerobic conditions, the half-life of moxidectin in the environment was found to be about two months. In water, moxidectin breaks down fairly rapidly through photodegradation, and has a half-life of 6.8 hours. Various studies on the effect of moxidectin and its metabolites upon non-target soil organisms have been equivocal. Some studies have shown adverse effects

[5] NOSB Recommendation on Fenbendazole. June 20, 2008. Retrieved from National Organic Program Petitioned Substances Database. Transcripts from the NOSB May 20–22, 2008 meeting can be retrieved from the NOP webpage in the NOSB section: *http://bit.ly/iemAwC.*

[6] The FDA regulations at 21 FR 520.905a state that the 10 mg fenbendazole suspension for beef cattle is restricted to use by or on the order of a licensed veterinarian. The FDA regulations do not stipulate that requirement for other dosage forms. The NOP requirement for a 90-day withdrawal period for milk or milk products from an animal treated with an allowed parasiticide also exceeds FDA requirements for use among nonorganic livestock. The 90-day milk withdrawal period was set based upon consumer expectations for organically raised animals and is only applicable to the use of this substance under the NOP regulations (65 FR 80573).

[7] The petition was submitted by Fort Dodge Animal Health and is retrievable from the NOP Web site in the Petitioned Substances Database, *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[8] According to the 2003 Technical Advisory Panel review, in a study submitted to the FDA by the manufacturer, less than 1% of the applied dose of moxidectin was found to wash off treated cattle when rainfall occurred within 30 minutes of product application.

upon non-target organisms, while others showed moxidectin to be comparatively less harmful to arthropods than other parasiticides, notably ivermectin, and to have no adverse impact on earthworms, dung fauna, plant germination or leaves of growing plants.

The FDA considered the environmental effects of the pour-on form of moxidectin for cattle and in 1997, issued a finding of no significant impact (FONSI) declaring that use of the drug would not have a significant effect on the human environment. The FONSI noted that based upon its similarities to avermectins, moxidectin is not expected to have a significant effect on dung-dependent insects as toxicity is mitigated by temporal and spatial distribution.[9] The TAP review prepared for the NOSB stated that some parasites which are resistant to ivermectin have been effectively reduced by moxidectin treatment.[10]

At its May 28–30, 2004, meeting in Chicago, IL, the NOSB recommended adding moxidectin to the National List, with the annotation that it be used only for internal control of parasites. In this open meeting, the NOSB evaluated moxidectin against the criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

In a proposed rule published in the **Federal Register** on July 17, 2006, (71 FR 40624), the USDA indicated that moxidectin would not be added to the National List as recommended by the NOSB because moxidectin is classified as a macrolide antibiotic. Moxidectin is a derivative of the antibiotic nemadectin, which is produced during the fermentation of *Streptomyces cyaneogriseus* sp. *noncyanogenus.* This decision was based upon the rationale that, although moxidectin was approved by FDA for use as a parasiticide in conventional livestock production, the substance is classified as an antibiotic due to its origin as a derivative of the antibiotic nemadectin, and, therefore, its use in organic livestock would be inconsistent with the prohibition of antibiotics at § 205.238(c)(1).

In response to the July 17, 2006, proposed rule (71 FR 40624), a number of comments were submitted in support of the NOSB recommendation that moxidectin be included on the National List for internal control of parasites.[11] The comments characterized USDA's decision not to add moxidectin to the list as arbitrary and without scientific or regulatory basis. The commenters argued that moxidectin is a parasiticide, and does not act as an antibiotic when used as a medical treatment to eliminate parasites from livestock. One comment stated that a defining feature of an antibiotic is its ability to inhibit the growth of microorganisms or kill them outright. The commenter further stated that moxidectin does not exhibit this capacity when used for parasites because it eliminates the parasitic organisms, rather than bacterial infections.

Based upon the evidence received through public comments on the July 17, 2006, proposed rule, the NOP verified the information supplied by commenters and, subsequently, concurred that moxidectin, though categorized as a macrolide antibiotic, does not function as such when used as a parasiticide. In a final rule (72 FR 70479) published in the **Federal Register** on December 12, 2007, USDA announced that moxidectin would be added to the National List through a future rulemaking action.

The FDA has approved oral, injectable and topical dosage forms of moxidectin for treatment in beef and dairy cattle, and sheep. The various approved dosage forms of moxidectin are summarized in Table 2.

TABLE 2—FDA APPROVED MOXIDECTIN FORMS AND USES [12]

| Moxidectin dosage form | Oral—solution | Injectable—solution | Topical |
|---|---|---|---|
| 21 CFR reference | 21 CFR 520.1454 | 21 CFR 522.1450 | 21 CFR 524.1451 |
| Animal species for which use is approved. | Sheep—excluding female sheep providing milk for human consumption. | Beef and non-lactating dairy cattle; no use in veal calves. | Beef and dairy cattle; no use in veal calves. |

Per the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), the FDA established tolerances for moxidectin in animal products to be used as food at 21 CFR 556.426. The acceptable daily intake (ADI) and residue tolerances are listed for liver, milk and meat of cattle and sheep.

The NOSB recommended the use of moxidectin for control of internal parasites only. The FDA approved indications for use of the topical and injectable solutions include internal and external parasites, therefore, this recommended limitation is only for the purposes of organic livestock production. Organic producers using moxidectin to treat infection would need to demonstrate that any use of moxidectin is for control of internal parasites only. Such information should be available as part of their animal health records.

In considering the NOSB deliberations on moxidectin and the TAP review, the NOP identified an inconsistency between the TAP review's data on persistence of moxidectin in the environment and the data reported as part of the recommendation from the NOSB Livestock Committee. The TAP review stated that moxidectin has a half-life of two months in aerobic soil conditions, but the NOSB Livestock Committee inadvertently recorded the half-life of moxidectin as six months in the soil on the committee recommendation submitted to the NOSB. Based upon the six month half-life, the Livestock Committee proposed an annotation restricting use of moxidectin to control for internal parasites as an effort to minimize the environmental impact of its use. While

[9] Retrieved from FDA's Animal and Veterinary area via NADA number for 141–099 CYDECTIN® 0.5% Pour-On for Cattle (Moxidectin): *http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm072419.htm.*

[10] Technical Advisory Panel review on Moxidectin. April 2003. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda/nop;* Transcripts from the NOSB May 28–30, 2004 meeting can be retrieved from the NOSB section of the NOP webpage.

[11] The public comments to proposed rule, TM–03–04, can be retrieved from the NOP Web site in the public comments area: *http://www.ams.usda.gov/AMSv1.0/NOPPublicComments.*

[12] The table does not include the FDA mandated limitations and restrictions on use. That information can be found in the referenced section of the CFR. This table only includes livestock applicable to organic production and does not include dogs for which certain injectable and oral forms of moxidectin are approved or horses and ponies not intended for food for which the moxidectin oral gel form is approved.

the discrepancy between the TAP review and the Livestock Committee recommendation was discussed at their May 28–30, 2004, meeting, the NOSB opted to recommended moxidectin with an annotation to limit its use for the treatment of internal parasites.[13]

The NOP regulations permit the use of synthetic parasiticides in breeder stock, excluding the last third of gestation and during lactation for progeny that will be sold, labeled or represented as organic, § 205.238(b)(1). The NOP regulations, at § 205.2, define breeder stock as "female livestock whose offspring may be incorporated into an organic operation at the time of their birth." In effect, this proposed action would allow the use of the applicable form of moxidectin among breeder stock for beef and dairy cattle, and sheep, provided it is not administered during the last third of gestation and during lactation for progeny that will be sold as organic. In accordance with the portions of the NOP regulations which pertain to the use of any approved parasiticide, §§ 205.238(b) and (c)(4)–(5), moxidectin must not be administered on a routine basis and must not be administered to slaughter stock. Per § 205.238(b), moxidectin may only be administered to dairy stock, a minimum of 90 days prior to the production of milk or milk products that are to be labeled as organic when preventive practices and veterinary biologics have failed.

The NOP engaged in consultations with the FDA and EPA concerning the approved use of the substance. The EPA deferred to FDA as the appropriate regulatory body. Based upon consultations with the FDA, the NOP was informed that moxidectin is approved for use by the FDA for treatment and control of internal and external parasites in beef and dairy cattle (21 CFR 524.1452). Further, the FDA regulations do not require a withdrawal time following the application of topical moxidectin to nonorganic beef and dairy cattle.[14] Therefore, the limitation on the use of moxidectin for control of internal parasites only, and the 90-day withdrawal period for organic milk/milk products following treatment with moxidectin are only applicable to the use of moxidectin among livestock under organic management.

After consulting with EPA and FDA and assessing public comments on the proposed rule (71 FR 40624), the Secretary proposes to accept NOSB's recommendation to amend § 205.603(a)(18) of the National List by adding newly designated section (iii), under the existing restrictions at § 205.603(a)(18) as follows: (iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only. Because of the discrepancy between the TAP review and the NOSB recommendation on the issue of persistence of the substance in the environment, the AMS invites specific comments on the need for the proposed annotation to limit the use of the moxidectin as an internal parasiticide only.

## III. Related Documents

Two notices were published regarding the meetings of the NOSB and deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** notices: (1) 73 FR 18491, April 4, 2008 (Fenbendazole); (2) 69 FR 18036, April 6, 2004 (Moxidectin).

In a July 17, 2006, proposed rule (71 FR 40624), the USDA announced its decision that moxidectin would not be proposed for inclusion on the National List, because of its macrolide antibiotic classification, which was inconsistent with NOP policy prohibiting the use of antibiotics in organic livestock production. On December 12, 2007, in a final rule (72 FR 70479), the USDA responded to comments from the proposed rule (71 FR 40624) and affirmed that the NOSB recommended use of moxidectin is as a parasiticide, not as an antibiotic.

## IV. Statutory and Regulatory Authority

The OFPA, as amended [7 U.S.C. 6501 *et seq.*], authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518 (k) and 6518 (n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at *http://www.ams.usda.gov/AMSv1.0/nop.*

*A. Executive Order 12866.*

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

*B. Executive Order 12988.*

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug

[13] Technical Advisory Report on Moxidectin. April 2003. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda/nop;* Transcripts from the NOSB May 28–30, 2004, meeting can be retrieved from the NOSB section of the NOP webpage.

[14] The FDA regulations, at 21 CFR 522.1450, require that cattle not be slaughtered within 21 days of treatment with the injectable form of moxidectin solution.

and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

*C. Regulatory Flexibility Act.*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the use of additional substances in agricultural production and handling. This action would relax the regulations published in the final rule and would provide small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $7,000,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

Based on USDA data from the Economic Research Service (ERS), the U.S. organic sector included nearly 13,000 certified organic crop and livestock operations at the end of 2008. These operations contained more than 4.8 million certified acres consisting of 2,665,382 acres of cropland and 2,160,577 acres of pasture and rangeland. The total acreage under organic management represents a twelve percent increase from 2007.[15] AMS believes that most of the certified production and handling operations would be classified as small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages have grown from $3.6 billion in 1997 to nearly $21.1 billion in 2008.[16] Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2009, organic food sales grew 5.1 percent.[17]

In addition, USDA has accredited 94 certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at *http://www.ams.usda.gov/nop.* AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

*D. Paperwork Reduction Act.*

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.,* or OMB's implementing regulation at 5 CFR part 1320.

The AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

*E. General Notice of Public Rulemaking.*

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to list two parasiticides on the National List. A 60-day period for interested persons to comment on this rule is provided and is deemed appropriate.

**List of Subjects in 7 CFR Part 205**

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is proposed to be amended as follows:

## PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

**Authority:** 7 U.S.C. 6501–6522.

2. In § 205.603, paragraph (a)(18) is revised to read as follows:

**§ 205.603 Synthetic substances allowed for use in organic livestock production.**

* * * * *

(a) * * *

(18) *Parasiticides.* Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in Subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210–67–9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288–86–7).

(iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only.

* * * * *

Dated: April 29, 2011.

**David R. Shipman,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2011–11045 Filed 5–4–11; 8:45 am]

BILLING CODE 3410–02–P

[15] U.S. Department of Agriculture, Economic Research Service, 2009. Data Sets: *U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992–2008. http://www.ers.usda.gov/Data/Organic/.*

[16] Dimitri, C., and L. Oberholtzer. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers,* Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, *http://www.ers.usda.gov/Publications/EIB58.*

[17] Organic Trade Association's *2010 Organic Industry Survey, http://www.ota.com.*

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 1208

**[Doc. No. AMS–FV–07–0077; FV–07–705–PR–2B]**

**RIN 0581–AC79**

## Proposed Processed Raspberry Promotion, Research, and Information Order

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule and Referendum Order.

**SUMMARY:** This document directs that a referendum be conducted among eligible producers of raspberries for processing and importers of processed raspberries to determine whether they favor the establishment of an industry-funded promotion, research, and information program for processed raspberries. The proposed program, Processed Raspberry Promotion, Research, and Information Order (Proposed Order), was submitted to the Department of Agriculture (Department) by the Washington Red Raspberry Commission (WRRC). Under the Proposed Order, producers of raspberries for processing and importers of processed raspberries would pay an assessment of up to one cent per pound, with the initial assessment rate being one cent per pound, which would be paid to the proposed National Processed Raspberry Council (Council). Producers and importers of less than 20,000 pounds annually of raspberries for processing and processed raspberries, respectively, would be exempt from the assessment. The proposed program would be implemented under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act). The Department is conducting an initial referendum to ascertain whether the persons to be covered by and assessed under the Proposed Order favor the implementation of the program prior to it going into effect. The Proposed Order would be implemented if it is approved by a majority of producers and importers voting in the referendum.

**DATES:** The voting period is June 8 through June 24, 2011. To be eligible to vote, producers must have produced 20,000 pounds of raspberries for processing and importers must have imported 20,000 pounds of processed raspberries during the representative period from January 1, 2010 through December 31, 2010. Ballots will be mailed to all known producers of raspberries for processing and importers of processed raspberries, on or before June 1, 2011. Ballots must be received by the referendum agent no later than the close of business 4:30 pm (Eastern Time) on June 24, 2011.

**ADDRESSES:** Copies of the Proposed Order may be obtained from: Referendum Agent, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0244, Room 0632–S, Washington, DC 20250–0244; telephone: (202) 720–9915 or (888) 720–9917 (toll free); or facsimile: (202) 205–2800; or can be viewed at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Kimberly Coy, Marketing Specialist, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Room 0632, Stop 0244, Washington, DC 20250–0244; *telephone:* (202) 720–9915 or (888) 720–9917 (toll free); or *facsimile:* (202) 205–2800; or *e-mail: Kimberly.Coy@ams.usda.gov.*

**SUPPLEMENTARY INFORMATION:** This rule is issued pursuant to the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

As part of this rulemaking, a proposed rule was published in the **Federal Register** on April 9, 2009 [74 FR 16289], with a 60-day comment period which closed on June 8, 2009. Twenty-one comments were received. A second proposed rule was published in the **Federal Register** on February 8, 2010 [75 FR 6131] addressing the comments. In addition, a separate final rule on referendum procedures was published in the **Federal Register** on February 8, 2010 [75 FR 6089].

Since publication of the second proposed rule, the industry worked with the 484(f) Committee (Committee) of the United States International Trade Commission (USITC) which is the committee that reviews requests for changes to the statistical reporting requirements of the HTS for imports, to determine the feasibility of separating red raspberry juice and juice concentrate from all other juice and juice concentrate, red raspberry paste and purees from all other pastes and purees, and red raspberry preserves from all other fruit preserves. According to the Committee, this separation was feasible. Accordingly, the Committee approved the petition for processed red raspberry statistical breakout in the Harmonized Tariff Schedule. The new number assigned to red raspberry juice and juice concentrate is 2009.80.60.55, the new number assigned to processed red raspberry pastes and purees is 2007.99.65.10, and the new number assigned to red raspberry preserves is 2008.99.20.20, effective July 1, 2010. The aforementioned changes will be reflected in the final rule. Also, assessments for imported red raspberry preserves will not begin until a conversion factor is developed.

### Executive Order 12866

This rule has been determined to be not significant for purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget (OMB).

### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act provides that the 1996 Act shall not affect or preempt any other Federal or state law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act, a person subject to an order may file a written petition with the Department stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and requesting a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, the Department will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of the Department's final ruling.

### Referendum Order

Pursuant to the 1996 Act, a referendum will be conducted to determine whether eligible producers of raspberries for processing and importers of processed raspberries favor issuance of the Proposed Order. The Proposed Order is authorized under the 1996 Act.

The representative period for establishing voter eligibility for the referendum shall be the period from January 1, 2010, through December 31, 2010. Producers must have produced

20,000 pounds of raspberries for processing and importers must have imported 20,000 pounds of processed raspberries during the representative period from January 1, 2010 through December 31, 2010, to be eligible to vote. The referendum shall be conducted by mail ballot from June 8 through June 24, 2011. Ballots must be received by the referendum agent no later than the close of business 4:30 p.m. (Eastern Time) on June 24, 2011, to be counted.

Section 518 of the 1996 Act authorizes the Department to conduct a referendum prior to the Order's effective date. The Order shall become effective only if it is determined that the Order has been approved by a majority of those eligible persons voting for approval.

Kimberly Coy, of the USDA, AMS, Research and Promotion Branch, is designated as the referendum agent to conduct this referendum. The referendum procedures [7 CFR 1208.100 through 1212.108], which were issued pursuant to the 1996 Act, shall be used to conduct the referendum.

The referendum agent will mail registration instructions to all known eligible producers and importers in advance of the referendum. Any producer or importer who does not receive registration instructions should contact the referendum agent cited under the "For Further Information" section no later than one week before the end of the registration period. Prior to the first day of the voting period, the referendum agent will mail the ballots to be cast in the referendum and voting instructions to all eligible voters. Persons who are producers and importers during the representative period are eligible to vote. Any producer or importer who does not receive a ballot should contact the referendum agent cited under the "For Further Information" section no later than one week before the end of the registration period. Ballots must be received by the referendum agent by the close of business on or before [insert last day of referendum], to be counted.

In accordance with the OMB regulation [5 CFR part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. 35], the referendum ballot, which represents the information collection and recordkeeping requirements that may be imposed by this rule, was submitted to OMB for approval and approved under OMB Number 0581–0257.

**List of Subjects in 7 CFR Part 1208**

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Raspberry promotion, Reporting and recordkeeping requirements.

**Authority:** 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

**David R. Shipman,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2011–11050 Filed 5–4–11; 8:45 am]

BILLING CODE 3410–02–P

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 1210

**[Document Number AMS–FV–10–0093]**

### Watermelon Research and Promotion Plan; Redistricting and Importer Representation

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule invites comments on changing the boundaries of all seven districts under the Watermelon Research and Promotion Plan (Plan) to reapportion the producer, handler, and importer memberships on the National Watermelon Promotion Board (Board). In addition, the Board is adding two importer seats based on the quantity of watermelon imports in the past three years. These changes are based on a review of the production and assessments paid in each district and the amount of watermelon import assessments, which the Plan requires at least every five years. As a result of these changes, the importer seats would increase from six to eight. Therefore, the total Board membership would increase from 35 to 37 members. In addition, a new CFR section is added to reflect the importer representation on the Board.

**DATES:** Comments must be received by June 6, 2011.

**ADDRESSES:** Interested persons are invited to submit written comments on the Internet at: *http://www.regulations.gov* or to the Research and Promotion Branch, Fruit and Vegetable Programs, Agricultural Marketing Service (AMS), U.S. Department of Agriculture, (USDA) Room 0632–S, Stop 0244, 1400 Independence Avenue, SW., Washington, DC 20250–0244; facsimile: (202) 205–2800. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours or it can be viewed at *http://www.regulations.gov.* All comments received will be posted without change, including any personal information provided. Please be advised that the identity of the individuals or entities submitting comments will be made public on the Internet at the address provided above.

**FOR FURTHER INFORMATION CONTACT:** Jeanette Palmer, Marketing Specialist, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, Stop 0244, 1400 Independence Avenue, SW., Room 0632–S, Washington, DC 20250–0244; telephone: (888) 720–9917; facsimile: (202) 205–2800; or electronic mail: *Jeanette.Palmer@ams.usda.gov.*

**SUPPLEMENTARY INFORMATION:** This rule is issued under the Watermelon Research and Promotion Plan [7 CFR part 1210]. The Plan is authorized under the Watermelon Research and Promotion Act (Act) [7 U.S.C. 4901–4916].

**Executive Orders 12886**

The Office of Management and Budget has waived the review process required by Executive Order 12866 for this action.

**Executive Order 12988**

In addition, this rule has been reviewed under Executive Order 12988, Civil Justice Reform. The rule is not intended to have retroactive effect.

The Act allows producers, producer-packers, handlers, and importers to file a written petition with the Secretary of Agriculture (Secretary) if they believe that the Plan, any provision of the Plan, or any obligation imposed in connection with the Plan, is not established in accordance with law. In any petition, the person may request a modification of the Plan or an exemption from the Plan. The petitioner will have the opportunity for a hearing on the petition. Afterwards, an Administrative Law Judge (ALJ) will issue a decision. If the petitioner disagrees with the ALJ's ruling, the petitioner has 30 days to appeal to the Judicial Officer, who will issue a ruling on behalf of the Secretary. If the petitioner disagrees with the Secretary's ruling, the petitioner may file, within 20 days, an appeal in the U.S. District Court for the district where the petitioner resides or conducts business.

**Initial Regulatory Flexibility Act and Paperwork Reduction Act**

In accordance with the Regulatory Flexibility Act [5 U.S.C. 601–612], AMS has examined the economic impact of

this rule on the small producers, handlers, and importers that would be affected by this rule.

The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (handlers and importers) as those having annual receipts of no more than $7 million. Under these definitions, the majority of the producers, handlers, and importers that would be affected by this rule would be considered small entities. Producers of less than 10 acres of watermelons are exempt from this program. Importers of less than 150,000 pounds of watermelons per year are also exempt.

USDA's National Agricultural Statistics Service (NASS) data for the 2010 crop year was about 310 hundredweight (cwt.) of watermelons were produced per acre. The 2010 grower price published by NASS was $12.00 per hundredweight. Thus, the value of watermelon production per acre in 2010 averaged about $3,720 (310 cwt. × $12.00). At that average price, a producer would have to farm over 202 acres to receive an annual income from watermelons of $750,000 ($750,000 divided by $3,720 per acre equals 202). Accordingly, as previously noted, a majority of the watermelon producers would be classified as small businesses.

Based on the Board's data, using an average of freight on board (f.o.b.) price of $.0164 per pound and the number of pounds handled in 2010, none of the watermelon handlers had receipts over the $7.5 million threshold. Therefore, the watermelon handlers would all be considered small businesses. A handler would have to ship over 457 million pounds of watermelons to be considered large (457,317,073 times $.0164 f.o.b. equals $7,500,000).

According to the Board, there are approximately 950 producers, 230 handlers, and 137 importers who are required to pay assessments under the program.

Based on the watermelon import assessments received for the year 2010, the United States imported watermelons worth over $260 million dollars. The largest imports of watermelon came from Mexico which accounted for 93 percent of the total in 2010. Other suppliers of imported watermelon are Guatemala at 3 percent and Honduras at 1 percent. The remaining 3 percent of imported watermelon came from Canada, Netherlands, Nicaragua, Nigeria, and Panama.

The Board's assessment records show imports for the years 2007, 2008, and 2009 at $681,565, $783,249, and $742,363 respectively. Based on this data, the three-year average annual imports for watermelon total $735,725 (2,207,177 divided by 3). This represents approximately 29 percent of the total assessments paid to the Board. Currently there are 6 importers on the Board representing 17 percent of the total members. Accordingly, two importer seats should be added to the Board. The new Board membership distribution would be 14 producers, 14 handlers, 8 importers, and 1 public member which would bring the percentage of seats for importers to 22 percent of the total seats on the Board.

Nominations and appointments to the Board are conducted pursuant to sections 1210.321 of the Plan. The Plan requires producers to be nominated by producers, handlers to be nominated by handlers, and importers to be nominated by importers. This would not change. Because some current members are in States or counties which would be moved to other districts under this rule, one producer member vacancy in the new District 2, one handler member vacancy in the new Districts 3, and one producer member vacancy in the new District 7 would result with this change. Nomination meetings will be held in the new districts to fill these vacancies.

Appointments to the Board are made by the Secretary from a slate of nominated candidates. The nominees for the two producer, one handler and two importer positions will be submitted to the Secretary for appointment to the Board.

The overall impact is favorable because the new district boundaries provide more equitable representation for the producers, handlers, and importers who pay assessments in the various districts.

The Board chose the realignment scenario that kept the States together. For instance, California is currently divided into two districts and the Board has realigned California so that all the counties in California are located in one district. The new realignment would also give Georgia and Texas their own respective districts. The other States will be divided up to reflect their watermelon production levels and grouped together for the four remaining districts.

The Board considered several alignments of the districts in an effort to provide balanced representation for each district. The Board selected the alignment described in this rule as it provides proportional representation on the Board of producers, handlers, and importers. The addition of two importers would allow for more importers representation on the Board's decision making and also potentially provide an opportunity to increase diversity on the Board.

In accordance with the Office of Management and Budget (OMB) regulation [5 CFR part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the background form, which represents the information collection and recordkeeping requirements that are imposed by the Plan have been approved previously under OMB number 0505–0001.

The Plan requires that two nominees be submitted for each vacant position. With regard to information collection requirements, adding two importers to the Board means that four additional importers will be required to submit background forms to USDA in order to be considered for appointment to the Board. However, serving on the Board is optional, and the burden of submitting the background form would be offset by the benefits of serving on the Board. The estimated annual cost of providing the information by four importers would be $33 or $8.25 per importer. The additional minimal burden will be included in the existing information collection package under OMB number 0505–0001.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

We have performed this Initial Regulatory Flexibility Analysis regarding the impact of this amendment to the Plan on small entities, and we invite comments concerning potential effects of this amendment.

**Background**

Under the Plan, the Board administers a nationally coordinated program of research, development, advertising, and promotion designed to strengthen the watermelon's position in the market place and to establish, maintain, and expand markets for watermelons. This program is financed by assessments on producers growing 10 acres or more of watermelons, handlers of watermelons, and importers of 150,000 pounds of watermelons or more per year. The Plan specifies that handlers are responsible for collecting and submitting both the producer and handler assessments to the Board, reporting their handling of watermelons, and maintaining records necessary to verify their reporting(s). Importers are responsible for payment of assessments to the Board on watermelons imported into the United States through the U.S. Customs Service and Border Protection. This action will not have any impact on the assessment

rates paid by producers, handlers, and importers.

Membership on the Board consists of two producers and two handlers for each of the seven districts established by the Plan, at least one importer, and one public member. The Board currently consists of 35 members: 14 producers, 14 handlers, 6 importers, and 1 public member.

The seven current districts were established in 2006. They are:

*District 1*—The Florida counties of Brevard, Broward, Charlotte, Citrus, Collier, Dade, DeSoto, Flagler, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Marion, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Putnam, Sarasota, Seminole, St. Johns, St. Lucie, Sumter, and Volusia.

*District 2*—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Clay, Columbia, Dixie, Duval, Escambia, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Nassau, Okaloosa, Santa Rosa, Suwannee, Taylor, Union, Wakulla, Walton, Washington, and the Georgia counties Early, Baker, Miller, Mitchell, Colquitt, Thomas, Grady, Decatur, Seminole, and the States of Alabama, Arkansas, Louisiana, Mississippi, North Carolina, Oklahoma, Tennessee, and Virginia.

*District 3*—The Georgia counties not included in District two and the State of South Carolina.

*District 4*—The States of North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Illinois, Missouri, Michigan, Indiana, Ohio, Kentucky, West Virginia, Maryland, New Hampshire, Maine, New Jersey, New York, Pennsylvania, Massachusetts, Rhode Island, Delaware, Vermont, Wisconsin, Connecticut, and Washington, DC.

*District 5*—The States of Alaska, Hawaii, Nevada, Oregon, and Washington and all of the counties in the state of California except for those California counties included in District Seven.

*District 6*—The counties in the state of Texas, except for those counties in Texas included in District Seven.

*District 7*—The counties in the state of Texas; Dallam, Sherman, Hanaford, Ochiltree, Lipscomb, Hartely, Moore, Hutchinson, Roberts, Hemphill, Oldham, Potter, Carson, Gray, Wheeler, Deaf Smith, Randall, Armstrong, Donley, Collingsworth, Parmer, Castro, Swisher, Briscoe, Hall, Childress, Bailey, Lamb, Hale, Floyd, Motley, Cottle, Cochran, Hockely, Lubbock, Crosby, Dickens, King, Yoakum, Terry, Lynn, Garza, Kent, Stonewall, the States of New Mexico, Arizona, Utah, Colorado, Idaho, Montana, and Wyoming, and the following counties in California; San Bernardino, Riverside, San Diego, and Imperial.

Pursuant to section 1210.320(c) of the Plan, the Board shall review the seven districts every five years to determine whether realignment of the districts is necessary. When making a review, the Plan specifies that the Board should consider factors such as the most recent three years of USDA production reports or Board assessment reports if USDA production reports are unavailable, shifts and trends in quantities of watermelons produced, and any other relevant factors. Any realignment should be recommended by the Board at least six months prior to the date of the call for nominations and should become effective at least 30 days prior to this date.

Pursuant to section 1210.320 (e) of the Plan, the Secretary shall review importer representation every five years. According to the Plan, the Secretary shall review a three-year average of watermelon import assessments and adjust, to the extent practicable, the number of importers on the Board.

The Board appointed a subcommittee to begin reviewing the U.S. districts and to determine whether realignment was necessary based on production and assessment collections in the current districts. During the review, as prescribed by the Plan, the subcommittee reviewed USDA's Annual Crop Summary reports for 2007 through 2009, which provided figures for the top 17 watermelon producing states, and the Board's assessment collection records for 2007 through 2009. Both sets of data showed similar trends in production among the various States. However, the Board used the assessment reports because USDA's Annual Crop Summary reports were available for only 17 of the 34 states in which watermelons are produced.

The subcommittee recommended to the Board that the boundaries of all seven districts be changed in order to provide for a better distribution of production among producers and handlers in the districts.

The subcommittee also considered the assessments of watermelon imports paid to the Board. The Board's assessment records show imports for the years 2007, 2008, and 2009 at $681,565, $783,249, and $742,363 respectively. Based on this data, the three-year average annual imports for watermelon total $735,725 (2,207,177 divided by 3). The average annual percentage of assessments paid by importers represents almost 29 percent of the Board's assessment income. In contrast to the 2006 realignment, the importer's assessment collection represented 20 percent of the Board's assessment income. Because there was a 9 percent increase in the assessments on imports, the Board recommended an increase in the number of importers on the Board. USDA has evaluated information concerning importer assessments and has determined that the number of importer representatives on the Board should be increased by two members. Therefore, the number of importer Board members would increase from six to eight.

Section 1647 (3)(A) of the Act authorizes the Board to have at least one or more importer representative to serve on the Board. However, there is no section in the Plan that identifies the number of importers on the Board. Section 1210.502 is currently reserved and will be used to reflect importer representation on the Board.

The realignment was approved by the Board at its November 13, 2010, meeting. Under the realignment, each district would represent, on average, 16 percent of total U.S. production. The composition of the Board would increase to a total of 37 members: 14 producers, 14 handlers, 8 importers, and 1 public member.

Therefore, this rule realigns the districts as follows:

*District 1*—The Florida counties of Brevard, Broward, Charlotte, Collier, Dade, Desoto, Glades, Hardee, Hendry, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Sarasota, Seminole, St. Lucie, and Volusia.

*District 2*—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Citrus, Clay, Columbia, Dixie, Duval, Escambia, Flagler, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Hernando, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Marion, Nassau, Okaloosa, Putnam, Santa Rosa, St. Johns, Sumter, Suwannee, Taylor, Union, Wakulla, Walton, and Washington, and the States of North Carolina and South Carolina.

*District 3*—The State of Georgia.

*District 4*—The States of Alabama, Connecticut, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Virginia, Vermont, Wisconsin, West Virginia, and Washington, DC.

*District 5*—The State of California.

*District 6*—The State of Texas.

*District 7*—The States of Alaska, Arkansas, Arizona, Colorado, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, and Wyoming.

Under this realignment: (1) The Florida counties of Citrus, Flagler, Hernando, Marion, Putnam, St. Johns and Sumter are moved from District 1 to District 2; (2) Alabama, Tennessee, and Virginia are moved from District 2 to District 4; (3) Arkansas, Louisiana, Mississippi, and Oklahoma are moved from District 2 to District 7; (4) Georgia counties Early, Baker, Miller, Mitchell, Colquitt, Thomas, Grady, Decatur, and Seminole are moved from District 2 to District 3, (5) South Carolina moved from District 3 to District 2; (6) Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota are moved from District 4 to District 7; (7) Alaska, Hawaii, Nevada, Oregon, and Washington are moved from District 5 to District 7; (8) The following counties in the State of Texas: Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Cochran, Collingsworth, Cottle, Crosby, Dallam, Deaf Smith, Dickens, Donley, Floyd, Garza, Gray, Hale, Hall, Hanaford, Hartely, Hemphill, Hockely, Hutchinson, Kent, King, Lamb, Lipscomb, Lubbock, Lynn, Moore, Motley, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Stonewall, Swisher, Terry, Wheeler, and Yoakum are moved from District 7 to District 6; (9) the following counties in California: San Bernardino, Riverside, San Diego, and Imperial are moved from District 7 to District 5.

Due to the re-alignment of districts, the following vacancies are created: one producer vacancy in District 2; one handler vacancy in District 3, one producer vacancy in District 7; and two importer vacancies. Current Board members would be affected because their States or counties would be moved to other districts. Nomination meetings will be held as soon as possible in the new districts to fill the vacancies.

A 30-day comment period is provided to allow interested persons to respond to this proposal. Thirty days is deemed appropriate so that the proposed amendments, if adopted, may be implemented to allow for the calendar year 2012 nomination meetings to take place before the appointments for new Board members are due. All written comments received in response to this rule by the date specified would be considered prior to finalizing this action.

**List of Subjects in 7 CFR Part 1210**

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Reporting and recordkeeping requirements, Watermelon promotion.

For the reasons set forth in the preamble, Part 1210, Chapter XI of Title 7 is proposed to be amended as follows:

## PART 1210—WATERMELON RESEARCH AND PROMOTION PLAN

1. The authority citation for 7 CFR Part 1210 continues to read as follows:

**Authority:** 7 U.S.C. 4901–4916 and 7 U.S.C. 7401.

### Subpart C—Rules and Regulations

2. Section 1210.501 is revised to read as follows:

**§ 1210.501 Realignment of districts.**

Pursuant to § 1210.320(c) of the Plan, the districts shall be as follows:

*District 1*—The Florida counties of Brevard, Broward, Charlotte, Collier, Dade, Desoto, Glades, Hardee, Hendry, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Sarasota, Seminole, St. Lucie, and Volusia.

*District 2*—The Florida counties of Alachua, Baker, Bay, Bradford, Calhoun, Citrus, Clay, Columbia, Dixie, Duval, Escambia, Flagler, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Hernando, Holmes, Jackson, Jefferson, Lafayette, Leon, Levy, Liberty, Madison, Marion, Nassau, Okaloosa, Putnam, Santa Rosa, St. Johns, Sumter, Suwannee, Taylor, Union, Wakulla, Walton, and Washington, and the States of North Carolina and South Carolina.

*District 3*—The State of Georgia.

*District 4*—The States of Alabama, Connecticut, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Virginia, Vermont, Wisconsin, West Virginia, and Washington, DC.

*District 5*—The State of California.

*District 6*—The State of Texas.

*District 7*—The States of Alaska, Arkansas, Arizona, Colorado, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, and Wyoming.

3. Section 1210.502 is added to read as follows:

**§ 1210.502 Importer members.**

Pursuant to § 1210.320(d) of the Plan, there are eight importer representatives on the Board based on the proportionate percentage of assessments paid by importers to the Board.

Dated: April 28, 2011.

**David R. Shipman,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2011–11043 Filed 5–4–11; 8:45 am]

BILLING CODE 3410–02–P

## DEPARTMENT OF ENERGY

## 10 CFR Part 431

**[Docket No. EERE–2011–BT–STD–0029]**

**RIN 1904–AC47**

## Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards for Commercial Heating, Air-Conditioning, and Water-Heating Equipment

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Notice of data availability and request for public comment.

**SUMMARY:** The Energy Policy and Conservation Act of 1975 (EPCA), as amended, directs the U.S. Department of Energy (DOE) to establish energy conservation standards for certain commercial and industrial equipment, including commercial heating, air-conditioning, and water-heating products. Of particular relevance here, the statute also requires that each time the corresponding consensus standard—the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE)/Illuminating Engineering Society of North America (IESNA) Standard 90.1—is amended by the industry, DOE must assess whether there is a need to update the uniform national energy conservation standards for the same equipment covered under EPCA. ASHRAE officially released an amended version of this industry standard (ASHRAE 90.1–2010) on October 29, 2010, thereby triggering DOE's related obligations under EPCA. In addition, the Energy Independence and Security Act of 2007 (EISA 2007) amended EPCA to require DOE to review the most recently published ASHRAE/IES Standard 90.1 with respect to single-package vertical air conditioners and single-package vertical heat pumps in accordance with the procedures established for reviewing the energy conservation standards for other

ASHRAE products. As a first step in meeting these statutory requirements, today's notice of data availability (NODA) discusses the results of DOE's analysis of the energy savings potential of amended energy conservation standards for certain types of commercial equipment covered by ASHRAE Standard 90.1, including single-package vertical air conditioners and single-package vertical heat pumps. The energy savings potentials are based upon either the efficiency levels specified in the amended industry standard (*i.e.*, ASHRAE Standard 90.1–2010) or more stringent levels that would result in significant additional conservation of energy and are technologically feasible and economically justified. DOE is publishing this NODA to: Announce the results and preliminary conclusions of DOE's analysis of potential energy savings associated with amended standards for this equipment, and request public comment on this analysis, as well as the submission of data and other relevant information.

**DATES:** DOE will accept comments, data, and information regarding this NODA submitted no later than June 6, 2011. See section IV, "Public Participation," of this notice for details.

**ADDRESSES:** Any comments submitted must identify the NODA for ASHRAE Products and provide the docket number EERE–2011–BT–STD–0029 and/or Regulatory Information Number (RIN) 1904–AC47. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
2. *E-mail: ASHRAE90.1-2011-STD-0029@ee.doe.gov*. Include the Docket Number EERE–2011–BT–STD–0029 and/or RIN number 1904–AC47 in the subject line of the message.
3. *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.
4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section IV of this document (Public Participation).

*Docket:* The docket is available for review at *www.regulations.gov*, including **Federal Register** notices, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket web page can be found at: *www.regulations.gov*. The *www.regulations.gov* web page contains a link to the docket for this notice, along with simple instructions on how to access all documents, including public comments, in the docket. See section IV.A for further information on how to submit comments through *www.regulations.gov*.

For further information on how to submit a comment or review other public comments and the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov*.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mohammed Khan, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–7892. E-mail: *Mohammed.Khan@ee.doe.gov*.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, Mailstop GC–71, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–9507. E-mail: *Eric.Stas@hq.doe.gov*.

For information on how to submit or review public comments, contact Ms. Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–2945. E-mail: *Brenda.Edwards@ee.doe.gov*.

**SUPPLEMENTARY INFORMATION:**

## Table of Contents

I. Introduction
A. Authority
B. Purpose of the Notice of Data Availability
C. Background
1. ASHRAE Standard 90.1–2010
2. ASHRAE Standard 90.1 Proposed Addenda
D. Summary of DOE's Preliminary Assessment of Equipment for Energy-Savings Analysis
II. Discussion of Changes in ASHRAE Standard 90.1–2010
A. Commercial Warm-Air Furnaces
B. Commercial Package Air-Conditioning and Heating Equipment
1. Water-Cooled Equipment
2. Evaporatively-Cooled Equipment
3. Variable Refrigerant Flow Equipment
4. Packaged Terminal Air Conditioners and Heat Pumps
5. Small-Duct, High-Velocity, and Through-The-Wall Equipment
6. Single-Package Vertical Air Conditioners and Single-Package Vertical Heat Pumps
C. Air Conditioners and Condensing Units Serving Computer Rooms
D. Test Procedures
1. Updates to AHRI 210/240 Test Method
2. Updates to AHRI 340/360 Test Method
3. Updates to UL 727 Test Method
4. Updates to ANSI Z21.47 Test Method
5. Updates to ANSI Z21.10.3 Test Method
III. Analysis of Potential Energy Savings
A. Annual Energy Use
1. Water-Cooled Air Conditioners
2. Evaporatively-Cooled Air Conditioners
3. Single-Package Vertical Air Conditioners and Heat Pumps
B. Shipments
C. Other Analytical Inputs
1. Site-to-Source Conversion
2. Product Lifetime
3. Compliance Date and Analysis Period
D. Estimates of Potential Energy Savings
IV. Public Participation
A. Submission of Comments
B. Issues on Which DOE Seeks Comment
V. Approval of the Office of the Secretary

## I. Introduction

### *A. Authority*

Title III, Part C[1] of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6311–6317, as codified), added by Public Law 95–619, Title IV, § 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which includes the commercial heating, air-conditioning, and water-heating equipment that is the subject of this rulemaking.[2] In general, this program addresses the energy efficiency of certain types of commercial and industrial equipment. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labelling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information

[1] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

[2] All references to EPCA in this document refer to the statute as amended through the Energy Independence and Security Act of 2007, Public Law 110–140.

and reports from manufacturers (42 U.S.C. 6316).

In relevant part here, EPCA contains mandatory energy conservation standards for commercial heating, air-conditioning, and water-heating equipment. (42 U.S.C. 6313(a)) Specifically, the statute sets standards for small, large, and very large commercial package air-conditioning and heating equipment, packaged terminal air conditioners (PTACs) and packaged terminal heat pumps (PTHPs), warm-air furnaces, packaged boilers, storage water heaters, instantaneous water heaters, and unfired hot water storage tanks. *Id.* In doing so, EPCA established Federal energy conservation standards that generally correspond to the levels in ASHRAE Standard 90.1, *Energy Standard for Buildings Except Low-Rise Residential Buildings,* as in effect on October 24, 1992 (*i.e.,* ASHRAE Standard 90.1–1989), for each type of covered equipment listed in 42 U.S.C. 6313(a). EISA 2007 further amended EPCA by adding definitions and setting minimum standards for single-package vertical air conditioners (SPVACs) and single-package vertical heat pumps (SPVHPs). (42 U.S.C. 6313(a)(10)(A)) The standards for SPVACs and SPVHPs established by EISA 2007 corresponded to the levels contained in ASHRAE Standard 90.1–2004, which originated as addendum "d" to Standard 90.1–2001.

In acknowledgement of technological changes that yield energy efficiency benefits, Congress directed DOE through EPCA to consider amending the existing Federal energy efficiency standard for each type of equipment listed, each time ASHRAE Standard 90.1 is amended with respect to such equipment. (42 U.S.C. 6313(a)(6)(A)) For each type of equipment, EPCA directs that if ASHRAE Standard 90.1 is amended,[3] DOE must adopt amended standards at the new efficiency level in ASHRAE Standard 90.1, unless clear and convincing evidence supports a determination that adoption of a more stringent level as a national standard would produce significant additional energy savings and be technologically feasible and economically justified. (42 U.S.C. 6313(a)(6)(A)(ii)) If DOE decides to adopt as a national standard the minimum efficiency levels specified in the amended ASHRAE Standard 90.1, DOE must establish such standard not later than 18 months after publication of the amended industry standard. (42 U.S.C. 6313(a)(6)(A)(ii)(I)) However, if DOE determines that a more stringent standard is justified under 42 U.S.C. 6313(a)(6)(A)(ii)(II), then DOE must establish such more stringent standard not later than 30 months after publication of the amended ASHRAE Standard 90.1. (42 U.S.C. 6313(a)(6)(B))

Additionally, EISA 2007 amended EPCA to require that DOE review the most recently published ASHRAE/IES Standard 90.1 with respect to single-package vertical air conditioners and single-package vertical heat pumps in accordance with the procedures established for ASHRAE products under paragraph 42 U.S.C. 6313(a)(6). (42 U.S.C. 6313(a)(10)(B)) However, DOE believes that this requirement is separate and independent from the requirement described in the paragraph above for all ASHRAE products and that it requires DOE to evaluate potential standards higher than the ASHRAE Standard 90.1–2010 level for single-package vertical air conditioners and heat pumps, even if the efficiency levels for SPVACs and SPVHPs have not changed since the last version of ASHRAE Standard 90.1.

As a preliminary step in the process of reviewing the changes to ASHRAE Standard 90.1, EPCA directs DOE to publish in the **Federal Register** for public comment an analysis of the energy savings potential of amended energy efficiency standards, within 180 days after ASHRAE Standard 90.1 is amended with respect to any of the covered products specified under 42 U.S.C. 6313(a). (42 U.S.C. 6313(a)(6)(A))

On October 29, 2010, ASHRAE officially released for distribution and made public ASHRAE Standard 90.1–2010.[4] This action by ASHRAE triggered DOE's obligations under 42 U.S.C. 6313(a)(6), as outlined above. This NODA embodies the analysis of the energy savings potential of amended energy efficiency standards, as required under 42 U.S.C. 6313(a)(6)(A)(i). This NODA also addresses DOE's obligations under 42 U.S.C. 6313(a)(10)(B) to consider the most recently published ASHRAE/IES Standard 90.1 with respect to single-package vertical air conditioners and single-package vertical heat pumps in accordance with the procedures established for ASHRAE products under paragraph 42 U.S.C. 6313(a)(6).

*B. Purpose of the Notice of Data Availability*

As explained above, DOE is publishing today's NODA as a preliminary step pursuant to EPCA's requirements for DOE to consider amended energy conservation standards for certain types of commercial equipment covered by ASHRAE Standard 90.1, whenever ASHRAE amends its standard to increase the energy efficiency level for that equipment type. This NODA also addresses the requirements to consider amended energy conservation standards for SPVACs and SPVHPs under 42 U.S.C. 6313(a)(10)(B). Specifically, this NODA presents for public comment DOE's analysis of the potential energy savings estimates for amended national energy conservation standards for these types of commercial equipment based on: (1) The amended efficiency levels contained within ASHRAE Standard 90.1–2010,[5] and (2) more stringent efficiency levels. DOE describes these analyses and preliminary conclusions and seeks input from interested parties, including the submission of data and other relevant information.

DOE is not required by EPCA to review additional changes in ASHRAE Standard 90.1–2010 for those equipment types where ASHRAE did not increase the efficiency level. For those types of equipment for which efficiency levels clearly did not change, DOE has conducted no further analysis (with the exception of SPVACs and SPVHPs, for which EPCA requires DOE to review standard levels regardless of whether there was a change to ASHRAE Standard 90.1). However, for certain

[3] Although EPCA does not explicitly define the term "amended" in the context of ASHRAE Standard 90.1, DOE provided its interpretation of what would constitute an "amended standard" in a final rule published in the **Federal Register** on March 7, 2007 (hereafter referred to as the "March 2007 final rule"). 72 FR 10038. In that rule, DOE stated that the statutory trigger requiring DOE to adopt uniform national standards based on ASHRAE action is for ASHRAE to change a standard for any of the equipment listed in EPCA section 342(a)(6)(A)(i) (42 U.S.C. 6313(a)(6)(A)(i)) by increasing the energy efficiency level for that equipment type. *Id.* at 10042. In other words, if the revised ASHRAE Standard 90.1 leaves the standard level unchanged or lowers the standard, as compared to the level specified by the national standard adopted pursuant to EPCA, DOE does not have the authority to conduct a rulemaking to consider a higher standard for that equipment pursuant to 42 U.S.C. 6313(a)(6)(A). DOE subsequently reiterated this position in a final rule published in the **Federal Register** on July 22, 2009. 74 FR 36312, 36313.

[4] This industry standard is developed with input from a number of organizations—most prominently ASHRAE, the American National Standards Institute (ANSI), and the Illuminating Engineering Society of North America (IESNA). Therefore, this document may sometime be referred to more formally as ANSI/ASHRAE/IESNA Standard 90.1–2010. *See http://www.ashrae.org* for more information.

[5] For SPVACs and SPVHPs, ASHRAE Standard 90.1–2010 did not change the efficiency levels from the Federal standards, so DOE did not review ASHRAE Standard 90.1 levels for those equipment classes for that purpose, and only estimated potential energy savings for more stringent efficiency levels.

equipment classes of ASHRAE covered equipment, DOE found that while ASHRAE had made changes in ASHRAE Standard 90.1–2010, it was not immediately clear that the revisions to Standard 90.1 would increase the efficiency requirement in that Standard as compared to the existing Federal energy conservation standards. For example, for commercial warm-air furnaces, ASHRAE Standard 90.1–2010 changes the efficiency metric to thermal efficiency from combustion efficiency, which was the metric used in the previous version of ASHRAE Standard 90.1 (*i.e.,* ASHRAE Standard 90.1–2007). However, as discussed in section II.A of this NODA, the change does not result in an increase to the required efficiency, so DOE did not perform additional analysis for that equipment. Therefore, DOE carefully examined the changes for such products in ASHRAE Standard 90.1 in order to thoroughly evaluate the amendments in ASHRAE 90.1–2010, thereby permitting DOE to determine what action, if any, is required under its statutory mandate.

Section II of this notice contains a discussion of DOE's evaluation of each ASHRAE equipment type for which energy conservation standards have been set pursuant to EPCA ("covered equipment"), in order for DOE to determine whether the amendments in ASHRAE Standard 90.1–2010 have resulted in increased efficiency levels. For covered equipment types determined to have increased efficiency levels in ASHRAE Standard 90.1–2010, DOE subjected that equipment to further analysis as discussed in section III of this NODA.

In summary, the energy savings analysis presented in this NODA is a preliminary step required under 42 U.S.C. 6313(a)(6)(A)(i) and 6313(a)(10)(B). After review of the public comments on this NODA, if DOE determines that the amended efficiency levels in ASHRAE Standard 90.1–2010 have the potential for additional energy savings for types of equipment currently covered by uniform national standards, DOE will commence a rulemaking to consider amended standards, based upon either the efficiency levels in ASHRAE Standard 90.1–2010 or more-stringent efficiency levels which would be expected to result in significant additional conservation of energy and are technologically feasible and economically justified. In conducting such rulemaking, DOE will address the general rulemaking requirements for all energy conservation standards, such as the anti-backsliding provision [6] (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(1)), the criteria for making a determination that a standard is economically justified [7] (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(2)(B)(i)–(ii)), and the prohibition on making unavailable existing products with performance characteristics generally available in the U.S.[8] (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(4)).

[6] EPCA contains what is commonly known as an "anti-backsliding" provision. (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(1)) This provision mandates that the Secretary not prescribe any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of covered equipment.

[7] In deciding whether a more stringent standard is economically justified, DOE must review comments on the proposed standard, and then determine whether the benefits of the standard exceed its burdens by considering the following seven factors to the greatest extent practicable:

(1) The economic impact on manufacturers and consumers subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the product in the type (or class), compared to any increase in the price, initial charges, or maintenance expenses of the products likely to result from the standard;

(3) The total projected amount of energy savings likely to result directly from the standard;

(4) Any lessening of product utility or performance likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, likely to result from the standard;

(6) The need for national energy conservation; and

(7) Other factors the Secretary considers relevant.

(42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(2)(B)(i)–(ii)).

[8] The Secretary may not prescribe an amended standard if interested persons have established by a preponderance of evidence that the amended standard would likely result in unavailability in the U.S. of any covered product type or class of performance characteristics, such as reliability, features, capacities, sizes, and volumes that are substantially similar to those generally available in the U.S. at the time of the Secretary's finding. (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(4)).

*C. Background*

1. ASHRAE Standard 90.1–2010

As noted above, ASHRAE released a new version of ASHRAE Standard 90.1 on October 29, 2010. The ASHRAE standard addresses efficiency levels for many types of commercial heating, ventilating, air-conditioning (HVAC), and water-heating equipment covered by EPCA. ASHRAE Standard 90.1–2010 revised the efficiency levels for certain commercial equipment, but for the remaining equipment, ASHRAE left in place the preexisting levels (*i.e.* the efficiency levels specified in EPCA or the efficiency levels in ASHRAE Standard 90.1–2007).

Table I.1 below shows the equipment classes (and corresponding efficiency levels) where ASHRAE Standard 90.1–2010 efficiency levels differed from the previous version of ASHRAE Standard 90.1 (*i.e.,* ASHRAE Standard 90.1–2007), as well as the requirements for SPVAC and SPVHP equipment (which were unchanged in ASHRAE Standard 90.1–2010 but which nonetheless must be addressed in this rulemaking for the reasons discussed above). Table I.1 also displays the existing Federal energy conservation standards and the corresponding standard levels in the latest version of ASHRAE Standard 90.1 for those equipment classes. Section II of this document assesses each of these equipment types to determine whether the amendments in ASHRAE Standard 90.1–2010 constitute increased energy efficiency levels, as would necessitate further analysis of the potential energy savings from amended Federal energy conservation standards, the conclusions of which are presented in the final column of Table I.1.

TABLE I.1—FEDERAL ENERGY CONSERVATION STANDARDS AND ENERGY EFFICIENCY LEVELS IN ASHRAE STANDARD 90.1–2010 FOR SPECIFIC TYPES OF COMMERCIAL EQUIPMENT *

| ASHRAE equipment class ** | Energy efficiency levels in ASHRAE standard 90.1–2007 | Energy efficiency levels in ASHRAE standard 90.1–2010 | Federal energy conservation standards | Energy-savings potential analysis required? |
|---|---|---|---|---|
| **Commercial Warm-Air Furnaces** | | | | |
| Gas-Fired Commercial Warm-Air furnace. | $E_c$ = 80% Interrupted or intermittent ignition device, jacket losses not exceeding 0.75% of input rating, power vent or flue damper ***. | $E_t$ = 80% Interrupted or intermittent ignition device, jacket losses not exceeding 0.75% of input rating, power vent or flue damper ***. | $E_t$ = 80% | No. See section II.A. |
| **Commercial Package Air-Conditioning and Heating Equipment—Water-Cooled** | | | | |
| Water-cooled Air Conditioner, ≥65,000 and <135,000 Btu/h, Electric Resistance Heating or No Heating. | 11.5 EER | 12.1 EER (as of 6/1/11) | 11.5 EER | Yes. See section II.B.1. |
| Water-cooled Air Conditioner, ≥65,000 and <135,000 Btu/h, All Other Heating. | 11.3 EER | 11.9 EER (as of 6/1/11) | 11.3 EER | Yes. See section II.B.1. |
| Water-cooled Air Conditioner, ≥135,000 and <240,000 Btu/h, Electric Resistance Heating or No Heating. | 11.0 EER | 12.5 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.1. |
| Water-cooled Air Conditioner, ≥135,000 and <240,000 Btu/h, All Other Heating. | 10.8 EER | 12.3 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.1. |
| Water-cooled Air Conditioner, ≥240,000 Btu/h, Electric Resistance Heating or No Heating. | 11.0 EER | 12.4 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.1. |
| Water-cooled Air Conditioner, ≥240,000 Btu/h, All Other Heating. | 10.8 EER | 12.2 EER (as of 6/1/11) | 10.8 EER | Yes. See section II.B.1. |
| **Commercial Package Air-Conditioning and Heating Equipment—Evaporatively-Cooled** | | | | |
| Evaporatively-cooled Air Conditioner, ≥65,000 and <135,000 Btu/h, Electric Resistance Heating or No Heating. | 11.5 EER | 12.1 EER (as of 6/1/11) | 11.5 EER | Yes. See section II.B.2. |
| Evaporatively-cooled Air Conditioner, ≥65,000 and <135,000 Btu/h, All Other Heating. | 11.3 EER | 11.9 EER (as of 6/1/11) | 11.3 EER | Yes. See section II.B.2. |
| Evaporatively-cooled Air Conditioner, ≥135,000 and <240,000 Btu/h, Electric Resistance Heating or No Heating. | 11.0 EER | 12.0 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.2. |
| Evaporatively-cooled Air Conditioner, ≥135,000 and <240,000 Btu/h, All Other Heating. | 10.8 EER | 11.8 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.2. |
| Evaporatively-cooled Air Conditioner, ≥240,000 and <760,000 Btu/h, Electric Resistance Heating or No Heating. | 11.0 EER | 11.9 EER (as of 6/1/11) | 11.0 EER | Yes. See section II.B.2. |
| Evaporatively-cooled Air Conditioner, ≥240,000 and <760,000 Btu/h, All Other Heating. | 10.8 EER | 11.7 EER† (as of 6/1/11) | 10.8 EER | Yes. See section II.B.2. |
| **Commercial Package Air-Conditioning and Heating Equipment—VRF Systems††** | | | | |
| VRF Air Conditioners, Air-cooled, <65,000 Btu/h. | N/A | 13.0 SEER | 13.0 SEER | No. See section II.B.3. |
| VRF Air Conditioners, Air-cooled, ≥65,000 and <135,000 Btu/h, Electric Resistance or No Heating. | N/A | 11.2 EER | 11.2 EER | No. See section II.B.3. |
| VRF Air Conditioners, Air-cooled, ≥135,000 and <240,000 Btu/h, Electric Resistance or No Heating. | N/A | 11.0 EER | 11.0 EER | No. See section II.B.3. |

TABLE I.1—FEDERAL ENERGY CONSERVATION STANDARDS AND ENERGY EFFICIENCY LEVELS IN ASHRAE STANDARD 90.1–2010 FOR SPECIFIC TYPES OF COMMERCIAL EQUIPMENT *—Continued

| ASHRAE equipment class ** | Energy efficiency levels in ASHRAE standard 90.1–2007 | Energy efficiency levels in ASHRAE standard 90.1–2010 | Federal energy conservation standards | Energy-savings potential analysis required? |
|---|---|---|---|---|
| VRF Air Conditioners, Air-cooled, ≥240,000 Btu/h, Electric Resistance or No Heating. | N/A | 10.0 EER | 10.0 EER | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, <65,000 Btu/h. | N/A | 13.0 SEER, 7.7 HSPF | 13.0 SEER, 7.7 HSPF | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥65,000 and <135,000 Btu/h, without heat recovery, Electric Resistance or No Heating. | N/A | 11.0 EER, 3.3 COP | 11.0 EER, 3.3 COP | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥65,000 and <135,000 Btu/h, with heat recovery, Electric Resistance or No Heating. | N/A | 10.8 EER, 3.2 COP | 11.0 EER (electric resistance heating), 10.8 EER (no electric resistance heating)††† 3.3 COP. | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥135,000 and <240,000 Btu/h, without heat recovery, Electric Resistance or No Heating. | N/A | 10.6 EER, 3.2 COP | 10.6 EER, 3.2 COP | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥135,000 and <240,000 Btu/h, with heat recovery, Electric Resistance or No Heating. | N/A | 10.4 EER, 3.2 COP | 10.6 EER (electric resistance heating), 10.4 (no electric resistance heating)††† 3.2 COP. | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥240,000 Btu/h, without heat recovery, Electric Resistance or No Heating. | N/A | 9.5 EER, 3.2 COP | 9.5 EER, 3.2 COP | No. See section II.B.3. |
| VRF Heat Pumps, Air-cooled, ≥240,000 Btu/h, with heat recovery, Electric Resistance or No Heating. | N/A | 9.3 EER, 3.2 COP | 9.5 EER (electric resistance heating), 9.3 EER (no electric resistance heating)††† 3.2 COP. | No. See section II.B.3. |
| VRF Heat Pumps, Water-source, <65,000 Btu/h, without heat recovery. | N/A | 12.0 EER, 4.2 COP | 11.2 EER (<17,000 Btu/h)††, 12.0 EER (≥17,000 Btu/h and <65,000 Btu/h) 4.2 COP. | Yes◊◊◊ for <17,000 Btu. No for ≥17,000 Btu/h and <65,000 Btu/h. See section II.B.3. |
| VRF Heat Pumps, Water-source, <65,000 Btu/h, with heat recovery. | N/A | 11.8 EER, 4.2 COP | 11.2 EER (< 17,000 Btu/h)†† 12.0 EER (≥ 17,000 Btu/h and <65,000 Btu/h), 4.2 COP. | Yes◊◊◊ for <17,000 Btu, No for ≥17,000 Btu/h and <65,000 Btu/h, See section II.B.3, |
| VRF Heat Pumps, Water-source, ≥65,000 and <135,000 Btu/h, without heat recovery. | N/A | 12.0 EER, 4.2 COP | 12.0 EER, 4.2 COP | No. See section II.B.3. |
| VRF Heat Pumps, Water-source, ≥65,000 and <135,000 Btu/h, with heat recovery. | N/A | 11.8 EER, 4.2 COP | 12.0 EER, 4.2 COP | No. See section II.B.3. |
| VRF Heat Pumps, Water-source, ≥135,000 Btu/h, without heat recovery. | N/A | 10.0 EER, 3.9 COP | N/A | Yes◊◊◊. See section II.B.3. |
| VRF Heat Pumps, Water-source, ≥135,000 Btu/h, with heat recovery. | N/A | 9.8 EER, 3.9 COP | N/A | Yes◊◊◊. See section II.B.3. |
| **Commercial Package Air-Conditioning and Heating Equipment—PTACs and PTHPs‡‡** | | | | |
| Package Terminal Air Conditioner, <7,000 Btu/h, Standard Size (New Construction)‡‡. | EER = 11.0 | EER = 11.7 (as of 10/8/12). | EER = 11.7 | No. See section II.B.4. |
| Package Terminal Air Conditioner, ≥7,000 and <15,000 Btu/h, Standard Size (New Construction)‡‡‡. | EER = 12.5—(0.213 × Cap◊). | EER = 13.8—(0.300 × Cap◊) (as of 10/8/12). | EER = 13.8—(0.300 × Cap◊). | No. See section II.B.4. |
| Package Terminal Air Conditioner, >15,000 Btu/h, Standard Size (New Construction)‡‡‡. | EER = 9.3 | EER = 9.3 | EER = 9.3 | No. See section II.B.4. |
| Package Terminal Heat Pump, <7,000 Btu/h, Standard Size (New Construction)‡‡‡. | EER = 10.8, COP = 3.0 | EER = 11.9, COP = 3.3 (as of 10/8/12). | EER = 11.9, COP = 3.3 | No. See section II.B.4. |

TABLE I.1—FEDERAL ENERGY CONSERVATION STANDARDS AND ENERGY EFFICIENCY LEVELS IN ASHRAE STANDARD 90.1–2010 FOR SPECIFIC TYPES OF COMMERCIAL EQUIPMENT *—Continued

| ASHRAE equipment class ** | Energy efficiency levels in ASHRAE standard 90.1–2007 | Energy efficiency levels in ASHRAE standard 90.1–2010 | Federal energy conservation standards | Energy-savings potential analysis required? |
|---|---|---|---|---|
| Package Terminal Heat Pump, ≥7,000 and <15,000 Btu/h, Standard Size (New Construction)‡‡‡. | EER = 12.3—(0.213 × Cap◊), COP = 3.2—(0.026 × Cap◊). | EER = 14.0—(0.300 × Cap◊), COP = 3.7—(0.052 × Cap◊) (as of 10/8/12). | EER = 14.0—(0.300 × Cap◊), COP = 3.7—(0.052 × Cap◊). | No. See section II.B.4. |
| Package Terminal Heat Pump, >15,000 Btu/h, Standard Size (New Construction)‡‡‡. | EER = 9.1, COP = 2.8 ... | EER = 9.5, COP = 2.9 ... | EER = 9.5, COP = 2.9 ... | No. See section II.B.4. |
| **Commercial Package Air-Conditioning and Heating Equipment—SDHV and TTW** | | | | |
| Through-the-Wall, Air-cooled Heat Pumps, ≤30,000 Btu/h. | 12.0 SEER, 7.4 HSPF .... | 13.0 SEER, 7.4 HSPF .... | 13.0 SEER, 7.7 HSPF .... | No. See section II.B.5. |
| Small-Duct, High-Velocity, Air-cooled Heat Pumps, <65,000 Btu/h. | 10.0 SEER, 6.8 HSPF .... | N/A◊◊ ..... | 13.0 SEER, 7.7 HSPF .... | No. See section II.B.5. |
| **Commercial Package Air-Conditioning and Heating Equipment—SPVACs and SPVHPs** | | | | |
| Single-Packaged Vertical Air Conditioners, <65,000 Btu/h. | 9.0 EER ..... | 9.0 EER ..... | 9.0 EER ..... | Yes. See section II.B.6. |
| Single-Packaged Vertical Air Conditioners, ≥65,000 and <135,000 Btu/h. | 8.9 EER ..... | 8.9 EER ..... | 8.9 EER ..... | Yes. See section II.B.6. |
| Single-Packaged Vertical Air Conditioners, ≥65,000 and <240,000 Btu/h. | 8.6 EER ..... | 8.6 EER ..... | 8.6 EER ..... | Yes. See section II.B.6. |
| Single-Packaged Vertical Heat Pumps, <65,000 Btu/h. | 9.0 EER, 3.0 COP ..... | 9.0 EER, 3.0 COP ..... | 9.0 EER, 3.0 COP ..... | Yes. See section II.B.6. |
| Single-Packaged Vertical Heat Pumps, ≥65,000 and <135,000 Btu/h. | 8.9 EER, 3.0 COP ..... | 8.9 EER, 3.0 COP ..... | 8.9 EER, 3.0 COP ..... | Yes. See section II.B.6. |
| Single-Packaged Vertical Heat Pumps, ≥65,000 and <240,000 Btu/h. | 8.6 EER, 2.9 COP ..... | 8.6 EER, 2.9 COP ..... | 8.6 EER, 2.9 COP ..... | Yes. See section II.B.6. |
| **Air Conditioners and Condensing Units Serving Computer Rooms** | | | | |
| Air conditioners, air-cooled, <65,000 Btu/h. | N/A ..... | 2.20 SCOP (downflow), 2.09 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, air-cooled, ≥65,000 and <240,000 Btu/h. | N/A ..... | 2.10 SCOP (downflow), 1.99 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, air-cooled, ≥240,000 Btu/h. | N/A ..... | 1.90 SCOP (downflow), 1.79 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, water-cooled, <65,000 Btu/h. | N/A ..... | 2.60 SCOP (downflow), 2.49 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C |
| Air conditioners, water-cooled, ≥65,000 and <240,000 Btu/h. | N/A ..... | 2.50 SCOP (downflow), 2.39 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, water-cooled, ≥240,000 Btu/h. | N/A ..... | 2.40 SCOP (downflow), 2.29 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, water-cooled with fluid economizer, <65,000 Btu/h. | N/A ..... | 2.55 SCOP (downflow), 2.44 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, water-cooled with fluid economizer, ≥65,000 and <240,000 Btu/h. | N/A ..... | 2.45 SCOP (downflow), 2.34 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, water-cooled with fluid economizer, ≥240,000 Btu/h. | N/A ..... | 2.35 SCOP (downflow), 2.24 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, glycol-cooled, <65,000 Btu/h. | N/A ..... | 2.50 SCOP (downflow), 2.39 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, glycol-cooled, ≥65,000 and <240,000 Btu/h. | N/A ..... | 2.15 SCOP (downflow), 2.04 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, glycol-cooled, ≥240,000 Btu/h. | N/A ..... | 2.10 SCOP (downflow), 1.99 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |
| Air conditioners, glycol-cooled with fluid economizer, <65,000 Btu/h. | N/A ..... | 2.45 SCOP (downflow), 2.34 SCOP (upflow). | N/A ..... | Yes◊◊◊. See section II.C. |

TABLE I.1—FEDERAL ENERGY CONSERVATION STANDARDS AND ENERGY EFFICIENCY LEVELS IN ASHRAE STANDARD 90.1–2010 FOR SPECIFIC TYPES OF COMMERCIAL EQUIPMENT *—Continued

| ASHRAE equipment class ** | Energy efficiency levels in ASHRAE standard 90.1–2007 | Energy efficiency levels in ASHRAE standard 90.1–2010 | Federal energy conservation standards | Energy-savings potential analysis required? |
|---|---|---|---|---|
| Air conditioners, glycol-cooled with fluid economizer, ≥65,000 and <240,000 Btu/h. | N/A | 2.10 SCOP (downflow), 1.99 SCOP (upflow). | N/A | Yes◊◊◊. See section II.C. |
| Air conditioners, glycol-cooled with fluid economizer, ≥240,000 Btu/h. | N/A | 2.05 SCOP (downflow), 1.94 SCOP (upflow). | N/A | Yes◊◊◊. See section II.C. |

* "$E_c$" means combustion efficiency; "$E_t$" means thermal efficiency; "EER" means energy efficiency ratio; "SEER" means seasonal energy efficiency ratio; "HSPF" means heating seasonal performance factor; "COP" means coefficient of performance; "Btu/h" means British thermal units per hour; and "SCOP" means sensible coefficient of performance.

** ASHRAE Standard 90.1–2010 equipment classes may differ from the equipment classes defined in DOE's regulations, but no loss of coverage will occur (*i.e.,* all previously covered DOE equipment classes remained covered equipment).

*** A vent damper is an acceptable alternative to a flue damper for those furnaces that draw combustion air from conditioned space.

† ASHRAE Standard 90.1–2010 specifies this efficiency level as 12.2 EER. However, as explained in section II.B of this NODA, DOE believes this level was a mistake and that the correct level is 11.7 EER.

†† Variable Refrigerant Flow (VRF) systems are newly defined equipment classes in ASHRAE Standard 90.1–2010. As discussed in section II.B.3 of this NODA, DOE believes these systems are currently covered by Federal standards for commercial package air conditioning and heating equipment.

††† For these equipment classes, ASHRAE sets lower efficiency requirements for equipment with heat recovery systems. DOE believes systems with heat recovery and electric resistance heating would be required to meet the current Federal standard for equipment with electric resistance heating (*i.e.,* the Federal standard level shown in the table). However, for equipment with heat recovery and no electric resistance heating, DOE believes heat recovery would be an "other" heating type allowing for a 0.2 EER reduction in the Federal minimum requirement.

‡ The Federal energy conservation standards for this equipment class are specified differently for equipment with cooling capacity <17,000 Btu/h. However, ASHRAE Standard 90.1–2010 does not distinguish this equipment class.

‡‡ For equipment rated according to the DOE test procedure, all EER values must be rated at 95 °F outdoor dry-bulb temperature for air-cooled products and evaporatively-cooled products, and at 85 °F entering water temperature for water-cooled products. All COP values must be rated at 47 °F outdoor dry-bulb temperature for air-cooled products, and at 70 °F entering water temperature for water-source heat pumps.

‡‡‡ "Standard size" refers to PTAC or PTHP equipment with wall sleeve dimensions ≥16 inches high, or ≥42 inches wide.

◊ "Cap" means cooling capacity in kBtu/h at 95°F outdoor dry-bulb temperature.

◊◊ ASHRAE Standard 90.1–2010 includes an efficiency level of 10.0 SEER for these products. However, as explained in section II.B.5 of this NODA, DOE believes that ASHRAE did not intend to set an efficiency level for these products.

◊◊◊ An energy-savings analysis for this class of equipment was not conducted due to either a lack of data or because there is no equipment on the market that would fall into this equipment class.

2. ASHRAE Standard 90.1 Proposed Addenda

Since officially releasing ASHRAE Standard 90.1–2010 on October 29, 2010, ASHRAE has released three proposed addenda relevant to today's NODA: Proposed Addendum h, Proposed Addendum i, and Proposed Addendum j. ASHRAE released all three addenda for first public review in March 2011, and the 45-day public review period ends May 9, 2011. Proposed Addendum h would remove the small-duct high-velocity (SDHV) product class from one of the tables of standards and correct the minimum efficiencies for through-the-wall products. In addition, it would amend the minimum energy efficiency standards (and change the product class names) for water-to-air heat pumps, including some product classes regulated by DOE (*e.g.,* "water-source" would become "water-to-air: Water loop"), with a proposed effective date immediately upon publication of the addendum.[9] Proposed Addendum i would amend the minimum energy efficiency standards for SPVACs and SPVHPs. It would also add a new product class designed to address SPVACs and SPVHPs in space-constrained applications. These would become effective January 1, 2012. Proposed Addendum j would remove SDHV from both tables of standards in which it was listed, and would also correct the EER for one product class of evaporatively-cooled units, as discussed in section II.B.5.

Because these proposed addenda have not yet been approved, DOE is not obligated to address these changes until the addenda are formally adopted and ASHRAE issues the next version of Standard 90.1 (expected in 2013). However, DOE acknowledges that these proposed addenda may affect the market which is addressed in today's NODA. As a result, DOE seeks comments on what impact, if any, these proposed addenda might have, if adopted, on the national energy savings analysis presented in today's NODA. This is Issue 1 under "Issues on Which DOE Seeks Comment" in section IV.B of this NODA.

*D. Summary of DOE's Preliminary Assessment of Equipment for Energy-Savings Analysis*

DOE has reached a preliminary conclusion for each of the classes of commercial equipment in ASHRAE Standard 90.1–2010 addressed in today's NODA. For each class of commercial equipment addressed in this NODA, section II presents DOE's initial determination as to whether ASHRAE increased the efficiency level for a given type of product, a change which would require an energy-savings potential analysis. Since DOE is not required by EPCA to review additional changes in ASHRAE Standard 90.1–2010 for those equipment types where ASHRAE did not increase the efficiency level, DOE has conducted no further analysis for those types of equipment where efficiency levels clearly did not change. Additionally, for equipment where ASHRAE Standard 90.1–2010 has increased the level in comparison to the previous version of ASHRAE Standard 90.1, but does not exceed the current Federal standard level, DOE does not have the authority to conduct a rulemaking to consider a higher standard for that equipment pursuant to 42 U.S.C. 6313(a)(6)(A) and did not perform an potential energy savings analysis. For those equipment classes where ASHRAE increased the efficiency level (in comparison to the Federal standard), DOE performed an analysis of the energy-savings potential,

[9] Ground water source (water to air: ground water) and ground source (brine to air: Ground loop) heat pumps are not covered products.

unless DOE found no products in the market in that equipment class (in which case there is no potential for energy savings) or there was a significant lack of data and information available that would allow DOE to reasonably estimate the potential for energy savings.

Based upon DOE's analysis discussed in section II, DOE has determined that ASHRAE increased the efficiency level for the following equipment classes:

- Small, Large, and Very Large Water-cooled Air Conditioners;
- Small, Large, and Very Large Evaporatively-cooled Air Conditioners;
- Certain Small (only those with cooling capacity < 17,000 Btu/h) and Large Variable Refrigerant Flow Water-Source Heat Pumps; and
- Air Conditioners and Condensing Units Serving Computer Rooms.

Out of those equipment classes, when DOE found that equipment is available on the market and adequate information exists to reasonably estimate potential energy savings, DOE performed the analysis of the energy-savings potential which is described in section III. However, when DOE did not find equipment available on the market (such as for small variable refrigerant flow water-source heat pumps with capacities below 17,000 Btu/h), or found that adequate efficiency and/or shipments data was unavailable (such as for air conditioners and condensing units serving computer rooms), DOE did not perform a potential energy savings analysis.

In addition, although ASHRAE did not increase the efficiency level for SPVACs and SPVHPs, DOE is required by EPCA to consider amending the energy conservation standards for these equipment classes using the procedures set forth by 42 U.S.C. 6313(a)(6) for ASHRAE products. Accordingly, DOE also performed an energy-savings analysis for SPVACs and SPVHPs and presents the results in section III.

## II. Discussion of Changes in ASHRAE Standard 90.1–2010

Before beginning an analysis of the potential energy savings that would result from adopting the efficiency levels specified by ASHRAE Standard 90.1–2010 or more-stringent efficiency levels, DOE first determined whether or not the ASHRAE Standard 90.1–2010 efficiency levels actually represented an increase in efficiency above the current Federal standard levels, thereby triggering DOE action. This section contains a discussion of each equipment class where the ASHRAE Standard 90.1–2010 efficiency level differs from the current Federal standard level, along with DOE's preliminary conclusion regarding the appropriate action to take with respect to that equipment. In addition, this section contains a discussion of DOE's determination with regard to newly created equipment classes in ASHRAE Standard 90.1–2010 (*i.e.,* VRF commercial package air-conditioning and heating equipment and air conditioners serving computer rooms), and DOE's decisions with regard to the requirements for analyzing SPVACs and SPVHPs in EPCA. Finally, this section provides a brief discussion of the test procedure updates contained in ASHRAE Standard 90.1–2010.

### *A. Commercial Warm-Air Furnaces*

Under 42 U.S.C. 6311(11)(A), a "warm air furnace" is defined as "a self-contained oil- or gas-fired furnace designed to supply heated air through ducts to spaces that require it and includes combination warm air furnace/electric air-conditioning units but does not include unit heaters and duct furnaces." In its regulations, DOE defines a "commercial warm air furnace" as a "warm air furnace that is industrial equipment, and that has a capacity (rated maximum input) of 225,000 Btu per hour or more." 10 CFR 431.72.

Gas-fired commercial warm-air furnaces are fueled by either natural gas or propane. The Federal minimum energy conservation standard for commercial gas-fired warm-air furnaces corresponds to the efficiency level in ASHRAE Standard 90.1–1989, which specifies for equipment with a capacity of 225,000 Btu/h or more, the thermal efficiency at the maximum rated capacity (rated maximum input) must be no less than 80 percent. 10 CFR 431.77(a). The Federal minimum energy conservation standard for gas-fired commercial warm-air furnaces applies to equipment manufactured on or after January 1, 1994. 10 CFR 431.77.

The current Federal standard for gas-fired commercial warm-air furnaces is in terms of "thermal efficiency," which is defined as "100 percent minus percent flue loss." 10 CFR 431.72. The previous version of ASHRAE Standard 90.1 (*i.e.,* ASHRAE 90.1–2007) specified a minimum efficiency level of 80 percent combustion efficiency, but it defined "combustion efficiency" as "100 percent minus flue losses" in the footnote to the efficiency table for commercial warm-air gas-fired furnaces, which references ANSI Z21.47–2001, "Standard for Gas-Fired Central Furnaces," as the test procedure. In its analysis for the 2009 notice of proposed rulemaking (NOPR) regarding standards for ASHRAE Products in which DOE considered the updates in ASHRAE Standard 90.1–2007, DOE noted that upon reviewing the efficiency levels and methodology specified in ASHRAE Standard 90.1–2007, it concluded that ASHRAE changed the efficiency metric for gas-fired commercial warm-air furnaces in name only, and not in the actual test or calculation method. 74 FR 12000, 12008–09 (March 20, 2009). Therefore, DOE stated its understanding that despite using the term "combustion efficiency" rather than "thermal efficiency," ASHRAE did not intend to change the substance of the metric. Consequently, DOE left the existing Federal energy conservation standards in place for gas-fired commercial warm-air furnaces, which specify a "thermal efficiency" of 80 percent using the definition of "thermal efficiency" presented at 10 CFR 431.72.

ASHRAE Standard 90.1–2010 updated the tabulated requirements for gas-fired commercial warm-air furnaces to specify a minimum efficiency level of 80 percent "thermal efficiency" and references ANSI Z21.47–2006, "*Standard for Gas-Fired Central Furnaces,*" as the test procedure. ANSI Z21.47–2006 defines "thermal efficiency" as "100 percent minus flue losses," which is the same as DOE's definition of "thermal efficiency" for this equipment. Because of this, DOE believes that the purpose of the ASHRAE metric change to "thermal efficiency" was to clarify the alignment to the existing Federal standards and the ANSI Z21.47–2006 test procedure. As a result, DOE tentatively concluded that this change does not constitute a revision to the actual efficiency level for gas-fired commercial warm-air furnaces and that no further action by the Department is required.

### *B. Commercial Package Air-Conditioning and Heating Equipment*

EPCA, as amended, defines "commercial package air conditioning and heating equipment" as air-cooled, evaporatively-cooled, water-cooled, or water source (not including ground water source) electrically operated, unitary central air conditioners and central air conditioning heat pumps for commercial use. (42 U.S.C. 6311(8)(A); 10 CFR 431.92) EPCA also defines "small," "large," and "very large" commercial package air conditioning and heating equipment based on the equipment's rated cooling capacity. (42 U.S.C. 6311(8)(B)–(D); 10 CFR 431.92) "Small commercial package air conditioning and heating equipment" means equipment rated below 135,000 Btu per hour (cooling capacity). (42 U.S.C. 6311(8)(B); 10 CFR 431.92) "Large

commercial package air conditioning and heating equipment" means equipment rated—(i) at or above 135,000 Btu per hour; and (ii) below 240,000 Btu per hour (cooling capacity). (42 U.S.C. 6311(8)(C); 10 CFR 431.92) "Very large commercial package air conditioning and heating equipment" means equipment rated—(i) at or above 240,000 Btu per hour; and (ii) below 760,000 Btu per hour (cooling capacity). (42 U.S.C. 6311(8)(D); 10 CFR 431.92)

1. Water-Cooled Equipment

The current Federal energy conservation standards for the six classes of water-cooled commercial package air conditioners for which ASHRAE Standard 90.1–2010 amended efficiency levels are shown in Table I.1. The Federal energy conservation standards for water-cooled equipment are differentiated based on the cooling capacity (*i.e.,* small, large, or very large) and heating type (*i.e.,* electric resistance heating/no heating or some other type of heating). ASHRAE Standard 90.1–2010 increased the energy efficiency levels for all six equipment classes to efficiency levels that surpass the current Federal energy conservation standard levels. Therefore, the Department conducted an analysis of the potential energy savings due to amended standards for these products, which is described in section III of this NODA.

2. Evaporatively-Cooled Equipment

The current Federal energy conservation standards for the six classes of evaporatively-cooled commercial package air conditioners for which ASHRAE Standard 90.1–2010 amended efficiency levels are shown in Table I.1. Similar to water-cooled equipment, Federal energy conservation standards divide evaporatively-cooled equipment based on the cooling capacity (*i.e.,* small, large, or very large) and heating type (*i.e.,* electric resistance heating/no heating or some other type of heating). ASHRAE Standard 90.1–2010 increased the energy efficiency levels for all six equipment classes to efficiency levels that surpass the current Federal energy conservation standard levels.

DOE reviewed the market for evaporatively-cooled equipment and could not identify any models available on the market in the "small" unit product class (*i.e.,* cooling capacity < 135,000 Btu/h) and the "large" unit product class (*i.e.,* cooling capacity ≥ 135,000 and < 240,000 Btu/h). Because there is currently no equipment in these classes being manufactured, DOE believes there are no energy savings associated with these classes at this time; therefore, it is not possible to assess the potential for additional energy savings at the levels in ASHRAE Standard 90.1–2010 or more-stringent levels. Thus, DOE did not perform a potential energy-savings analysis for the small and large equipment classes of evaporatively-cooled commercial package air conditioners. DOE seeks comments from interested parties on its assessment of the market and energy savings potential for this equipment type. This is Issue 2 under "Issues on Which DOE Seeks Comment" in section IV.B of this NODA.

For very large (*i.e.,* cooling capacity ≥ 240,000 Btu/h) evaporatively-cooled air conditioners, DOE was able to identify a number of models on the market, and, therefore, DOE conducted an analysis of the potential energy savings for these products which is discussed in section III. For very large evaporatively-cooled air conditioners, ASHRAE Standard 90.1–2010 set the efficiency level for equipment with electric resistance or no heating at 11.9 EER and for equipment with all other heating at 12.2 EER. However, ASHRAE historically has set the levels for equipment with other heating at 0.2 EER points below the efficiency levels for equipment with electric heating or no heating, which would make the expected efficiency level for very large evaporatively-cooled equipment with other heating 11.7 EER. In February 2011, the Department received a letter from the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) indicating that the ASHRAE Standard 90.1–2010 efficiency level for very large evaporatively-cooled equipment with other heating is incorrect, and that the correct minimum energy efficiency standard for this category is 11.7 EER, as would be expected given the historical ASHRAE Standard 90.1 efficiency levels for these products. (AHRI, No. 0001 at p. 1) Further, AHRI indicated that at its winter 2011 meeting, the ASHRAE 90.1 committee approved an addendum for public review that corrects this error. In March 2011, ASHRAE released proposed Addendum j to ASHRAE Standard 90.1–2010, which corrects the value from 12.2 to 11.7 EER. Based on release of the public review draft of this addendum, the Department has tentatively decided to analyze the potential energy savings for this category at an ASHRAE Standard 90.1 level of 11.7 EER.

3. Variable Refrigerant Flow Equipment

ASHRAE 90.1–2010 created a separate product class for variable refrigerant flow (VRF) air-conditioning and heating equipment. These products are currently covered under DOE's standards for commercial air conditioners and heat pumps, but they are not broken out as a separate product class.

In general, a VRF system will have a single condensing unit serving multiple evaporator coils within a building. Specific "subclasses" of variable refrigerant flow heat pumps equipped with heat recovery capability have been specified in ASHRAE/IES Standard 90.1–2010 with lower efficiency requirements than specified for VRF systems without heat recovery. (Heat recovery capability provides for shuttling of heat from one part of the building to another and allows for simultaneous cooling and heating of different zones within a building.) Specifically, the efficiency requirements in ASHRAE Standard 90.1–2010 for air-cooled VRF heat pumps with heat recovery are equivalent to the Federal minimum energy conservation standards defined for air-cooled heat pumps with "all other heating system types that are integrated into the equipment," and the efficiency requirements for air-cooled VRF heat pumps without heat recovery are equivalent to the Federal minimum standards for air-cooled heat pumps with electric or no heating.[10] The VRF systems with heat recovery specified by ASHRAE may often have electric resistance heating systems, as a back-up. For air-cooled VRF heat pump systems that have both electric resistance heating and heat recovery heating capability, the Department has tentatively concluded that these systems must meet the efficiency requirements contained in EPCA for small, large, and very large air-cooled central air-conditioning heat pumps with electric resistance heating, which are codified at 10 CFR 431.97(b). (42 U.S.C. 6313(a)(7)–(9)) In addition, the Department has tentatively concluded that air-cooled VRF systems without electric resistance heating but with heat recovery can qualify as having an "other" means of heating and that these systems must meet the efficiency requirements contained in EPCA for small, large, and very large air-cooled central air-conditioning heat pumps with other heating, which are codified at 10 CFR 431.97(b). (42 U.S.C. 6313(a)(7)–(9))

Table II.1 shows the ASHRAE Standard 90.1–2010 efficiency levels for

[10] Section 136 of the Energy Policy Act of 2005 (EPACT 2005; Pub, L. 109–58) amended EPCA to include separate minimum efficiency requirements for commercial package air-cooled air conditioners and heating equipment with "all other heating system types that are integrated into the equipment" and with electric resistance or no heating.

VRF water-source heat pumps in comparison to the current Federal minimum energy conservation standards for water-source heat pumps, which DOE has preliminarily determined would apply to VRF systems. For water-source VRF heat pumps, ASHRAE Standard 90.1–2010 generally maintains the existing energy efficiency requirements that apply to commercial package air-conditioning and heating equipment for the VRF systems, with several notable exceptions. For VRF water-source heat pumps under 17,000 Btu/h and VRF water-source heat pumps over 135,000 Btu/h, ASHRAE Standard 90.1–2010 raises the efficiency levels above current Federal energy conservation standards (or in the case of water-source heat pumps over 135,000 Btu/h, ASHRAE sets standards for products where DOE did not previously have standards). As a result, the Department conducted further analysis for these classes. DOE began by reviewing the current market for VRF water-source heat pumps with cooling capacities below 17,000 Btu/h or above 135,000 Btu/h and less than 760,000 Btu/h. The Department did not identify any models under 17,000 Btu/h on the market. DOE did identify 19 models above 135,000 Btu/h on the market and attempted to contact the manufacturer producing most of these models, but DOE was unable to obtain EER information for most of the models and has no shipment information for this product class. Because DOE could not identify any VRF water-source heat pumps being manufactured with cooling capacities below 17,000 Btu/h, DOE believes that there are no energy savings associated with this equipment class. Therefore, DOE did not perform a potential energy-savings analysis for this equipment. In addition, due to the lack of available information and data on VRF water-source heat pumps with cooling capacities above 135,000 Btu/h at this time, the Department has not conducted a preliminary energy saving estimate for the additional energy savings beyond the levels anticipated in ASHRAE Standard 90.1–2010 for this VRF water source heat pump product class. DOE is requesting public comment regarding the market for this equipment and is seeking data and information that would allow it to accurately characterize the energy savings from amended energy conservation standards for these products. This is identified as Issue 3 in section IV.B "Issues on Which DOE Seeks Comment."

In addition to the changes for the two equipment classes discussed above, ASHRAE Standard 90.1–2010 includes efficiency levels for VRF water-source heat pumps that provide for a 0.2 EER reduction in the efficiency requirement for systems with heat recovery. However, the current Federal minimum standards for water-source heat pumps do not provide for any reduction in the EER requirements for equipment with "other" heating types. Therefore, the 0.2 EER reduction below the current Federal standard levels for the VRF water-source heat pump equipment classes in which ASHRAE did not raise the standard from the existing Federal minimum for water-source heat pumps (*i.e.,* water-source heat pumps with cooling capacities ≥17,000 and <65,000 Btu/h and ≥65,000 and <135,000 Btu/h) would result in a decrease in stringency in comparison to current standards. As noted in section I.A, if ASHRAE Standard 90.1 lowers its efficiency level as compared to the Federal minimum standard level, DOE does not have the authority to conduct a rulemaking to consider a higher standard for that equipment pursuant to 42 U.S.C. 6313(a)(6)(A). Therefore, DOE did not consider the lower EER requirements for systems with heat recovery and will not perform an analysis of those product classes.

TABLE II.1—COMPARISON OF FEDERAL ENERGY CONSERVATION STANDARDS FOR WATER-SOURCE HEAT PUMPS TO ASHRAE STANDARD 90.1–2010 REQUIREMENTS FOR VRF WATER-SOURCE HEAT PUMPS

| Existing Federal equipment class | Federal minimum energy conservation standard | ASHRAE Standard 90.1–2010 efficiency level for newly established VRF equipment class |
|---|---|---|
| Water-source Heat Pump < 17,000 Btu/h | 11.2 EER | 12.0 EER (without heat recovery). |
| | | 11.8 EER (with heat recovery). |
| | 4.2 COP | 4.2 COP. |
| Water-source Heat Pump ≥ 17,000 and < 65,000 Btu/h | 12.0 EER | 12.0 EER (without heat recovery). |
| | | 11.8 EER (with heat recovery). |
| | 4.2 COP | 4.2 COP. |
| Water-source Heat Pump ≥ 65,000 and < 135,000 Btu/h | 12.0 EER | 12.0 EER (without heat recovery). |
| | | 11.8 EER (with heat recovery). |
| | 4.2 COP | 4.2 COP. |
| Water-source Heat Pump ≥ 135,000 and < 760,000 Btu/h | N/A | 10.0 EER (without heat recovery). |
| | | 9.8 EER (with heat recovery). |
| | | 3.9 COP. |

4. Packaged Terminal Air Conditioners and Heat Pumps

EPCA defines a "packaged terminal air conditioner" as "a wall sleeve and a separate unencased combination of heating and cooling assemblies specified by the builder and intended for mounting through the wall. It includes a prime source of refrigeration, separable outdoor louvers, forced ventilation, and heating availability by builder's choice of hot water, steam, or electricity." (42 U.S.C. 6311(10)(A)) EPCA defines a "packaged terminal heat pump" as "a packaged terminal air conditioner that utilizes reverse cycle refrigeration as its prime heat source and should have supplementary heat source available to builders with the choice of hot water, steam, or electric resistant heat." (42 U.S.C. 6311(10)(B)) DOE codified these definitions in 10 CFR 431.92 in a final rule published in the **Federal Register** on October 21, 2004. 69 FR 61962, 61970.

DOE adopted amended energy conservation standards for this class of equipment in a final rule published in the **Federal Register** on October 7, 2008. 73 FR 58772, 58828–30. The adopted Federal standards exceeded the standards in ASHRAE Standard 90.1–2007. These Federal standards apply to standard size equipment manufactured on or after October 7, 2012, and non-standard size equipment manufactured on or after October 8, 2010. ASHRAE Standard 90.1–2010 increased the efficiency levels for standard size equipment in comparison to the efficiency levels in ASHRAE Standard 90.1–2007. However, the efficiency levels specified by ASHRAE Standard 90.1–2010 for these equipment classes

meet and do not exceed the Federal standards established by DOE in the October 2008 final rule. Because ASHRAE seems to be harmonizing the levels in ASHRAE Standard 90.1–2010 with the Federal levels rather than increasing the minimum efficiency, DOE has tentatively concluded that it is not required to take action on these products at this time.

5. Small-Duct, High-Velocity, and Through-The-Wall Equipment

EPCA does not separate small-duct high-velocity (SDHV) or through-the-wall (TTW) heat pumps from other types of small commercial package air-conditioning and heating equipment in its definitions. (42 U.S.C. 6311(8)) Therefore, EPCA's definition of "small commercial package air conditioning and heating equipment" would include SDHV and TTW heat pumps.

ASHRAE Standard 90.1–2010 increased some of the efficiency levels for these classes of equipment. Specifically, ASHRAE Standard 90.1–2010 increased the efficiency requirements for TTW heat pumps to 13.0 SEER and 7.4 HSPF in comparison to the efficiency levels of 12.0 SEER and 7.4 HSPF in ASHRAE Standard 90.1–2007. However, in March 2011, ASHRAE issued Proposed Addendum h for public review that would correct the minimum SEER for these products to 12.0 SEER. For SDHV heat pumps, ASHRAE Standard 90.1–2010 did not increase the cooling efficiency requirement of 10.0 SEER beyond that in ASHRAE 90.1–2007. In addition, although ASHRAE 90.1–2007 specified a heating efficiency requirement of 6.8 HSPF, ASHRAE 90.1–2010 did not specify any heating efficiency level for SDHV heat pumps. However, Proposed Addenda h and j would remove the SDHV product class from the standards tables entirely, stating: "In addition the small duct high velocity requirements have been dropped by DOE and they are only allowing such systems under waiver clause so the addendum has also made a change to remove the small duct high velocity systems from table 6.8.1a and table 6.8.1b." Therefore, DOE believes that ASHRAE did not intend to specify any efficiency levels for these products in ASHRAE Standard 90.1–2010.

The DOE standards for both TTW and SDHV heat pumps, which are 13.0 SEER and 7.7 HSPF, were established for the overall equipment category of small commercial package air-conditioning and heating equipment by EISA 2007, which amended EPCA. (42 U.S.C. 6313(a)(7)(D)) Because the ASHRAE Standard 90.1–2010 efficiency levels for TTW equipment meet or do not exceed the DOE standards and because DOE believes that SDHV are no longer meant to be covered separately by ASHRAE Standard 90.1–2010, DOE has tentatively concluded that it is not required to take action on these products at this time.

6. Single-Package Vertical Air Conditioners and Single-Package Vertical Heat Pumps

DOE issued standards for single-package vertical air conditioner and heat pump units (SPVUs) as part of the March 23, 2009 final rule technical amendment in response to mandated efficiency levels for SPVUs established in the EISA 2007 legislation. 74 FR 12058. However, SPVUs are subject to a unique "look back" provision established by EISA 2007, which amended the applicable provisions of EPCA such that not later than three years after the date of this statutory provision's enactment (*i.e.,* December 19, 2007), the Secretary must review the most recently published ASHRAE/IES Standard 90.1 with respect to single-package vertical air conditioners and single-package vertical heat pumps using the procedures established under 42 U.S.C. 6313(a)(6). (42 U.S.C. 6313(a)(10)(B))

As noted in section I.A, the Department interprets the provision at 42 U.S.C. 6313(a)(10)(B) as constituting a separate trigger to evaluate standards higher than the ASHRAE Standard 90.1 level. SPVUs are considered classes within the broader scope of small and large commercial package air-conditioning and heating equipment; however, because of their special status (*i.e.,* that the efficiency levels for this equipment were statutorily prescribed by EISA 2007), Congress intended that DOE review them for potential energy savings and higher standards along the lines of the 18 month time frame review for other products (*i.e.,* do everything in part (6) with regard to analysis, but ignore the triggering requirement of ASHRAE Standard 90.1 changing its efficiency levels). EPCA, as amended, directs DOE to conduct a review of the energy savings potential sometime in the three-year interval, and DOE believes this separate trigger is a one-time mechanism, after which SPVUs revert to the normal "ASHRAE trigger." Accordingly, DOE has commenced analytical work on these products along with the other equipment which is subject to the current "ASHRAE trigger."

Upon review of the SPVU market, DOE identified several models of SPVUs in the small equipment class. However, DOE did not identify any models of SPVUs in the very large category or any models of SPVHPs in the large category. The Department identified only five models of SPVACs in the large category, and these were all close to the upper size limit of the small category, at 70,000 Btu/h or less. As a result of the apparent lack of a market for very large SPVUs and large SPVHPs, and a lack of shipment estimates for the large SPVACs, DOE conducted complete preliminary energy saving estimates for only the small equipment classes. Additionally, DOE used the energy saving results for small SPVACs to derive an estimate of the potential energy savings for large SPVACs. DOE requests comments regarding the market for SPVUs, specifically on the market for large and very large equipment. This is identified as Issue 4 in section IV.B "Issues on Which DOE Seeks Comment."

*C. Air Conditioners and Condensing Units Serving Computer Rooms*

Air conditioners and condensing units serving computer rooms operate similarly to other types of commercial packaged air conditioners in that they provide space conditioning using a refrigeration cycle consisting of a compressor, condenser, expansion valve, and evaporator. However, air conditioners and condensing units serving computer rooms are typically designed to maintain the temperature in the conditioned space at 72 degrees Fahrenheit, and maintain a specific relative humidity. This equipment is commonly capable of humidifying or dehumidifying the air and then, if necessary, reheating it to maintain a specific humidity.

ASHRAE Standard 90.1–2010 created a separate product class for "air conditioners and condensing units serving computer rooms," and set efficiency levels using the sensible coefficient of performance (SCOP) metric as measured using the test method in ASHRAE Standard 127–2007, "Method of Testing for Rating Computer and Data Processing Room Unitary Air Conditioners." The product classes and efficiency levels established in ASHRAE Standard 90.1–2010 are shown in Table I.1 above.

Prior to this equipment having separate efficiency levels and test procedures specified in ASHRAE Standard 90.1, DOE discussed such units using the terminology "computer room air conditioners" in an August 9, 2000 NOPR (65 FR 48828, 48830–31) and an October 21, 2004 direct final rule (69 FR 61962, 61967). In the August 2000 NOPR, DOE determined that computer room air conditioners were not covered as part of the commercial

packaged air conditioning and heating equipment classes in EPCA and subsequently upheld this position in the October 2004 final rule. DOE made this determination because at the time of passage of the Energy Policy Act of 1992 (EPACT 1992, Pub. L. 102–486, which gave DOE the authority to cover commercial package air-conditioning and heating equipment), the statute excluded this equipment, and as a result, DOE concluded that it lacked the authority to regulate this equipment. The basis for DOE's decision stemmed from the scope of ASHRAE Standard 90.1, which at the time specified that the standard did not cover "equipment and portions of building systems that use energy primarily to provide for industrial, manufacturing, or commercial processes." (See section 2.3.c. of ASHRAE 90.1 standards prior to ASHRAE Standard 90.1–2010). Further, the House Report on EPACT 1992 (H.R. Rep. No. 474, 102d Cong., 2d Sess., pt. 1 at 175 (1992)) pointed out that the efficiency standards contained in the bill were developed by ASHRAE in ASHRAE Standard 90.1. DOE concluded that this indicated that the efficiency standards for commercial products in EPACT 1992 would have the same scope as the version of ASHRAE Standard 90.1 current at the time of the legislation's enactment, which did not cover computer room air conditioners. As a result, DOE concluded at the time that it did not have the authority to cover computer room air conditioners. However, DOE stated in both the NOPR and final rule that "if some of the relevant circumstances were to change—if, for example, ASHRAE Standard 90.1 were to incorporate efficiency standards and test procedures for this equipment or the equipment was to become widely used for conventional air conditioning applications—the Department might revisit this issue." 65 FR 48828, 48831 (August 9, 2000); 69 FR 61962, 61967 (Oct. 21, 2004).

ASHRAE Standard 90.1–2010 expanded the scope from previous versions of ASHRAE Standard 90.1 to include process loads (*e.g.,* computer rooms) and created a separate product class for "air conditioners and condensing units serving computer rooms." EPCA generally directs DOE to follow ASHRAE Standard 90.1 when it is amended with respect to certain equipment types, including commercial package air conditioning and heating equipment. Thus, DOE has tentatively concluded that because ASHRAE has expanded the scope of Standard 90.1 to include air conditioners and condensing units serving computer rooms, the scope of DOE's requirements with regard to ASHRAE products in EPCA is also expanded to encompass these products. As such, DOE has tentatively concluded it has the authority to review the ASHRAE Standard 90.1–2010 efficiency levels for air conditioners and condensing units serving computer rooms and to establish minimum energy conservation standard levels for this equipment. DOE seeks comment on how best to establish minimum energy conservation standards for air conditioners and condensing units serving computer rooms. This is identified as Issue 5 in section IV.B, "Issues on Which DOE Seeks Comment."

Although DOE has tentatively concluded that it has the authority to consider adopting minimum efficiency standards for air conditioners and condensing units serving computer rooms at or above the ASHRAE Standard 90.1–2010 efficiency levels, DOE did not perform a potential energy savings analysis for these products as a part of this NODA due to the lack of available data. The State of California requires manufacturers of computer room air conditioners to certify the EER of their computer room air conditioning equipment (20 CCR 1605.3(c)(2)),[11] and DOE examined the information in the California Energy Commission (CEC) appliance database [12] for computer room air conditioners. The CEC database contained over 300 models, indicating that there is a potentially significant market for computer room air conditioners. However, the database only contains efficiency information in the form of EER, and manufacturers currently do not report SCOP in the CEC database or in their literature. Because the efficiency levels in ASHRAE Standard 90.1–2010 are in SCOP, the EER efficiency information is of little use to DOE in analyzing the potential energy savings of the SCOP efficiency levels in ASHRAE Standard 90.1–2010. Since these equipment classes of air conditioners and condensing units serving computer rooms and the SCOP metric specified by ASHRAE Standard 90.1–2010 are newly-defined requirements, DOE was unable to obtain reliable efficiency data for the majority of models or shipments data that would allow DOE to characterize the energy savings potential of this equipment in a reasonably accurate manner. DOE is requesting data and information from interested parties regarding air conditioners and condensing units serving computer rooms that could be used in performing an energy savings analysis at a future stage of this rulemaking (*e.g.,* SCOP efficiency ratings, shipments information). This is identified as Issue 6 under section IV.B "Issues on Which DOE Seeks Comment."

Lastly, although DOE addressed computer room air conditioners in the August 2000 NOPR and October 2004 direct final rule, DOE never formally defined this equipment. In reviewing ASHRAE Standard 90.1–2010, DOE noted that ASHRAE does not define a class of equipment but rather an application (*i.e.,* "serving computer rooms"). Because air conditioners and condensing units serving computer have the same basic components as conventional air conditioners, there is some difficulty in defining air conditioners and condensing units serving computer rooms such that they can be clearly differentiated from conventional commercial packaged air conditioners and heat pumps. DOE reviewed the definitions in both ASHRAE 127–2007 (the test procedure specified in ASHRAE Standard 90.1–2010 for air conditioners and condensing units serving computer rooms) and Title 20 in the California Code of Regulations (which establishes California's requirements for this equipment), and found that the definitions in each do not contain criteria that would allow DOE to clearly differentiate these equipment from conventional equipment, without overlap between the types of equipment. DOE seeks comment on approaches for developing appropriate definitions for this equipment that would not result in overlap between "air conditioners and condensing units serving computer rooms" and the other types of commercial packaged air-conditioning and heating equipment covered by EPCA. This is identified as Issue 7 in section IV.B under "Issues for Which DOE Seeks Comment."

*D. Test Procedures*

EPCA requires the Secretary to amend the test procedures for ASHRAE products to the latest version generally accepted by industry or the rating procedures developed or recognized by AHRI or by ASHRAE, as referenced by ASHRAE/IES Standard 90.1, unless the Secretary determines by clear and convincing evidence that the latest version of the industry test procedure does not meet the requirements for test

[11] For more information *see* California Code of Regulations. Title 20, Public Utilities and Energy, Division 2, State Energy Resources Conservation and Development Commission (August 2008) (Available at: *http://www.energy.ca.gov/2008publications/CEC–140–2008–001/CEC–140–2008–001–REV1.PDF*).

[12] The CEC Appliance Efficiency Database is available at: *http://www.appliances.energy.ca.gov/.*

procedures described in paragraphs (2) and (3) of 42 U.S.C. 6314(a).[13] (42 U.S.C. 6314(a)(4)(B)) ASHRAE Standard 90.1–2010 updated several of its test procedures for ASHRAE products. Specifically, ASHRAE Standard 90.1–2010 updated to the most recent editions of test procedures for small commercial package air conditioners and heating equipment (AHRI 210/240–2008, *Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment*), large and very large commercial package air conditioners and heating equipment (AHRI 340/360–2007, *Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment*), commercial warm-air furnaces (UL 727–2006, *Standard for Safety for Oil-Fired Central Furnaces,* and ANSI Z21.47–2006, *Standard for Gas-Fired Central Furnaces*), and commercial water heaters (ANSI Z21.10.3–2006, *Gas Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous*). Additionally, ASHRAE Standard 90.1–2010 adopts new test procedures for measuring the efficiency of variable refrigerant flow equipment (AHRI 1230–2010, *Performance Rating of Variable Refrigerant Flow (VRF) Multi-Split Air-Conditioning and Heat Pump Equipment*) and air conditioners and condensing units serving computer rooms (ASHRAE 127–2007, *Method of Testing for Rating Computer and Data Processing Room Unitary Air Conditioners*). Lastly, ASHRAE Standard 90.1–2010 specifies ARI 390–2003, *Performance Rating of Single Packaged Vertical Air-Conditioners and Heat Pumps,* as the test procedure for SPVACs and SPVHPs.

DOE has preliminarily reviewed each of the test procedures that were updated in ASHRAE Standard 90.1–2010 and discusses the changes to the test procedures below. For the newly established test procedures AHRI 1230 and ASHRAE 127, DOE is in the process of assessing the appropriateness of these test methods with respect to the requirements for test procedures specified by EPCA pursuant to 42 U.S.C. 6314(a)(4)(B), and will provide a preliminary determination regarding those test procedures in the notice of proposed rulemaking (NOPR) that will follow this NODA. EISA 2007 established separate equipment classes and efficiency levels for SPVACs and SPVHPs, but the statute did not specify test procedures for this equipment. As a result, DOE is also considering the test procedure for SPVACs and SPVHPs in ASHRAE Standard 90.1–2010 (*i.e.,* AHRI 390) pursuant to the requirements in 42 U.S.C. 6314(a)(4)(B), and will provide a preliminary determination regarding that test procedure in the NOPR as well. DOE seeks comment on the appropriateness of AHRI 1230, ASHRAE 127, and AHRI 390 as the test method for VRF equipment, air conditioners and condensing units serving computer rooms, and SPVACs and SPVHPs, respectively. This is identified as Issue 8 in section IV.B, "Issues on Which DOE Seeks Comment."

1. Updates to AHRI 210/240 Test Method

In 2008, AHRI updated AHRI 210/240, *Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment,* which is incorporated by reference as the DOE test procedure for commercial small air conditioners and air-source heat pumps with a cooling capacity below 65,000 Btu/h at 10 CFR 431.95. AHRI made numerous reorganizational and additive changes to this standard from the version currently incorporated by reference in DOE's test procedures for commercial air conditioners and heat pumps (*i.e.,* AHRI 210/240–2003).

The AHRI 210/240–2008 test procedure references and includes as Appendix C the DOE test procedure for residential central air conditioners and heat pumps at 10 CFR part 430, subpart B, Appendix M. In section 3 of AHRI 210/240–2008, *Definitions,* AHRI changed the definitions of heating seasonal performance factor (HSPF) and seasonal energy efficiency ratio (SEER) to match the definitions for those terms that are contained in the test procedure for residential central air conditioners and heat pumps (which consequently are also contained in Appendix C of AHRI 210/240–2008). Also, AHRI added definitions for tested combination for multiple-split air conditioners and heat pumps, small-duct, high-velocity systems, space-constrained products, and through-the-wall air conditioners and heat pumps that match DOE's definitions at 10 CFR 430.2.

In section 6, *Rating Requirements,* AHRI updated the tables that specify the standard rating conditions specified for equipment covered by the standard. AHRI reorganized the existing tables for air conditioners and heat pumps, and it created several new tables listing the standard rating conditions for equipment with variable air volume fans, two-stage compressors, or variable-speed compressors. AHRI also added a minimum external static pressure requirement for small-duct, high-velocity systems. In addition to updating the tables and tests in section 6, AHRI also reorganized section 6.1.3.3, *Indoor-Coil Airflow Rate,* and added a new section 6.1.4, *Conditions for Standard Rating Tests* (which is the section where tables discussed above are located).

The updates made to AHRI 210/240–2008 from the 2003 version of the standard were identical to updates made by DOE to its test procedure for residential central air conditioners and heat pumps at 10 CFR part 430, subpart B, Appendix M. The updates discussed in the preceding paragraph were described in detail and previously were evaluated by DOE in two test procedure final rules for residential central air conditioners and heat pumps, published in the **Federal Register** on October 11, 2005 and October 22, 2007. 70 FR 59122; 72 FR 59906. In each of those test procedure amendments, DOE concluded that the changes did not have a significant impact on product efficiency as measured by the test procedure that would cause DOE to revise its existing energy conservation standards. 70 FR 59122, 51932 (Oct. 11, 2005); 72 FR 59906, 59917–18 (Oct. 22, 2007). Because the major changes to AHRI 210/240 have already been approved for the residential central air conditioner and heat pump test procedure and because DOE previously concluded that those changes do not impact the efficiency of residential units, DOE believes that the changes also do not impact the energy efficiency measurements for small commercial air conditioners and heat pumps with a cooling capacity less than 65,000 Btu/h (the ASHRAE equipment for which AHRI 210/240–2008 applies). DOE seeks comments on this tentative conclusion. This is identified as Issue 9 in section IV.B, "Issues on Which DOE Seeks Comment."

2. Updates to AHRI 340/360 Test Method

In 2007, AHRI updated AHRI 340/360, *Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump*

[13] Specifically, the relevant provisions (42 U.S.C. 6314(a)(2)–(3)) provide that test procedures must be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs of a type (or class) of industrial equipment during a representative average use cycle, and must not be unduly burdensome to conduct. Moreover, if the test procedure is for determining estimated annual operating costs, it must provide that such costs will be calculated from measurements of energy use in a representative average-use cycle, and from representative average unit costs of the energy needed to operate the equipment during such cycle. The Secretary must provide information to manufacturers of covered equipment regarding representative average unit costs of energy.

*Equipment.* The primary purpose of the update was to change the part-load rating metric from integrated part-load value (IPLV) to integrated energy efficiency ratio (IEER). AHRI also expanded the scope of the test procedure to include air-cooled packaged unitary air-conditioners with a cooling capacity from 250,000 Btu/h to less than 760,000 Btu/h in addition to equipment that was included in the scope of the previous AHRI 340/360 standard (which covered air-cooled, water-cooled, and evaporatively-cooled unitary air-conditioning, air-source unitary heat pump equipment, and air-conditioning condensing units rated at or above 65,000 Btu/h but below 250,000 Btu/h). AHRI also added a tolerance criterion for the minimum external static pressure test (from −0.0 in $H_2O$ to +0.05 in $H_2O$). Since DOE does not regulate or require manufacturers to certify part-load ratings, the change from IPLV to IEER does not affect the Federal energy conservation standards. Also, DOE believes that the added tolerance criterion does not significantly impact the measure of energy efficiency. DOE seeks comments on its preliminary determination that the changes to AHRI 340/360–2007 do not significantly impact energy efficiency ratings. This is identified as Issue 9 in section IV.B, "Issues on Which DOE Seeks Comment."

3. Updates to UL 727 Test Method

In 2006, Underwriters Laboratories (UL) updated its standard UL 727, *Standard for Safety for Oil-Fired Central Furnaces.* DOE's test procedure for measuring the energy efficiency of commercial warm-air furnaces at 10 CFR 431.76 only references the procedures pertinent to the measurement of the steady-state efficiency for this equipment in UL 727 (*i.e.,* the measurements described in sections 1 through 3, 37 through 42 (but not 40.4 and 40.6.2 through 40.6.7), 43.2, 44, 45, and 46 of UL 727). Therefore, when reviewing the test procedure, DOE only looked at the changes to these sections. Most of the changes to UL 727 were to reorganize the document and convert it to the Standard Generalized Markup Language (SGML) [14] as a way of keeping the data consistent, reusable, shareable, and portable. In addition, UL removed a section from the scope that allowed a manufacturer to propose appropriate revisions to requirements of UL 727 if the product's new features, components, materials, or systems are unsafe to be tested with the UL 727 Standard, provided that the new revisions conforms to the intent of the Standard. DOE believes that these changes to UL 727–2006 do not significantly impact the energy efficiency ratings and seeks comments as to its tentative conclusion. This is identified as Issue 9 in section IV.B, "Issues on Which DOE Seeks Comment."

4. Updates to ANSI Z21.47 Test Method

In 2006, the American National Standards Institute (ANSI) updated ANSI Z21.47, *Standard for Gas-Fired Central Furnaces.* DOE's test procedure for measuring the energy efficiency of gas-fired warm air furnaces at 10 CFR 431.76 only references the procedures contained in ANSI Z21.47 that are relevant to the steady-state efficiency measurement (*i.e.,* sections 1.1, 2.1 through 2.6, 2.38, and 4.2.1 of ANSI Z21.47). As a result, DOE focused its test procedure review on the relevant sections of ANSI Z21.47 that DOE's test procedure references. In those sections referenced by DOE's test procedures, ANSI made several updates. First, ANSI updated the scope section to include optional special construction provisions for furnaces designed to operate at altitudes over 2000 feet. ANSI also added an entirely new section for a Proved Igniter and renumbered the other sections to accommodate this addition. The newly added section does not fall under the procedures relevant for steady-state efficiency measurement; however, it does cause the Thermal Efficiency section (which is relevant for the steady-state efficiency measurement) to move from section 2.38 to section 2.39 of the test procedure. DOE preliminarily determined that these changes to ANSI Z21.47–2006 do not impact the energy efficiency ratings for gas-fired furnaces and seeks comments regarding this tentative conclusion. This is identified as Issue 9 in section IV.B, "Issues on Which DOE Seeks Comment."

5. Updates to ANSI Z21.10.3 Test Method

In 2004, ANSI updated ANSI Z21.10.3, *Gas Water Heaters, Volume III, Storage Water Heaters with Input Ratings Above 75,000 Btu Per Hour, Circulating and Instantaneous.* DOE's test procedure for gas-fired water heaters at 10 CFR 431.106 only references sections 2.9 (Thermal Efficiency) and 2.10 (Standby Loss) of the ANSI Z.21.10 test procedure. Accordingly, DOE's review focused on those sections, as well as any other sections to which sections 2.9 and 2.10 refer. In the updated version, ANSI moved both of these sections to Exhibit G. In addition, ANSI added a provision to limit the duration of the standby loss test to a maximum of 48 hours if there is no cutout (*i.e.,* the thermostat acts to shut off the burner) after the 24-hour mark. Currently, there is already an additional stipulation in DOE's test procedure at 10 CFR 431.106 that the standby test should last from the first fuel and/or electric consumption measurement until either the first cutout after the 24-hour mark or a maximum of 48 hours, if the water heater is not in the heating mode at that time. This stipulation was added by a direct final rule amending the test procedure for commercial water heaters (which was published on October 21, 2004) to limit the duration of the standby test and reduce the testing burden for manufacturers. 69 FR 61974, 61979.

DOE notes that its provision limiting the duration of the standby loss test is slightly different than the provision included in ANSI Z 21.10.3–2004. Using DOE's test procedure, if the water heater is in heating mode at the 48-hour mark, the tester is instructed to let the heating mode complete before ending the test. However, the updated ANSI Z21.10.3 test method directs the tester to end the test at 48 hours regardless of whether the water heater is in heating mode. DOE believes that this slight difference between the ANSI test procedure and the current DOE test procedure may have a very small impact on the measured energy efficiency if the water heater has not yet cut off after 24 hours and is in heating mode at the 48-hour mark. In such a situation, the DOE test procedure would allow the water heater to continue operating in heating mode to continue until a cutout before ending the test, whereas the ANSI test method would end the test immediately and possibly not capture the energy used during that final heating cycle. However, as noted above, DOE's test procedure already includes a provision to address the standby mode energy loss that is independent of the ANSI Z21.10.3 test method. Therefore, the update to the provision for the duration of the standby mode test in ANSI Z21.10.3 would be superseded by DOE's test requirements at 10 CFR 431.106 and would not change the standby test method. As a result, DOE believes that the new changes to ANSI Z21.10.3 would not significantly affect the measure of energy efficiency. DOE seeks comment regarding its preliminary conclusion that the updated ANSI Z21.10.3–2004 does not significantly impact energy efficiency ratings of

[14] SGML is a document markup language developed by the International Organization for Standardization (ISO) to allow for the sharing of machine-readable documents in government or law.

commercial gas-fired water heaters. This is identified as Issue 9 in section IV.B, "Issues on Which DOE Seeks Comment."

## III. Analysis of Potential Energy Savings

As required under 42 U.S.C. 6313(a)(6)(A), DOE performed an analysis to determine the energy-savings potential of amending Federal minimum energy conservation standard levels to the efficiency levels specified in ASHRAE Standard 90.1–2010, as well as more-stringent efficiency levels than those specified in ASHRAE Standard 90.1–2010. As explained above, DOE's energy-savings analysis is limited to types of equipment covered by Federal energy conservation standards for which the amended ASHRAE Standard 90.1–2010 increased the efficiency levels and for which a market exists and sufficient data are available.[15] Based upon the conclusions reached in section II, DOE is conducting the energy-savings analysis for eight equipment classes of water-cooled and evaporatively-cooled products: (1) Small water-cooled air conditioners with electric resistance or no heating (65,000 to less than 135,000 Btu/h); (2) small water-cooled air conditioners with other heating (65,000 to less than 135,000 Btu/h); (3) large water-cooled air conditioners with electric resistance or no heating (135,000 to less than 240,000 Btu/h); (4) large water-cooled air conditioners with other heating (135,000 to less than 240,000); (5) very large water-cooled air conditioners with electric resistance or no heating (240,000 Btu/h to less than 760,000 Btu/h); (6) very large water-cooled air conditioners with other heating (240,000 Btu/h to less than 760,000 Btu/h); (7) very large evaporatively-cooled air conditioners with electric resistance or no heating (240,000 Btu/h to less than 760,000 Btu/h); and (8) very large evaporatively-cooled air conditioners with other heating (240,000 Btu/h to less than 760,000 Btu/h).

In addition, although ASHRAE did not increase the efficiency level for SPVACs and SPVHPs, DOE is required by EPCA to consider amending the energy conservation standards for these equipment classes using the procedures set forth by 42 U.S.C. 6313(a)(6) for ASHRAE products. Accordingly, DOE also performed an energy-savings analysis for four equipment classes of SPVACs and SPVHPs where there is a market and sufficient data are available: (1) Single-phase SPVACs under 65,000 Btu/h; (2) three-phase SPVACs under 65,000 Btu/h; (3) single-phase SPVHPs under 65,000 Btu/h; and (4) three-phase SPVHPs under 65,000 Btu/h.

The following discussion provides an overview of the energy-savings analysis conducted for these twelve classes of products, followed by summary results of that analysis. For each efficiency level analyzed, DOE calculated the potential energy savings to the Nation as the difference between a base-case forecast (without amended standards) and the standards-case forecast (with amended standards). The national energy savings (NES) refers to cumulative energy savings for a 30-year period that differs by product. The analysis is based on a stock accounting method. In the standards case, equipment that is more efficient gradually replaces less-efficient equipment over time. This affects the calculation of the potential energy savings, which are a function of the total number of units in use and their efficiencies. Savings depend on annual shipments and equipment lifetime. Inputs to the energy-savings analysis are presented below, and details are available in the ASHRAE NODA TSD on DOE's website.[16]

While DOE did not have sufficient data to follow this analytical method for large SPVACs, DOE approximated the energy savings potential for this product class based on the energy savings results from the small SPVAC product classes. The calculation method and results for estimating the energy savings potential for large SPVACs are summarized in section III.D.

### *A. Annual Energy Use*

DOE's analysis of the annual unit energy consumption (UEC) for each class of equipment analyzed was based on the use of building simulation models or previously available building simulation data for equipment at or near the current Federal standard baseline for each equipment class analyzed. DOE then used a scaling process to assess the UEC corresponding to higher efficiency levels, including the efficiency levels provided in ASHRAE 90.1–2010. These UEC estimates form the basis of the national energy savings estimates discussed in section III.D.

This section describes the energy use analysis performed for water-cooled and evaporatively-cooled products, as well as for SPVUs. For each of these equipment types, the Federal standard and higher efficiency levels are expressed in terms of an efficiency metric or metrics (EER for cooling efficiency, Coefficient of Performance (COP) for heating efficiency). For each equipment class, this section describes how DOE developed estimates of annual energy consumption at the baseline efficiency level and higher levels for each equipment type. More detailed discussion is found in the ASHRAE NODA TSD.

#### 1. Water-Cooled Air Conditioners

The analysis to assess the per-unit energy saving of water-cooled air conditioners began with review of the existing market, as well as the review of historical shipments data provided by AHRI for the period from 1989–2009.[17] The review of the market for equipment from 65,000 Btu/h to 760,000 Btu/h suggested that most of the water-cooled air conditioner units currently on the market are designed for installation inside of commercial buildings (as opposed to on building rooftops), and the shipments data suggested that in recent years, shipments were dominated by larger equipment (≥ 240,000 Btu/h capacity), with relatively few shipments of smaller-capacity units. Given these findings, DOE's analysis of energy savings focused on typical applications for this larger equipment. Review of manufacturer's literature suggested that a common application is floor-by-floor cooling in a multi-story building.

To provide an estimate of the energy use of water-cooled air conditioners in this application, DOE used annual hourly simulation data developed from computer simulations of a prototypical commercial office building. The prototype building model was a 3-story, 53,600 square foot (sf) commercial office building developed as part of DOE's commercial reference building models.[18] This building has each floor

[15] As discussed in section II, when no products are available on the market or no reliable data exist for calculating potential energy savings, DOE did not perform an analysis. The products for which ASHRAE Standard 90.1–2010 increased the efficiency level, but for which DOE did not perform an analysis due to lack of a market or lack of data include: (1) VRF water-source heat pumps under 17,000 Btu/h (see section II.B.3); (2) VRF water-source heat pumps over 135,000 Btu/h (see section II.B.3); and (3) air conditioners and condensing units serving computer rooms (see section II.C).

[16] The ASHRAE NODA TSD is available on the webpage for ASHRAE Products at: *http://www1.eere.energy.gov/buildings/appliance_standards/commercial/ashrae_products_docs_meeting.html.*

[17] Air-Conditioning, Heating, and Refrigeration Institute, *Historical Shipment Data Commercial Air Conditioners Water Cooled,* 2011. This information was provided by AHRI to the U.S. Department of Energy on March 4, 2011.

[18] The commercial reference building models are available on DOE's website as Energy Plus input files at: *http://www1.eere.energy.gov/buildings/commercial_initiative/new_construction.html.* Documentation of the model development is provided in: Deru, M., *et al.* U.S. Department of Energy Commercial Reference Building Models of the National Building Stock. (NREL/TP–5500–46861) (2011).

served by a separate packaged air-conditioning unit. The hourly data used in this analysis were previously developed from simulations using the DOE EnergyPlus [19] building simulation software and reflected building simulations in 15 climate locations in the U.S., with each climate representing one of 15 climate regions that have been developed in DOE's Building Energy Codes Program and subsequently used in the development of the commercial reference building models.

The office building model selected utilized packaged variable air volume rooftop cooling units in the original reference building simulations, with each packaged unit serving one floor of the office model. DOE determined that the cooling thermal loads from modeling of this type of equipment would be representative of similar cooling distribution systems served by larger water-cooled equipment that also provides floor-by-floor cooling and serves multiple building thermal zones. EnergyPlus does not have an equipment simulation model developed around a water-cooled air conditioner for this application. For this reason, DOE relied on using the previously developed hourly cooling thermal load, air flow, and system air temperature data for the air-cooled packaged rooftop equipment used in the medium office reference building model. Since the thermal loads for the specific application would be essentially the same whether served by air-cooled or water-cooled packaged cooling equipment, and since the water-cooled packaged air conditioner equipment performance would be modeled explicitly in the spreadsheet, DOE believes this is approach provides an accurate method of estimating energy consumption for the water-cooled equipment classes.

To process the hourly data into annual equipment energy consumption for water-cooled air conditioners, DOE developed a spreadsheet model of the typical equipment performance using actual manufacturer performance data for a 25-ton water-cooled air conditioner. Cooling capacity and condenser power consumption curve fits to this data were developed using polynomial relationships and the independent variables recommended for modeling of cooling efficiency for water-source heat pumps in Energy Plus. In addition, DOE used part-load performance degradation curves previously developed for air-source air conditioners that already existed in the medium office reference building model. As these part-load curves reflect the effects of compressor cycling at part load, it was determined that these curves should be representative of the compressor cycling impacts for water-cooled air conditioners as well.

For each climate, DOE's spreadsheet model sized the equipment to reflect the sizing in the original simulation's hourly load data. To accurately account for fan power, DOE used the normalized fan power-versus-supply air flow curves in the original office reference building model.

The performance equations developed in this spreadsheet model separately accounted for the water-cooled gross cooling capacity and power consumption as a function of entering air conditions and supply water temperature and flow rate. In addition, the spreadsheet model requires an hourly entering water temperature and entering water flow rate. For this analysis, a simple cooling tower supply water temperature model was developed based on a defined control profile with minimum 70 °F return water temperature and using a 7 °F approach temperature (the temperature between the return water temperature from the cooling tower and the outdoor air wet bulb temperature). Condenser water flow rates were assumed to be equivalent to the nominal rating condition water flow rates for all cooling hours.

For analysis of energy use at each specific efficiency (EER) level, DOE first developed estimates for the condenser efficiency (condenser-only cooling COP) based on the nominal rating conditions. This was done by backing out the estimated fan power at nominal rating conditions from the input power and separately accounting for the impact of fan heat to arrive at the gross cooling capacity of the equipment. DOE developed estimates of peak fan power at design air flow conditions and used the fan power versus flow relationships to adjust the fan power appropriately for periods when air flow was not at design air flow rates.

Using the spreadsheet model, for each of the 15 climates, DOE first developed the annual equipment condenser energy consumption and blower energy consumption for nominal 11 EER water-cooled equipment, with 11 EER being the current Federal standard for water-cooled air conditioners with electric resistance or no heating, 240,000 Btu/h to less than 760,000 Btu/h . These were then normalized by dividing by the equipment capacity in cooling tons. The sum of the resulting condenser energy per cooling ton and blower energy per cooling ton represents the annual energy consumption per cooling ton for equipment at the 11 EER efficiency level. The resulting per-ton energy consumption figures were then multiplied by the typical equipment capacities developed for each water-cooled equipment class analyzed to establish the Unit Energy Consumption (UEC) values for each equipment class at that 11 EER level.

To assess the annual energy consumption at the specific efficiency levels analyzed, DOE developed estimates of the condenser-only cooling COP for each efficiency level. It then multiplied the annual condenser energy consumption for the 11 EER equipment for each climate by the ratio of the baseline condenser-only cooling COP to the condenser-only cooling COP at the higher efficiency levels.

The annual fan energy consumption estimates were held constant at the baseline level for all higher standards. A detailed engineering analysis of higher efficiency options might suggest a number of different ways to improve the EER including reducing supply fan energy consumption. However, several downsides to this approach were identified. First, the supply fan accounts for a relatively small portion of the energy use as compared to the condenser at the rating condition. In addition, because it appears that much of this equipment is installed inside the building space, changes which reduce fan power, such as increased case size and lower face velocity over the evaporator coil, would decrease the amount of rentable space available within the building. Accordingly, for the assessment of energy savings in this NODA, supply fan energy use was held constant. The UEC for each efficiency level analyzed is the sum of the annual condenser energy consumption and the fan power. From these climate-region-specific results, DOE developed national average UEC values at each efficiency level using weighting factors developed for medium and large commercial office building floor space as part of the development of the DOE reference building models. A comparison of these office weighting factors with cumulative weighting factors developed for the larger stock of commercial floor space is provided in the ASHRAE NODA TSD.

Table III.1 shows the UEC estimates for the current Federal baseline levels, the proposed ASHRAE levels, and for the higher efficiency levels for the six water-cooled air conditioner classes analyzed.

[19] For more information on EnergyPlus, refer to DOE's EnergyPlus documentation, available at: *http://apps1.eere.energy.gov/buildings/energyplus/energyplus_documentation.cfm.* EnergyPlus software is freely available for public download at: *http://apps1.eere.energy.gov/buildings/energyplus/energyplus_about.cfm.*

TABLE III.1—NATIONAL UEC ESTIMATES FOR WATER-COOLED AIR CONDITIONERS

| | Small water-cooled air conditioners electric or no heat 65,000–135,000 Btu/h | Small water-cooled air conditioners other heat 65,000–135,000 Btu/h | Large water-cooled air conditioners electric or no heat 135,000–240,000 Btu/h | Large water-cooled air conditioners other heat 135,000–240,000 Btu/h | Very large water-cooled air conditioners electric or no heat 240,000–760,000 Btu/h | Very large water-cooled air conditioners other heat 240,000–760,000 Btu/h |
|---|---|---|---|---|---|---|
| Average Cooling Capacity (tons) | 8 | 8 | 15 | 15 | 35 | 35 |
| **Efficiency Level (EER)** | | | | | | |
| Base Case—Federal Standard .... | 11.5 | 11.3 | 11.0 | 11.0 | 11.0 | 10.8 |
| Efficiency Level 1 | 12.1 | 11.9 | 12.5 | 12.3 | 12.4 | 12.2 |
| Efficiency Level 2 | 13.0 | 13.0 | 13.0 | 13.0 | 13.0 | 13.0 |
| Efficiency Level 3 | 14.0 | 14.0 | 14.0 | 14.0 | 14.0 | 14.0 |
| Efficiency Level 4 | 15.0 | 15.0 | 15.0 | 15.0 | * NA | * NA |
| Efficiency Level 5—"Max-Tech"— ..... | 16.4 | 16.4 | 16.1 | 16.1 | 14.8 | 14.8 |
| **Unit Energy Consumption (kWh/yr)** | | | | | | |
| Base Case—Federal Standard .... | 9,199 | 9,322 | 17,838 | 17,838 | 41,621 | 42,205 |
| Efficiency Level 1 | 8,855 | 8,966 | 16,206 | 16,402 | 38,041 | 38,504 |
| Efficiency Level 2 | 8,396 | 8,396 | 15,743 | 15,743 | 36,733 | 36,733 |
| Efficiency Level 3 | 7,953 | 7,953 | 14,911 | 14,911 | 34,793 | 34,793 |
| Efficiency Level 4 | 7,566 | 7,566 | 14,186 | 14,186 | *NA | *NA |
| Efficiency Level 5—"Max-Tech"— ..... | 7,101 | 7,101 | 13,490 | 13,490 | 33,422 | 33,422 |

*An efficiency level 4 was not identified for very large water-cooled air conditioners.

2. Evaporatively-Cooled Air Conditioners

The analysis to assess the per-unit energy use of evaporatively-cooled air conditioners began with review of the existing market. DOE did not identify any current models of evaporatively-cooled air conditioners with less than 240,000 Btu/h cooling capacity. The review of the market suggested that all of the currently shipping units appeared to be packaged rooftop evaporatively-cooled air conditioner units. Based on the available models, DOE estimated the average capacity at 40 tons. Because of this, DOE's analysis of energy savings focused on typical applications for the very large equipment class. Because of the large capacity, DOE believes that a common system design would also be a packaged variable air volume (VAV) system. DOE modified the 3-story office reference building model discussed previously to serve as the simulation model for the very large evaporatively-cooled air conditioner equipment class.

The Energy Plus simulation tool has the capability to model evaporatively-cooled unitary air conditioners with only minor modifications from the air-cooled unitary air conditioner equipment models that were used in the original DOE medium office reference building model. DOE was not able to derive separate performance curves for evaporatively-cooled equipment, as these data were not available in the manufacturer literature reviewed. Therefore, DOE modified the air-cooled model using simulation defaults provided in the Energy Plus documentation for modeling evaporatively-cooled air conditioners. These modifications are discussed in the ASHRAE NODA TSD.

DOE performed simulations of the medium office reference building model in the 15 climates identified previously at an 11 EER efficiency level, because 11 EER is the current Federal standard for evaporatively-cooled air conditioners with electric resistance or no heating. To do this, DOE first developed estimates for the condenser-only cooling COP based on the nominal rating conditions as input for the simulation models. DOE used the fan power performance curves and peak fan power assumptions in the reference building model directly.

Using the spreadsheet model, for each of the 15 climates, DOE developed the annual equipment condenser energy consumption and blower energy consumption for the 11 EER evaporatively-cooled equipment simulated. These values were then normalized by dividing by the equipment capacity in cooling tons. The sum of the resulting condenser energy per cooling ton and blower energy per cooling ton represents the annual energy consumption per cooling ton for equipment at that 11 EER efficiency level. These per-ton energy consumption figures were then multiplied by the selected equipment capacities for the evaporatively-cooled equipment class analyzed to establish the UEC values for each equipment class at an 11 EER level.

To assess the annual energy consumption at the specific efficiency levels analyzed, DOE developed estimates of the condenser-only cooling COP for each efficiency level. It then multiplied the baseline annual condenser energy consumption developed for each climate by the ratio of the baseline condenser-only cooling COP at 11 EER to the condenser-only cooling COP at the efficiency levels analyzed.

The annual fan energy consumption estimates were held constant at the baseline level for all higher standards. As with water-cooled air conditioners, a detailed engineering analysis might suggest that reduction in supply fan power might be a path to improved EER; however, DOE did not conduct such a detailed analysis. Because supply fan power is a relatively small fraction of total system power at rating conditions, DOE concluded that improvement in condenser efficiency is likely a necessary path to achieve the most

significant system efficiency improvements. The UEC for each efficiency level analyzed is the sum of the annual condenser energy consumption and the fan power. As with water-cooled air conditioners discussed previously, DOE developed national average UEC values at each efficiency level using weighting factors developed for medium and large commercial office building floor space as part of the development of the DOE reference building models.

Table III.2 shows the unit energy consumption estimates for the current Federal baseline levels, the proposed ASHRAE levels, and for the higher efficiency levels for the very large evaporatively-cooled air conditioner classes.

TABLE III.2—NATIONAL UEC ESTIMATES FOR EVAPORATIVELY-COOLED AIR CONDITIONERS

| | Large evaporatively-cooled air conditioner electric or no heat 240,000–760,000 Btu/h | Large evaporatively-cooled air conditioner other heat 240,000–760,000 Btu/h |
|---|---|---|
| Average Cooling Capacity (tons) | 40 | 40 |
| **Efficiency Level (EER)** | | |
| Base case | 11.0 | 10.8 |
| Level 1—ASHRAE | 11.9 | 11.7 |
| Level 2 | 12.5 | 12.5 |
| Max Tech | 13.1 | 13.1 |
| **Unit Energy Consumption (kWh/yr)** | | |
| Base case | 47,171 | 47,766 |
| Level 1—ASHRAE | 44,732 | 45,243 |
| Level 2 | 43,294 | 43,294 |
| Max Tech | 41,983 | 41,983 |

3. Single-Package Vertical Air Conditioners and Heat Pumps

Based on data developed during previous analysis of SPVU equipment by DOE,[20] the Department believes that approximately 60 percent of the SPVU shipments go to educational facilities, the majority of which are for space conditioning of modular classroom buildings. Another approximately 20 percent of the shipments go to providing cooling for non-comfort cooling applications such as telecommunications and electronics enclosures. The remainder is used in a wide variety of commercial buildings including offices, temporary buildings, and some lodging facilities. In many of these commercial building applications, the buildings served are expected to be of modular construction.

For its initial estimate of energy savings for SPVAC and SPVHP, DOE focused its analysis on the education market, in particular, modular classrooms, which DOE believes to represent the majority of the usage for this equipment. To estimate the energy use of single-package vertical air conditioners and heat pumps in these educational facilities, DOE developed a modular classroom building simulation model using the Energy Plus software. Schedules and load profiles were taken from classroom-space data found in the DOE Primary School reference building models. Internal loads were based on equipment power and occupancy figures for the primary school reference building model. Lighting power requirements were based on levels found in ASHRAE Standard 90.1–2004. DOE believes that this is largely representative of classroom lighting power in the building stock.

DOE simulated this building in each of the 15 climates as was done for water-cooled air conditioners and evaporatively-cooled air conditioners. Simulations were done for the buildings with SPVAC equipment and electric resistance heating, and then a separate set of simulations was done for buildings with SPVHP equipment. DOE used the current Federal standard efficiencies of 9.0 EER for SPVAC equipment and 9.0 EER and 3.0 COP for SPVHP equipment in the ≤65,000 Btu/h cooling capacity range. Fan power at these efficiency levels was based on manufacturers' literature and reported fan power consumption data. In addition, based on DOE's review of the existing market, the supply air blower motors for this baseline equipment used permanent split-capacitor motors.

Using the fan power data, DOE converted the baseline EER to condenser cooling COP at rating conditions. DOE converted the baseline heating COP to condenser heating COP at the heating rating conditions. These values were used as inputs for the equipment simulations. Further details of the building model and the simulation inputs used for modeling the energy consumption of the SPVAC and SPVHP equipment can be found in the ASHRAE NODA TSD.

From the annual simulation results for SPVAC equipment, DOE extracted the condenser energy use for cooling, the blower energy use, and the equipment capacity. From these, DOE developed the annual cooling energy per ton and annual blower energy per ton for the baseline efficiency simulated. These per-ton values were then added together and multiplied by the average cooling capacity estimated for SPVUs in the ≤65,000 Btu/h capacity range to arrive at the baseline UEC for SPVAC. This average unit capacity was estimated at 3 tons (*i.e.,* 36,000 Btu/h).

To estimate the UEC for higher efficiency levels for SPVAC, DOE multiplied the baseline condenser cooling energy by the ratio of the baseline condenser cooling COP to the condenser cooling COP calculated for higher efficiency levels. As a review of the market indicated that ECM motors were the norm at high efficiency levels

[20] U.S. Department of Energy, Technical Support Document: Energy Efficiency Program for Commercial and Industrial Equipment: Efficiency Standards for Commercial Heating, Air-Conditioning, and Water Heating Equipment Including Packaged Terminal Air-Conditioners and Packaged Terminal Heat Pumps, Small Commercial Packaged Boiler, Three-Phase Air-Conditioners and Heat Pumps <65,000 Btu/h, and Single-Package Vertical Air Conditioners and Single-Package Vertical Heat Pumps <65,000 Btu/h (March 2006) (Available at: *http://www1.eere.energy.gov/buildings/appliance_standards/commercial/ashrae_products_docs_meeting.html*).

(with a corresponding lower fan power), DOE used the available market data to establish estimates of the fraction of the market using ECM motors at each higher efficiency level analyzed. It then calculated the blower energy consumption per ton for both the baseline fan power (PSC motor) and the fan power assuming ECM motors. The latter was achieved by multiplying the baseline fan energy consumption by the ratio of the rated fan power reported for products using ECM motors to the rated fan power for products using PSC blower motors. Using the relative market fractions of the SPVACs and SPVHPs using each motor at approximately the efficiency levels analyzed, DOE developed weighted-average annual fan energy consumption for each higher efficiency level. The condenser energy per ton and blower energy per ton at each efficiency level were then added together and the result multiplied by the 3-ton average capacity to develop SPVAC UEC estimates for each higher efficiency level analyzed.

The analytical method for SPVHP was carried out in a similar fashion; however, for heat pumps, DOE included the heating energy from the simulation results. From the SPVHP simulation results at the baseline 9.0 EER and 3.0 COP levels, DOE extracted the compressor cooling energy, blower energy, compressor heating energy, backup electric resistance heating energy, and the cooling capacity. From these, DOE developed per-ton energy consumption values for each of these four electrical loads. These per-ton energy figures were summed and multiplied by the nominal capacity to arrive at the baseline UEC for SPVHP. To establish UEC estimates for higher efficiency levels, the baseline condenser cooling energy was scaled by multiplying it by the ratio of the baseline condenser-only cooling COP to that of the condenser-only cooling COP for each higher efficiency level. Similarly, for the analysis of higher COP efficiencies, the condenser heating energy was multiplied by the ratio the baseline condenser-only heating COP to that of the condenser-only heating COP calculated for the higher efficiency levels. The annual blower energy consumption was calculated based on the estimated relative fractions for ECM and PSC motors for each analyzed efficiency levels. The backup electric resistance heat from the baseline simulations was not adjusted for higher efficiency levels, because it was assumed to be unaffected by higher efficiency levels. These scaled electrical consumption values for these four energy uses were then summed to provide the UEC estimate for each higher efficiency level. For details of this analysis, see the ASHRAE NODA TSD.

DOE developed national average UEC values at each efficiency level using weighting factors developed for primary and secondary school education building floor space as part of the development of the DOE reference building models.

Table III.3 shows the annual UEC estimates for SPVAC and SPVHP corresponding to the EER and COP levels analyzed. Note that Level 2, with an EER of 10.0, matches the minimum standard for SPVUs in Proposed Addendum i to ASHRAE Standard 90.1–2010. Therefore, although DOE analyzed SPVUs under a separate requirement from an amendment to ASHRAE Standard 90.1 (as discussed in section I.A), potential energy savings for this level provide an estimate of the savings that would occur should this addendum be approved.

TABLE III.3—NATIONAL UEC ESTIMATES FOR SPVAC AND SPVHP EQUIPMENT

| | SPVAC 1-phase <65,000 Btu/h | SPVAC 3-phase <65,000 Btu/h | SPVHP 1-phase <65,000 Btu/h | | SPVHP 3-phase <65,000 Btu/h | |
|---|---|---|---|---|---|---|
| Average Capacity (tons) | 3 | 3 | 3 | 3 | 3 | 3 |
| | **Efficiency Level (EER)** | | | | | |
| | EER | EER | EER | COP | EER | COP |
| Baseline | 9.0 | 9.0 | 9.0 | 3.0 | 9.0 | 3.0 |
| Level 1 | 9.5 | 9.5 | 9.5 | 3.1 | 9.5 | 3.0 |
| Level 2 | 10.0 | 10.0 | 10.0 | 3.1 | 10.0 | 3.1 |
| Level 3 | 11.0 | 11.0 | 11.0 | 3.2 | 11.0 | 3.2 |
| Level 4 | 12.0 | 12.0 | 12.0 | 3.3 | 12.0 | 3.3 |
| Level 5—"Max-Tech" | 12.6 | 12.6 | 12.5 | 3.4 | 12.5 | 3.3 |
| | **Unit Energy Consumption (kWh/yr)** | | | | | |
| Baseline | 6,660 | 6,660 | 6,648 | 6,280 | 6,648 | 6,281 |
| Level 1 | 6,301 | 6,301 | 6,290 | 6,234 | 6,290 | 6,240 |
| Level 2 | 5,962 | 5,962 | 5,952 | 6,189 | 5,952 | 6,201 |
| Level 3 | 5,537 | 5,537 | 5,325 | 6,105 | 5,325 | 6,126 |
| Level 4 | 5,057 | 5,057 | 5,048 | 6,026 | 5,048 | 6,055 |
| Level 5—"Max-Tech" | 4,911 | 4,911 | 4,925 | 5,988 | 4,925 | 6,021 |

DOE seeks input on its analysis of UEC for the above equipment classes and its use in establishing the energy savings potential for higher standards. Of particular interest, DOE is seeking input on the other building applications for SPVU equipment and the value of incorporating them into its analysis. DOE identified this as Issue 10 under "Issues on Which DOE Seeks Comment" in section IV.B of this NODA.

*B. Shipments*

DOE obtained historical (1989–2009) water-cooled commercial air conditioner shipment data from AHRI.[21] Table III.4 exhibits the shipment data provided for a selection of years, while the full data set can be found in the

[21] Air-Conditioning, Heating, and Refrigeration Institute, *Historical Shipment Data Commercial Air Conditioners Water Cooled,* 2011. This information was provided by AHRI to the U.S. Department of Energy on March 4, 2011. (AHRI, No. 0002 at p. 2)

ASHRAE NODA TSD. DOE used these shipment data to create two shipment scenarios: (1) Based on historical trends, and (2) shipments held constant at 2009 levels. For small and large AC, the historical trends are exponential (decreasing), while for very large AC, the closest trend is linear (decreasing). As these trends result in few shipments by the end of the analysis period, DOE used the second shipment scenario to represent more of an upper bound on shipments.

TABLE III.4—TOTAL SHIPMENTS OF WATER-COOLED AC BY EQUIPMENT CLASS

| Equipment class * | 1989 | 1999 | 2009 |
|---|---|---|---|
| Small AC (65,000–134,900 Btu/h) | 1,437 | 874 | 152 |
| Large AC (135,000–249,000 Btu/h) | 793 | 477 | 182 |
| Very Large AC (250,000 & Over Btu/h) | 1,622 | 898 | 585 |

* Although the Btu/h ranges AHRI uses to categorize equipment into small, large, and very large do not exactly match the definitions for those categories provided in EPCA, in this analysis, DOE did not attempt to adjust the shipments to take into account these small differences.

DOE broke out the shipment data into the discrete classes required for this analysis. DOE could not identify data that would allow the shipments provided by AHRI to be separated into products with electrical resistance or no heating, and those with other types of heating. However, DOE believes that most small and large water-cooled equipment does not provide heating, and as a result, DOE assigned 90 percent of shipments in those categories to the no heating class, and 10 percent to the other heating class. For very large equipment, DOE believes that most equipment are roof-top units that are combined with gas furnaces, and as a result assigned 10 percent of very large shipments to the "no heating class" and 90 percent to the "other heating class."

DOE identified nine models of very large evaporatively-cooled equipment, but no shipment data were available. For this product class, DOE used the ratio of very large evaporatively-cooled to water-cooled models on the market (9:35) and applied this ratio to the water-cooled shipments to estimate evaporatively-cooled shipments. The same fraction as for very large water-cooled equipment was used to separate units into the relevant heating categories.

The complete historical data set and the projected shipments for each equipment class can be found in the ASHRAE NODA TSD. DOE seeks input on its allocation of shipments to the eight classes of water-cooled and evaporatively-cooled equipment for which analysis was performed, as well as the future market and shipment scenarios for these products. DOE identified this as Issue 11 under "Issues on Which DOE Seeks Comment" in section IV.B of this NODA.

For SPVUs, DOE did not create two shipment scenarios, but rather relied upon SPVU shipment data from the Technical Support Document for the March 13, 2006 Notice of Document Availability on Efficiency Standards for Commercial Heating, Air-Conditioning, and Water Heating Equipment.[22] In this document, DOE provided 2005 shipments data based on Air-Conditioning and Refrigeration Institute (ARI, now AHRI) estimates, as shown in Table III.5.

TABLE III.5—TOTAL SHIPMENTS OF SPVUS BY EQUIPMENT CLASS

| Equipment class | 2005 |
|---|---|
| SPVAC <65,000 Btu/h, single-phase | 31,976 |
| SPVHP <65,000 Btu/h, single-phase | 13,125 |
| SPVAC <65,000 Btu/h, three-phase | 14,301 |
| SPVHP <65,000 Btu/h, three-phase | 6,129 |

As the market for SPVUs is larger and better understood than the market for water-cooled and evaporatively-cooled products and the estimated growth rate over time is increasing, DOE did not include a shipment scenario with shipments fixed to 2009. DOE only used that scenario for water-cooled and evaporatively-cooled products to provide an upper bound on shipments and energy savings, as it is unclear if the historical trend toward extremely few units in those product classes will continue.

DOE projected shipments of SPVUs according to the average growth rate of 2.18 percent noted in the 2006 TSD. This was based on analysis of AHRI data for commercial unitary AC products 65,000 Btu/h to 240,000 Btu/h for DOE's commercial unitary AC and HP rulemaking.

DOE then reviewed the AHRI certified products directory, as well as manufacturer Web sites, to determine the distribution of efficiency levels for commercially-available models within each equipment class of water-cooled and evaporatively-cooled products and SPVUs. DOE bundled the efficiency levels into "efficiency ranges" and determined the percentage of models within each range. The distribution of efficiencies in the base case for each equipment class can be found in the ASHRAE NODA TSD on DOE's Web site.

For the standards case, DOE assumed shipments at lower efficiencies were most likely to roll up into higher efficiency levels in response to more-stringent energy conservation standards. For each efficiency level analyzed within a given equipment class, DOE used a "roll-up" scenario to establish the market shares by efficiency level for the year that standards become effective (*i.e.,* 2012). DOE estimated that the efficiencies of equipment in the base case that did not meet the standard level under consideration would roll up to meet the standard level. Available information also suggests that all equipment efficiencies in the base case that were above the standard level under consideration would not be affected. Table III.6 shows an example of the distribution of efficiencies within the base-case and the roll-up scenarios to establish the distribution of efficiencies in the standards cases for very large water-cooled equipment. For all the tables of the distribution of efficiencies in the base case and standards cases by equipment class, see the ASHRAE NODA TSD.

[22] U.S. Department of Energy, *Technical Support Document: Energy Efficiency Program for Commercial and Industrial Equipment: Efficiency Standards for Commercial Heating, Air-Conditioning, and Water Heating Equipment Including Packaged Terminal Air-Conditioners and Packaged Terminal Heat Pumps, Small Commercial Packaged Boiler, Three-Phase Air-Conditioners and Heat Pumps <65,000 Btu/h, and Single-Package Vertical Air Conditioners and Single-Package Vertical Heat Pumps <65,000 Btu/h* (March 2006).

TABLE III.6—DISTRIBUTION OF EFFICIENCIES IN THE BASE CASE AND STANDARDS CASES FOR VERY LARGE WATER-COOLED COMMERCIAL AC WITH OTHER HEAT

| Efficiency level | Efficiency ranges (EER) * | | | | |
|---|---|---|---|---|---|
| | 10.8–11.59 | 11.6–12.69 | 12.7–13.49 | 13.5–14.39 | 14.4–14.89 |
| Base Case—Federal Standard (10.8 EER) | 14% | 23% | 29% | 14% | 20% |
| Efficiency Level 1—ASHRAE (12.2 EER) | ..... | 37% | 29% | 14% | 20% |
| Efficiency Level 2—(13.0 EER) | ..... | ..... | 66% | 14% | 20% |
| Efficiency Level 3—(14.0 EER) | ..... | ..... | ..... | 80% | 20% |
| Efficiency Level 5—"Max-Tech"—(14.8 EER) | ..... | ..... | ..... | ..... | 100% |

* DOE binned models into efficiency ranges surrounding the EER of each efficiency level; the specific bins were chosen to maintain the same market average efficiency (when the number of models in each range is multiplied by the efficiency level EER) as calculated using the full distribution of models.

DOE seeks input on its determination of the base-case distribution of efficiencies and its prediction on how amended energy conservation standards affect the distribution of efficiencies in the standards case. DOE identified this as Issue 12 under "Issues on Which DOE Seeks Comment" in section IV.B of this NODA.

Using the distribution of efficiencies in the base case and in the standards cases for each equipment class analyzed in today's NODA, as well as the UECs for each specified EER (discussed previously), DOE calculated market-weighted average efficiency values. The market-weighted average efficiency value represents the average efficiency of the total units shipped at a specified amended standard level. The market-weighted average efficiency values for the base case and the standards cases for each efficiency analyzed within the equipment classes is provided in the ASHRAE NODA TSD found on DOE's Web site.

*C. Other Analytical Inputs*

1. Site-to-Source Conversion

DOE converted the annual site energy savings into the annual amount of energy saved at the source of electric generation (*i.e.,* primary energy), using site-to-source conversion factors over the analysis period (calculated from the Energy Information Agency's (EIA's) *Annual Energy Outlook 2010* (*AEO2010*) projections).[23] DOE derived the annual conversion factors by dividing the delivered electricity to the commercial sector plus loss for each forecast year in the United States, as indicated in *AEO2010,* by the delivered electricity to the commercial sector for each forecasted year.

2. Product Lifetime

For both water-cooled and evaporatively-cooled products and SPVUs, DOE estimated the product lifetime from the advanced notice of proposed rulemaking on Energy Conservation Standards for Commercial Unitary Air Conditioners and Heat Pumps published in the **Federal Register** on July 29, 2004. 69 FR 45460, 45480. The product lifetime from the prior TSD was estimated to be a mean of 15.4 years. More recent sources confirm this estimate including the 2008 California Database for Energy Efficient Resources (15 years).[24] For this preliminary analysis, DOE used a single-value lifetime of 15 years.

3. Compliance Date and Analysis Period

For purposes of calculating the national energy savings (NES) for water-cooled and evaporatively-cooled equipment, DOE used an analysis period of 2013 (the assumed compliance date if DOE were to adopt the ASHRAE levels as Federal standards for small products) or 2014 (the assumed compliance date if DOE were to adopt the ASHRAE levels as Federal standards for large and very large products) through 2042 and 2043, respectively. This is the standard analysis period of 30 years that DOE typically uses in its NES analysis. While the analysis period remains the same for assessing the energy savings of Federal standard levels higher than the ASHRAE levels, those energy savings would not begin accumulating until 2017 (the assumed compliance date if DOE were to determine that standard levels more stringent than the ASHRAE levels are justified).

If DOE were to propose a rule prescribing energy conservation standards at the efficiency levels contained in ASHRAE Standard 90.1–2010, EPCA states that any such standards shall become effective on or after a date which is two or three years (depending on equipment size) after the effective date of the applicable minimum energy efficiency requirement in the amended ASHRAE standard (*i.e.,* ASHRAE Standard 90.1–2010). (42 U.S.C. 6313(a)(6)(D)) For all water-cooled and evaporatively-cooled equipment in this rulemaking, the effective date in ASHRAE Standard 90.1–2010 is June 1, 2011. Thus, if DOE decides to adopt the levels in ASHRAE Standard 90.1–2010, the rule would apply to small equipment (two product classes) manufactured on or after June 1, 2013, which is two years from the effective date specified in ASHRAE Standard 90.1–2010, and to large and very large equipment (six product classes) manufactured on or after June 1, 2014, which is three years from the effective date specified in ASHRAE Standard 90.1–2010.

If DOE were to propose a rule prescribing energy conservation standards higher than the efficiency levels contained in ASHRAE Standard 90.1–2010, under EPCA, any such standard will become effective for products manufactured four years after the date of publication in the **Federal Register**. (42 U.S.C. 6313(a)(6)(D)) Thus, for products for which DOE might adopt a level more stringent than the ASHRAE efficiency level, the rule would apply to products manufactured on or after a date which is four years from the date of publication of the final rule adopting standards higher than the ASHRAE efficiency levels (30 months after publication of the revised ASHRAE Standard 90.1, which was October 29, 2010). Under this timeline, compliance with such more-stringent standards would be required no later than April 29, 2017.

For purposes of calculating the NES for SPVUs, DOE used a 30-year analysis period of 2017–2046. As all efficiency levels being considered for SPVUs are higher than the ASHRAE efficiency levels, any rule adopted would apply to products manufactured on or after a date which is four years from the date of publication of the final rule adopting standards higher than the ASHRAE

[23] *AEO2010* can be accessed at: *http://www.eia.doe.gov/oiaf/archive/aeo10/index.html.*

[24] California Public Utility Commission 2008, Database for Energy Efficient Resources (Available at: *http://www.deeresources.com/).*

efficiency levels (30 months after publication of the revised ASHRAE Standard 90.1, which was October 29, 2010). Under this timeline, compliance with such more-stringent standards would be required no later than April 29, 2017.

For each equipment class for which DOE developed a potential energy savings analysis, Table III.7 exhibits the approximate compliance dates of an amended energy conservation standard.

TABLE III.7—APPROXIMATE COMPLIANCE DATE OF AN AMENDED ENERGY CONSERVATION STANDARD FOR EACH EQUIPMENT CLASS

| Equipment class | Approximate compliance date for adopting the efficiency levels in ASHRAE standard 90.1–2010 | Approximate compliance date for adopting more stringent efficiency levels than those in ASHRAE standard 90.1–2010 |
|---|---|---|
| Small Water-Cooled AC with Electric Resistance or No Heat | 06/2013 | 04/2017 |
| Small Water-Cooled AC with Other Heat | 06/2013 | 04/2017 |
| Large Water-Cooled AC with Electric Resistance or No Heat | 06/2014 | 04/2017 |
| Large Water-Cooled AC with Other Heat | 06/2014 | 04/2017 |
| Very Large Water-Cooled AC with Electric Resistance or No Heat | 06/2014 | 04/2017 |
| Very Large Water-Cooled AC with Other Heat | 06/2014 | 04/2017 |
| Very Large Evaporatively-Cooled AC with Electric Resistance or No Heat | 06/2014 | 04/2017 |
| Very Large Evaporatively-Cooled AC with Other Heat | 06/2014 | 04/2017 |
| SPVAC <65,000 Btu/h, single-phase | * N/A | 04/2017 |
| SPVAC <65,000 Btu/h, three-phase | * N/A | 04/2017 |
| SPVHP <65,000 Btu/h, single-phase | * N/A | 04/2017 |
| SPVHP <65,000 Btu/h, three-phase | * N/A | 04/2017 |

* The efficiency levels specified for SPVACs and SPVHPs in ASHRAE 90.1–2010 are already in effect as Federal minimum energy conservation standards.

*D. Estimates of Potential Energy Savings*

DOE estimated the potential primary energy savings in quads (*i.e.,* $10^{15}$ Btu) for each efficiency level considered within each equipment class analyzed. Table III.8—Table III.19 show the potential energy savings resulting from the analyses conducted as part of this NODA.

TABLE III.8—POTENTIAL ENERGY SAVINGS FOR SMALL WATER-COOLED EQUIPMENT WITH ELECTRIC RESISTANCE OR NO HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—12.1 EER | 0.000005 | 0.000011 |
| Level 2—13 EER | 0.000018 | 0.000060 |
| Level 3—14 EER | 0.000044 | 0.000144 |
| Level 4—15 EER | 0.000074 | 0.000238 |
| Level 5—"Max-Tech"—16.4 EER | 0.000121 | 0.000388 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.9—POTENTIAL ENERGY SAVINGS ESTIMATES FOR SMALL WATER-COOLED EQUIPMENT WITH OTHER HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—11.9 EER | 0.0000005 | 0.0000013 |
| Level 2—13 EER | 0.0000024 | 0.0000082 |
| Level 3—14 EER | 0.0000053 | 0.0000174 |
| Level 4—15 EER | 0.0000085 | 0.0000276 |
| Level 5—"Max-Tech"—16.4 EER | 0.0000137 | 0.0000441 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.10—POTENTIAL ENERGY SAVINGS ESTIMATES FOR LARGE WATER-COOLED EQUIPMENT WITH ELECTRIC RESISTANCE OR NO HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—12.5 EER | 0.00014 | 0.00027 |
| Level 2—13 EER | 0.00002 | 0.00008 |
| Level 3—14 EER | 0.00013 | 0.00032 |
| Level 4—15 EER | 0.00024 | 0.00056 |
| Level 5—"Max-Tech"—16.1 EER | 0.00039 | 0.00089 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.11—POTENTIAL ENERGY SAVINGS ESTIMATES FOR LARGE WATER-COOLED EQUIPMENT WITH OTHER HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—12.3 EER | 0.00001 | 0.00003 |
| Level 2—13 EER | 0.00001 | 0.00001 |
| Level 3—14 EER | 0.00002 | 0.00004 |
| Level 4—15 EER | 0.00003 | 0.00007 |
| Level 5—"Max-Tech"—16.1 EER | 0.00005 | 0.00010 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.12—POTENTIAL ENERGY SAVINGS ESTIMATES FOR VERY LARGE WATER-COOLED EQUIPMENT WITH ELECTRIC RESISTANCE OR NO HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—12.4 EER | 0.0002 | 0.0001 |
| Level 2—13 EER | 0.0001 | 0.0001 |
| Level 3—14 EER | 0.0005 | 0.0003 |
| Level 4—"Max-Tech"—14.8 EER | 0.0008 | 0.0005 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.13—POTENTIAL ENERGY SAVINGS ESTIMATES FOR VERY LARGE WATER-COOLED EQUIPMENT WITH OTHER HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—12.2 EER | 0.002 | 0.001 |
| Level 2—13 EER | 0.001 | 0.001 |
| Level 3—14 EER | 0.005 | 0.003 |
| Level 4—"Max-Tech"—14.8 EER | 0.008 | 0.005 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.14—POTENTIAL ENERGY SAVINGS ESTIMATES FOR VERY LARGE EVAPORATIVELY-COOLED EQUIPMENT WITH ELECTRIC RESISTANCE OR NO HEAT

| Efficiency level | Primary energy savings estimate * (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—11.9 EER | 0.00013 | 0.00009 |
| Level 2—12.5 EER | 0.00008 | 0.00005 |
| Level 3—"Max-Tech"—13.1 EER | 0.00017 | 0.00011 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.15—POTENTIAL ENERGY SAVINGS ESTIMATES FOR VERY LARGE EVAPORATIVELY-COOLED EQUIPMENT WITH ELECTRIC RESISTANCE OR NO HEAT

| Efficiency level | Primary energy savings estimate* (quads) | |
|---|---|---|
| | Historical shipment trend | Shipments fixed to 2009 |
| Level 1—ASHRAE—11.7 EER ** | 0.0011 | 0.0007 |
| Level 2—12.5 EER | 0.0010 | 0.0007 |
| Level 3—"Max-Tech"—13.1 EER | 0.0019 | 0.0012 |

* The potential energy savings for efficiency levels more stringent than those specified by ASHRAE Standard 90.1–2010 were calculated relative to the efficiency levels that would result if ASHRAE Standard 90.1–2010 standards were adopted.

TABLE III.16—POTENTIAL ENERGY SAVINGS ESTIMATES FOR SMALL SINGLE-PHASE SPVAC

| Efficiency level | Primary energy savings estimate (quads) |
|---|---|
| Level 1—9.5 EER | 0.035 |
| Level 2—10 EER | 0.076 |
| Level 3—11 EER | 0.139 |
| Level 4—12 EER | 0.226 |
| Level 5—"Max-Tech"—12.6 EER | 0.253 |

TABLE III.17—POTENTIAL ENERGY SAVINGS ESTIMATES FOR SMALL THREE-PHASE SPVAC

| Efficiency level | Primary energy savings estimate (quads) |
|---|---|
| Level 1—9.5 EER | 0.010 |
| Level 2—10 EER | 0.023 |
| Level 3—11 EER | 0.046 |
| Level 4—12 EER | 0.083 |
| Level 5—"Max-Tech"—12.6 EER | 0.095 |

TABLE III.18—POTENTIAL ENERGY SAVINGS ESTIMATES FOR SMALL SINGLE-PHASE SPVHP

| Efficiency level | Primary energy savings estimate * (quads) |
|---|---|
| Level 1—9.5 EER | 0.012 |
| Level 2—10 EER | 0.026 |
| Level 3—11 EER | 0.064 |
| Level 4—12 EER | 0.089 |
| Level 5—"Max-Tech"—12.5 EER | 0.101 |

* For SPVHPs, the primary energy savings estimates are based on both cooling savings (EER) and heating savings (COP).

TABLE III.19—POTENTIAL ENERGY SAVINGS ESTIMATES FOR SMALL THREE-PHASE SPVHP

| Efficiency level | Primary energy savings estimate* (quads) |
|---|---|
| Level 1—9.5 EER | 0.004 |
| Level 2—10 EER | 0.009 |
| Level 3—11 EER | 0.025 |
| Level 4—12 EER | 0.037 |
| Level 5—"Max-Tech"—12.5 EER | 0.042 |

* For SPVHPs, the primary energy savings estimates are based on both cooling savings (EER) and heating savings (COP).

As mentioned previously, due to the small size of the market for large SPVACs (five models) and a lack of shipment estimates, DOE could not perform a full analysis of energy savings for this product class. However, DOE used the results from small SPVACs to approximate the energy savings for large SPVACs.

DOE notes that analysis of the market shows only a narrow range of efficiencies for large SPVACs, with two out of the five existing models (40 percent) at 10.0 EER and three out of the five models (60 percent) at 9.5 EER. DOE also estimates that the UEC for a typical large SPVAC at a 9.5 or 10.0 EER will be approximately twice that calculated for a small SPVAC at the same efficiency levels, as the equipment capacity of the available large SPVAC products is approximately twice that of the average size for the small SPVAC equipment. While DOE has no data on shipments for large SPVACs, it notes that the number of available models of large SPVACs is approximately 1.4 percent of small SPVACs based on its market analysis.

Assuming relative shipments of large SPVACs to small SPVACs could be characterized by the ratio of models available, and that the per-unit energy savings in going from 9.5 to 10.0 EER (the highest available efficiency) is twice that of the small SPVACs going between these levels, DOE estimates that the potential energy savings for standards set at the market maximum 10.0 EER level is roughly 1.68 percent of the difference in the energy savings calculated for the small SPVAC standards at 10.0 EER and at 9.5 EER (shown in table III.16 and III.17). This would suggest an energy savings potential of approximately 0.0009 quads, shown in Table III.20.[25]

TABLE III.20—POTENTIAL ENERGY SAVINGS ESTIMATES FOR LARGE SPVAC

| Efficiency level | Primary energy savings estimate (quads) |
|---|---|
| Level 1—10.0 EER | 0.0009 |

## IV. Public Participation

### *A. Submission of Comments*

DOE will accept comments, data, and information regarding this NODA no later than the date provided in the **DATES** section at the beginning of this notice. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

*Submitting comments via www.regulations.gov.* The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section below.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

*Submitting comments via email, hand delivery/courier, or mail.* Comments and documents submitted via email, hand delivery, or mail also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in

[25] Estimated as [60 percent of the large SPVAC market being affected at the 10.0 EER standard level times twice the UEC savings of the small SPVAC products in going from 9.5 to 10.0 EER times 1.4 percent of the total shipments, or equal to $0.60 \times 2 \times 0.014 \times [(0.076+0.023)-(.035+.01)]$] quads. DOE did not separate this product class into single-phase and three-phase units because the savings would be even more speculative at this level, and the breakdown is not required.

your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. Email submissions are preferred. If you submit via mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case, it is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

*Campaign form letters.* Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

*Confidential business information.* Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: one copy of the document marked "confidential" that includes all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

*B. Issues on Which DOE Seeks Comment*

Although DOE welcomes comments on any aspect of this notice, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) The impact of proposed addenda h, i, and j to ASHRAE Standard 90.1–2010 on the energy savings presented in today's NODA;

(2) The energy savings potential of small and large evaporatively-cooled commercial package air conditioners;

(3) The market for VRF water-source heat pumps with cooling capacities below 17,000 Btu/h and above 135,000 Btu/h. DOE is seeking data and information that would allow it to accurately characterize the energy savings from amended energy conservation standards for these products;

(4) The market for large and very large SPVACs and SPVHPs;

(5) Approaches for establishing energy conservation standards for covering air conditioners and condensing units serving computer rooms;

(6) Data and information for air conditioners and condensing units serving computer rooms that could be used in performing an energy savings analysis at a future stage of this rulemaking;

(7) Approaches for developing appropriate definitions for "air conditioners and condensing units serving computer rooms" that would not result in overlap between this equipment and the other types of commercial packaged air conditioning and heating equipment covered by EPCA;

(8) The use of AHRI 1230, ASHRAE 127, and AHRI 390 as the test method for VRF equipment, air conditioners and condensing units serving computer rooms, and SPVACs and SPVHPs, respectively; and

(9) DOE's preliminary conclusion that the updates to the most recent versions of AHRI 210/240, AHRI 340/360, UL 727, ANSI Z21.47, and ANSI Z21.10.3 do not have a substantive impact on the measurement of energy efficiency for the associated equipment types for each test procedure;

(10) DOE's analysis of UEC for the water-cooled, evaporatively-cooled, SVPU equipment classes and its use in establishing the energy savings potential for higher standards. Of particular interest are other building applications for SPVU equipment and the value of incorporating these into the analysis of UEC.

(11) DOE's allocation of shipments to the eight classes of water-cooled and evaporatively-cooled equipment for which analysis was performed, as well as the future market and shipment scenarios for these products; and

(12) DOE's determination of the base-case distribution efficiencies and its prediction on how amended energy conservation standards affect the distribution of efficiencies in the standards case for the twelve classes of equipment for which analysis was performed.

## V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of data availability.

Issued in Washington, DC, on April 27, 2011.

**Kathleen Hogan,**

*Deputy Assistant Secretary for Energy Efficiency, Office of Technology Development, Energy Efficiency and Renewable Energy.*

[FR Doc. 2011–10877 Filed 5–4–11; 8:45 am]

**BILLING CODE 6450–01–P**

---

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 25

**[Docket No. NM454 Special Conditions No. 25–11–11–SC]**

## Special Conditions: Gulfstream Model GVI Airplane; Limit Engine Torque Loads for Sudden Engine Stoppage

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

**ACTION:** Notice of proposed special conditions.

**SUMMARY:** This action proposes special conditions for the Gulfstream GVI airplane. This airplane will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These design features include

engine size and the potential torque load imposed by sudden engine stoppage. These proposed special conditions pertain to their effects on the structural performance of the airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** We must receive your comments by June 20, 2011.

**ADDRESSES:** You must mail two copies of your comments to: Federal Aviation Administration, Transport Airplane Directorate, *Attn:* Rules Docket (ANM–113), Docket No. NM454, 1601 Lind Avenue SW., Renton, Washington 98057–3356. You may deliver two copies to the Transport Airplane Directorate at the above address. You must mark your comments: Docket No. NM454. You can inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

**FOR FURTHER INFORMATION CONTACT:** Carl Niedermeyer, FAA, Airframe/Cabin Safety Branch, ANM–115, Transport Standards Staff, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2279; electronic mail *Carl.Neidermeyer@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. You can inspect the docket before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want us to acknowledge receipt of your comments on this proposal, include with your comments a self-addressed, stamped postcard on which you have written the docket number. We will stamp the date on the postcard and mail it back to you.

## Background

On March 29, 2005, Gulfstream Aerospace Corporation (hereafter referred to as "Gulfstream") applied for an FAA type certificate for its new Gulfstream Model GVI passenger airplane. Gulfstream later applied for, and was granted, an extension of time for the type certificate, which changed the effective application date to September 28, 2006. The Gulfstream Model GVI airplane will be an all-new, two-engine jet transport airplane with an executive cabin interior. The maximum takeoff weight will be 99,600 pounds, with a maximum passenger count of 19 passengers.

## Type Certification Basis

Under provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Gulfstream must show that the Gulfstream Model GVI airplane (hereafter referred to as "the GVI") meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–119, 25–122, and 25.124. If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the GVI because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design features, the special conditions would also apply to the other model under provisions of § 21.101.

In addition to complying with the applicable airworthiness regulations and special conditions, the GVI must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36. The FAA must also issue a finding of regulatory adequacy pursuant to section 611 of Public Law 92–574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

## Novel or Unusual Design Features

The GVI will have high bypass engines. Engines of this size, configuration, and failure modes were not envisioned when § 25.361, which addresses loads imposed by engine seizure, was adopted in 1965. Worst case engine seizure events have become increasingly more severe with increasing engine size because of the higher inertia of the rotating components. The GVI engines are sufficiently different and novel to justify issuance of a special condition to establish appropriate design standards.

## Discussion of Proposed Special Conditions

Section 25.361(b)(1) requires that for turbine engine installations, the engine mounts and the supporting structures must be designed to withstand a "limit engine torque load imposed by sudden engine stoppage due to malfunction or structural failure." Limit loads are expected to occur about once in the lifetime of any airplane. Section 25.305 requires that supporting structures be able to support limit loads without detrimental permanent deformation, meaning that supporting structures should remain serviceable after a limit load event.

Since adoption of § 25.361(b)(1), the size, configuration, and failure modes of jet engines have changed considerably. Current engines are much larger and are designed with large bypass fans. In the event of a structural failure, these engines are capable of producing much higher transient loads on the engine mounts and supporting structures.

As a result, modern high bypass engines are subject to certain rare-but-severe engine seizure events. Service history shows that such events occur far less frequently than limit load events. Although it is important for the airplane to be able to support such rare loads safely without failure, it is unrealistic to expect that no permanent deformation will occur.

Given this situation, Aviation Rulemaking Advisory Committee (ARAC) has proposed a design standard for today's large engines. For the commonly-occurring deceleration events, the proposed standard would require engine mounts and structures to support maximum torques without detrimental permanent deformation. For the rare-but-severe engine seizure events such as loss of any fan, compressor, or turbine blade, the proposed standard would require engine mounts and structures to support maximum torques

without failure, but allows for some deformation in the structure.

The FAA concludes that modern large engines, including those on the GVI, are novel and unusual compared to those envisioned when § 25.361(b)(1) was adopted and thus warrant special conditions. The proposed special conditions contain design criteria recommended by ARAC. The proposed special conditions also clarify the design criteria that apply to auxiliary power units.

## Applicability

As discussed above, these proposed special conditions are applicable to the GVI. Should Gulfstream apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, these proposed special conditions would apply to that model as well.

## Conclusion

This action affects only certain novel or unusual design features of the GVI. It is not a rule of general applicability.

## List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

## The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for the GVI airplanes.

In lieu of § 25.361(b) the following special conditions are proposed:

1. For turbine engine installations, the engine mounts, pylons and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum limit torque loads imposed by each of the following:

(a) Sudden engine deceleration due to a malfunction which could result in a temporary loss of power or thrust; and

(b) The maximum acceleration of the engine.

2. For auxiliary power unit installations, the power unit mounts and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum limit torque loads imposed by each of the following:

(a) Sudden auxiliary power unit deceleration due to malfunction or structural failure; and

(b) The maximum acceleration of the power unit.

3. For engine supporting structure, an ultimate loading condition must be considered that combines 1g flight loads with the transient dynamic loads resulting from:

(a) The loss of any fan, compressor, or turbine blade; and

(b) Separately, where applicable to a specific engine design, any other engine structural failure that results in higher loads.

4. The ultimate loads developed from the conditions specified in paragraphs 3(a) and 3(b) are to be multiplied by a factor of 1.0 when applied to engine mounts and pylons and multiplied by a factor of 1.25 when applied to adjacent supporting airframe structure.

5. Any permanent deformation that results from the conditions specified in paragraph 3 must not prevent continued safe flight and landing.

Issued in Renton, Washington, on April 20, 2011.

**KC Yanamura,**

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

[FR Doc. 2011–10922 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–13–P**

---

## DEPARTMENT OF EDUCATION

## 34 CFR Chapter VI

**[Docket ID ED–2011–OPE–0003]**

## Negotiated Rulemaking Committees; Public Hearings

**AGENCY:** Office of Postsecondary Education, Department of Education.

**ACTION:** Intent to establish negotiated rulemaking committees.

**SUMMARY:** We announce our intention to establish one or more negotiated rulemaking committees to propose regulations under the Higher Education Act of 1965, as amended (HEA). The committees will include representatives of organizations or groups with interests that are significantly affected by the subject matter of the proposed regulations, as described more fully in the *Regulatory Issues* section of this document. We also announce three public hearings, at which interested parties may suggest additional issues that should be considered for action by the negotiating committees. In addition, for anyone unable to attend a public hearing, we announce that the Department will accept written comments.

Finally, the Department announces that it will conduct roundtable discussions that focus on the areas of teacher preparation, college completion, and the Department's proposed "First in the World" competition, as more fully described in the Roundtable Discussions section of this document.

**DATES:** The dates, times, and locations of the public hearings and the roundtable discussions are listed under the **SUPPLEMENTARY INFORMATION** section of this notice. We must receive written comments suggesting issues that should be considered for action by the negotiating committees on or before May 20, 2011.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by e-mail. Please submit your comments only one time, in order to ensure that we do not receive duplicate copies. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for finding a notice, submitting a comment, finding a comment, and signing up for e-mail alerts, is available on the site under "How to Use Regulations.gov" in the Help section.
- *Postal Mail, Commercial Delivery, or Hand Delivery.* If you mail or deliver your comments about these proposed regulations, address them to Nikki Harris, U.S. Department of Education, 1990 K Street, NW., room 8033, Washington, DC 20006.

**Privacy Note:** The Department's policy for comments received from members of the public (including those comments submitted by mail, commercial delivery, or hand delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the Internet.

**FOR FURTHER INFORMATION CONTACT:** For information about the public hearings and roundtable discussions, go to *http://www2.ed.gov/policy/highered/reg/hearulemaking/2011/hearings.html* or contact: Nikki Harris, U.S. Department of Education, 1990 K Street, NW., room 8033, Washington, DC 20006. Telephone: (202) 219–7050. You may also e-mail your questions about the public hearings to: *negreg.2011@ed.gov.*

For information about negotiated rulemaking in general, go to *The Negotiated Rulemaking Process for Title*

*IV Regulations, Frequently Asked Questions* at *http://www.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html* or contact: Wendy Macias, U.S. Department of Education, 1990 K Street, NW., room 8017, Washington, DC 20006. Telephone: (202) 502–7526. You may also e-mail your questions about negotiated rulemaking to: *Wendy.Macias@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting Nikki Harris, U.S. Department of Education, 1990 K Street, NW., room 8033, Washington DC 20006 Telephone: (202) 219–7050.

**SUPPLEMENTARY INFORMATION:** Section 492 of the HEA requires that, before publishing any proposed regulations to implement programs authorized under title IV of the HEA, the Secretary obtain public involvement in the development of the proposed regulations. After obtaining advice and recommendations from the public, the Secretary conducts negotiated rulemaking to develop the proposed regulations. We announce our intent to develop proposed title IV, HEA regulations by following the negotiated rulemaking procedures in section 492 of the HEA.

We intend to select participants for each negotiated rulemaking committees from nominees of the organizations and groups that represent the interests significantly affected by the proposed regulations. To the extent possible, we will select, from the nominees, individual negotiators who reflect the diversity among program participants, in accordance with section 492(b)(1) of the HEA.

In addition, the Secretary is interested in receiving public comment on the issues summarized in the *Roundtable Discussions* section of this notice. The Secretary is particularly interested in receiving public comment on the development of proposed regulations under sections 205 and 207 in title II of the HEA on streamlining institutional reporting requirements and improving State identification of low-performing teacher preparation programs.

## Regulatory Issues

We intend to convene at least one committee to develop proposed regulations to address title IV loan program issues. These regulations would address issues such as those arising from the changes made to the HEA by the Student Aid Fiscal Responsibility Act (SAFRA), title II of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which ended the origination of loans under the Federal Family Education Loan (FFEL) Program as of July 1, 2010. With this statutory change, all new Stafford, PLUS and Consolidation loan originations with a first disbursement on or after July 1, 2010, are made under the William D. Ford Federal Direct Loan (Direct Loan) Program. As a result of the statutory change, the Department intends to streamline the loan program regulations by repealing unnecessary FFEL Program regulations in 34 CFR part 682 and incorporating and modifying necessary requirements within the Direct Loan Program regulations in 34 CFR part 685, as appropriate. In addition, we intend to address, through negotiated rulemaking, other issues in the Federal student loan programs, including possible changes in the regulations governing the income-contingent and income-based repayment plans and the process for making total and permanent disability determinations.

As noted elsewhere in this notice, we are also considering developing proposed regulations to streamline institutional reporting requirements, and proposed regulations regarding better State identification of low-performing teacher preparation programs pursuant to sections 205 and 207 of the HEA through focusing reporting on improved measures of program quality.

After a complete review of the public comments presented at the public hearings and in the written submissions, we will publish a subsequent document (or documents) announcing the specific subject areas for which we intend to establish one or more negotiated rulemaking committees, and a request for nominations for individual negotiators who represent the interests significantly affected by the proposed regulations.

## Public Hearings

We will hold three public hearings for interested parties to discuss the rulemaking agenda. The public hearings will be held on:

- May 16, 2011, at Pacific Lutheran University in Tacoma, Washington
- May 19, 2011, at Loyola University-Lakeshore Campus in Chicago, Illinois
- May 26, 2011, at College of Charleston in Charleston, South Carolina

The public hearings will be held from 9:00 a.m. to 4:00 p.m., local time. Further information on the public hearing sites, including addresses and directions, is available at *http://www2.ed.gov/policy/highered/reg/hearulemaking/2011/hearings.html.*

Individuals desiring to present comments at the public hearings must register by sending an e-mail to *negreg.2011@ed.gov.* The e-mail should include the name of the presenter along with a general timeframe during which the individual would like to speak (for example, a presenter could indicate morning or afternoon, or before 11:00 a.m. or after 3:00 p.m.). We will attempt to accommodate each speaker's preference but, if we are unable to do so, we will make the determination based on the time and date the e-mail was received. It is likely that each participant will be limited to five minutes. The Department will notify registrants indicating the specific location and time slot reserved for them. An individual may make only one presentation at the public hearings. If we receive more registrations than we are able to accommodate, the Department reserves the right to reject the registration of an entity or individual that is affiliated with an entity or individual that is already scheduled to present comments, and to select among registrants to ensure that a broad range of entities and individuals is allowed to present. We will accept walk-in registrations for any remaining time slots on a first-come first-served basis beginning at 8:30 a.m. on the day of the public hearing at the Department's on-site registration table.

Speakers may also submit written comments. In addition, for anyone who does not present comments at a public hearing, the Department will accept written comments through May 20, 2011. (See the **ADDRESSES** sections of this document for submission information.)

## Roundtable Discussions

On the day following each public hearing, the Department intends to conduct roundtable discussions at the same location as each public hearing, from 9:00 a.m. to 1:00 p.m. local time. The Department also intends to conduct roundtable discussions from 9:00 a.m. to 1:00 p.m. local time at Tennessee State University in Nashville, Tennessee on May 12, 2011. The Department may hold additional roundtable discussions, which will be announced on the Department's Web site at: *http://www2.ed.gov/policy/highered/reg/hearulemaking/2011/roundtable.html.*

These roundtable discussions are intended to complement the hearings, which will have a broader focus, and inform the policy development process in the specific areas of teacher

preparation, college completion, and a "First in the World" competition. For those unable to attend one of the policy roundtable discussions, we will also accept written comments and suggestions on the topics discussed at the roundtable.

The Department intends to use these roundtable discussions to inform our postsecondary education policies in three key areas—teacher preparation, college completion, and the proposed "First in the World" grant competition, proposed in the President's fiscal year (FY) 2012 budget under the Fund for the Improvement of Postsecondary Education (FIPSE). The three roundtable discussions at each of the four locations announced above will each focus on one of these areas.

The first topic will be the design and implementation plans for teacher preparation programs. We will discuss: (1) The proposed Presidential Teaching Fellows program along with the already authorized Honorable Augustus F. Hawkins Centers for Excellence program (subpart 2, part B, title II of the HEA) for which the Administration has requested funding; (2) ways in which the Department can streamline institutional reporting requirements; and (3) State identification of low-performing teacher preparation programs pursuant to sections 205 and 207 of the HEA.

A second topic will be college completion, with a focus on obtaining information about State-level reform efforts that show the most promise for increasing college completion. We will also discuss the College Completion Incentive Grants program, proposed in the President's fiscal year (FY) 2012 budget, which would encourage States to make systemic reforms in their higher education systems to increase the number of students who complete a postsecondary degree or certificate program and also reward institutions within those States that increase their completion rates.

The third topic will be possible priorities and structure for the (FIPSE) "First in the World" competition. The purpose of this discussion is to obtain information about institutional reform efforts that show the most promise for increasing college completion, expanding institutional capacity, and improving quality of student outcomes. This input will be used to inform the development of competitive preferences and invitational priorities and the structure of the FIPSE "First in the World" competition.

While the Department is inviting representatives of students, families, teachers, teacher educators, college access professionals, and college success practitioners to participate in these roundtable discussions, the roundtable discussions will also be open to the public, with opportunities to provide public comment. Individuals desiring to participate in the roundtable discussions must register by sending an email to *HigherEducationRoundtable.2011@ed.gov.* The email should include the name of the participant and his or her affiliation, and identify which policy roundtable discussion she or he would like to participate in, and at which location. We will attempt to accommodate each participant's preference but, if we are unable to do so, we will make the determination based on the time and date the email was received. The Department will notify each registrant by email of the specific location and roundtable discussion he or she was selected to participate in. An individual may only participate in one roundtable discussion per location. If we receive more registrations than we are able to accommodate, the Department reserves the right to reject the registration of an entity or individual that is affiliated with an entity or individual that is already scheduled to participate in the same roundtable discussion, and to select among registrants to ensure that a broad range of entities and individuals are allowed to present. We will accept walk-in participants on a first-come first-served basis beginning at 8:30 a.m. on the day of each roundtable discussion at the Department's on-site registration table.

The public hearing/roundtable sites are accessible to individuals with disabilities. Individuals needing an auxiliary aid or service to participate in the hearing or a roundtable discussion (e.g., interpreting service, assistive listening device, or materials in alternative format), should notify the contact person identified for information about hearings listed under **FOR FURTHER INFORMATION CONTACT** in this document in advance of the scheduled hearing date. Although we will attempt to meet any request we receive, we may not be able to make available the requested auxiliary aid or service if we do not have sufficient time to arrange it.

*Schedule for Negotiations*

We anticipate that any negotiated rulemaking committees established after these public hearings will begin negotiations in August or September 2011, with each committee meeting for up to three sessions of approximately three days at roughly monthly intervals. The committees will meet in the Washington, DC area. The dates and locations of these meetings will be announced in a subsequent document in the **Federal Register**, and will be posted on the Department's Web site at: *http://www2.ed.gov/policy/highered/reg/hearulemaking/2011/hearings.html.*

*Electronic Access to This Document:* The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *http://www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *http://www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

**Program Authority:** 20 U.S.C. 1022–1022h, 1098a.

Dated: April 28, 2011.

**Eduardo M. Ochoa,**

*Assistant Secretary for Postsecondary Education.*

[FR Doc. 2011–10909 Filed 5–4–11; 8:45 am]

**BILLING CODE 4000–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[EPA–R08–OAR–2009–0556; FRL–9302–3]**

## Approval and Promulgation of Air Quality Implementation Plans; North Dakota; Revisions to the Air Pollution Control Rules

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve revisions to the North Dakota State Implementation Plan that the Governor of North Dakota submitted with a letter dated April 6, 2009. The revisions affect North Dakota's air pollution control rules regarding general provisions (including rules regarding shutdowns and malfunctions), ambient air quality standards, emissions of particulate matter, permitting, and fees. In addition, EPA is proposing administrative corrections to the regulatory text for

North Dakota that will be codified in the Code of Federal Regulations; we made errors in the identification of plan table when we approved the North Dakota State Implementation Plan revisions for Interstate Transport of pollution, which the Governor also submitted on April 6, 2009. This action is being taken under section 110 of the Clean Air Act.

**DATES:** Comments must be received on or before June 6, 2011.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2009–0556, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- E-mail: *Fallon.Gail@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** section if you are faxing comments).
- Mail: Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- Hand Delivery: Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–R08–OAR–2009–0556. 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section I, "General Information," of the **SUPPLEMENTARY INFORMATION** section of this document.

*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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Gail Fallon, EPA Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, CO 80202–1129, (303) 312–6281, *Fallon.Gail@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Table of Contents

I. General Information
II. Background
III. Analysis of SIP Revisions
IV. Corrections to Regulatory Text
V. Section 110(l)
VI. Proposed Action
VII. Statutory and Executive Order Reviews

## Definitions

For the purpose of this document, the following definitions apply:

(i) The words or initials *Act* or *CAA* mean or refer to the Federal Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The initials *NAAQS* mean or refer to the National Ambient Air Quality Standards.

(v) The words *State* or *ND* mean the State of North Dakota, unless the context indicates otherwise.

(vi) The initials *NDDH* mean or refer to the North Dakota Department of Health.

## I. General Information

### *A. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *http://regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

## II. Background

The Act requires States to follow certain procedures in developing implementation plans and plan revisions for submission to us. Sections 110(a)(2) and 110(l) of the Act provide that each implementation plan must be adopted after reasonable notice and public hearing.

To provide for public comment, the North Dakota Department of Health (NDDH), after providing notice, held a public hearing on October 7, 2008 to consider the revisions to the Air Pollution Control Rules. Following the public hearing, comment period, and legal review by the North Dakota Attorney General's Office, NDDH adopted the revisions. The revisions to the Air Pollution Control Rules became effective on April 1, 2009. The North Dakota Governor submitted the SIP revisions to us with a letter dated April 6, 2009. This submittal also included (1) SIP revisions to address Interstate Transport requirements related to the 1997 8-hour ozone and $PM_{2.5}$ NAAQS, which we acted on in 2010 (75 FR 31290, June 3, 2010, and 75 FR 71023, November 22, 2010), and (2) SIP revisions (commonly referred to as "infrastructure" requirements) to address implementation of current NAAQS for $PM_{10}$, $PM_{2.5}$, and ozone, which we will be acting on separately. In our June 3, 2010 and November 22, 2010 actions on North Dakota's Interstate Transport SIP revisions, we made errors in the identification of plan table located in 40 CFR 52.1820(e). We describe these errors in section IV, below.

## III. Analysis of SIP Revisions

The SIP revisions in the April 6, 2009 submittal that we are proposing to act on in this document involve the following chapters of the North Dakota Administrative Code (N.D.A.C.): 33–15–01, "General Provisions;" 33–15–02, "Ambient Air Quality Standards;" 33–15–05, "Emissions of Particulate Matter Restricted;" 33–15–14, "Designated Air Contaminant Sources, Permit to Construct, Minor Source Permit to Operate, Title V Permit to Operate;" and 33–15–23, "Fees." The following is our description and analysis of the revisions.

### *A. Chapter 33–15–01, N.D.A.C., General Provisions*

The State revised sections 33–15–01–04, 33–15–01–05, and 33–15–01–13 and submitted the entire revised sections to us for approval. In section 33–15–01–04, the State made the following changes: (1) The State revised the definition of "air contaminant" to add the words, "emitted to the ambient air" to the end of definition; (2) the State added definitions for "excess emissions" and "$PM_{2.5}$;" (3) the State re-numbered the definitions to account for the addition of new definitions; and (4) the State cross-referenced and incorporated by reference the version of 40 CFR 51.100(s) as it existed on March 1, 2008 for purposes of defining "volatile organic compounds" (the prior date used was January 1, 2006). These changes are minor and are consistent with relevant CAA and regulatory requirements.

In section 33–15–01–05, the State added abbreviations for PM and $PM_{2.5}$. These revisions are minor and are consistent with the CAA.

The State made several revisions to 33–15–01–13, "Shutdown and Malfunction of an Installation—Requirement for notification." In 33–15–01–13.1, "Maintenance shutdowns," the State adopted new subdivision f, which reads, "Nothing in this subsection shall in any manner be construed as authorizing or legalizing the emission of air contaminants in excess of the rate allowed by this article or a permit issued pursuant to this article." Previously, we had been concerned that the language of 33–15–01–13.1 could be construed as exempting from enforcement excess emissions during shutdown of air pollution control equipment for scheduled maintenance. EPA's interpretation is that the CAA requires that all periods of excess emissions, regardless of cause, be treated as violations and that automatic exemptions from emissions limits are not appropriate.[1] Subdivision f clarifies that excess emissions are not authorized during maintenance shutdowns. Subdivision f is consistent with CAA requirements.

In 33–15–01–13.2, "Malfunctions," the State removed certain language and added other language. In 33–15–01–13.2.a, the State removed language indicating that the State could permit the continued operation of an installation during a malfunction resulting in a violation of an emissions limit. We were concerned that this language could be construed to exempt excess emissions caused by malfunctions when the State granted permission to continue operations. EPA's interpretation is that such an exemption would be inconsistent with the CAA. The removal of the language is consistent with CAA requirements.

The State added 33–15–01–13.2.c to 33–15–01–13.2. This new subdivision c identifies procedures sources and the State will follow with respect to unavoidable malfunctions. Where a source believes that excess emissions have resulted from an unavoidable malfunction, the source must submit a written report to the State that includes evidence relevant to six criteria specified in the rule. The report must be submitted within thirty days of the end of the calendar quarter in which the malfunction occurred or within thirty days of a written request by North Dakota, whichever is sooner. The rule provides that North Dakota will evaluate the information submitted by the source on a case-by-case basis to determine whether to pursue enforcement action and that North Dakota may elect not to pursue enforcement action after considering whether excess emissions resulted from an unavoidable equipment malfunction. The rule also provides that the burden of proof is on the source to provide sufficient information to demonstrate that an unavoidable equipment malfunction occurred.

Under EPA's interpretations of the CAA as set forth in the 1982, 1983, and 1999 Memoranda, if a state in its SIP chooses to address violations that occur as a result of claimed malfunctions, the state may take two approaches. The first, the "enforcement discretion" approach, allows a state director to refrain from taking enforcement action for a violation if certain criteria are met. The second, the "affirmative defense" approach, allows a source to avoid penalties if it can prove that certain

[1] This interpretation has been expressed in several documents. Most relevant to this action are the following: Memorandum dated September 28, 1982, from Kathleen M. Bennett, Assistant Administrator for Air, Noise, and Radiation, entitled "Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions" (the 1982 Memorandum); a clarification to that memorandum from Kathleen M. Bennett issued on February 15, 1983 (the 1983 Memorandum); and a memorandum dated September 20, 1999 entitled "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown," from Steven A. Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Robert Perciasepe, Assistant Administrator for Air and Radiation (the 1999 Memorandum). As explained in these memoranda, because excess emissions might aggravate air quality so as to prevent attainment and maintenance of the NAAQS and compliance with other CAA requirements, EPA views all periods of excess emissions as violations of the applicable emission limitation. Therefore, EPA will disapprove SIP revisions that automatically exempt from enforcement excess emissions claimed to result from an equipment malfunction. In addition, as made explicit in the 1999 Memorandum, EPA will disapprove SIP revisions that give discretion to a state director to determine whether an instance of excess emissions is a violation of an emission limitation, because such a determination could bar EPA and citizens from enforcing applicable requirements.

conditions are met. North Dakota's 33–15–01–13.2.c follows the enforcement discretion approach.

We have evaluated North Dakota's enforcement discretion provisions for excess emissions caused by unavoidable equipment malfunctions and find that they are consistent with EPA's interpretations of the CAA as described in the memoranda above. In particular, the criteria specified in 33–15–01–13.2.c that the State will consider in deciding whether to pursue an enforcement action generally parallel the criteria outlined in the 1982 and 1983 Memoranda.

As noted in footnote 1, above, the 1999 Memorandum also discusses a point not explicitly addressed in North Dakota's new rule—i.e., EPA will not approve SIP revisions that recognize or appear to recognize a state's decision not to pursue enforcement as barring enforcement action by EPA or citizens. Rule 33–15–01–13.2.c only addresses the State's exercise of its enforcement discretion and contains no language suggesting that a State decision not to pursue an enforcement action for a particular violation bars EPA or citizens from taking an enforcement action. Therefore, EPA interprets the rule, consistent with EPA's interpretations of the CAA, as not barring EPA and citizen enforcement of violations of applicable requirements when the State declines enforcement.

In 33–15–01–13.3, "Continuous emission monitoring system failures," the State removed the phrase, "acceptable to the department," from the text, "When a failure of a continuous emission monitoring system occurs, an alternative method, acceptable to the department, for measuring or estimating emissions must be undertaken as soon as possible." Following this sentence, the State added a new sentence that reads as follows: "The owner or operator of a source that uses an alternative method shall have the burden of demonstrating that the method is accurate." We had asked the State to remove the language "acceptable to the department" from the rule and find that the new language is consistent with CAA requirements.

In previous rulemakings, we referenced an April 11, 2003 submission of revisions to 33–15–01–13 and indicated that we would act on that submission at a later date. See 69 FR 61762, October 21, 2004; 70 FR 45539, October 8, 2005; and 71 FR 3764, January 24, 2006. However, in an August 17, 2009 letter, North Dakota advised EPA that the April 11, 2003 submission erroneously indicated there had been revisions to 33–15–01–13.1.d, and that in fact the cited revisions to 33–15–01–13.1.d had not been adopted and were not submitted to EPA with the Governor's April 11, 2003 letter. Therefore, there are no remaining revisions from the April 11, 2003 submittal awaiting EPA's action.

*B. Chapter 33–15–02, N.D.A.C., Ambient Air Quality Standards*

Table 1 was revised to amend the $PM_{10}$ and ozone standards and to add the 2006 $PM_{2.5}$ standard. These revisions were made to reflect the Federal standards and are consistent with CAA requirements.

*C. Chapter 33–15–05, N.D.A.C., Emissions of Particulate Matter Restricted*

The State removed section 33–15–05–03.2.2.d., which provided that the State could approve continued operation of a trash incinerator during a malfunction of combustion equipment, emission control equipment, monitoring equipment, or waste charging equipment. We were concerned that section 33–15–05–03.2.2.d could be construed to exempt excess emissions at trash incinerators caused by malfunctions when the State granted permission to the source to continue operations. EPA's interpretation is that such an exemption would be inconsistent with the CAA. We asked the State to address our concern. The removal of section 33–15–05–03.2.2.d addresses our concern and is consistent with CAA requirements. The SIP will no longer provide a potential exemption to trash incinerators operating during malfunctions based on State approval of continued operation during such periods. Instead, malfunctions at trash incinerators would be treated the same as malfunctions at other sources subject to SIP requirements—i.e., the source would need to follow the procedures contained in section 33–15–01–13.2.

*D. Chapter 33–15–14, N.D.A.C., Designated Air Contaminant Sources, Permit To Construct, Minor Source Permit To Operate, Title V Permit To Operate*

In section 33–15–14–01, "Designated Air Contaminant Sources," the State revised the list of sources "capable of causing or contributing to air pollution." Specifically, the State added the word "major" to 33–15–14–01.14 so that it now reads as follows: "Any major source to which a national emission standard for hazardous air pollutants for source categories (40 CFR 63) would apply." This change only affects the applicability of certain permitting requirements contained in Chapter 33–15–14. It does not affect emission limits in the SIP or other requirements that would affect ambient concentrations of criteria pollutants. It also does not affect the applicability of 40 CFR part 63 requirements. This change is consistent with CAA requirements.

*E. Chapter 33–15–23, N.D.A.C., Fees*

The State revised section 33–15–23–03, "Minor source permit to operate fees." The State simplified the definition of a "designated" source. (The rule establishes a fee for designated sources.) The State also expanded the exemption from fees for State government facilities to include local government facilities. This latter revision simply codified the State's standing practice of not collecting fees from local governments. In addition, the State made a minor change to the due date for sources to submit the annual permit fee; the fee is now due within 60 days following the date of the State's fee notice rather than within 60 days of receipt of the fee notice. These are minor clarifying changes that do not impact compliance with CAA requirements.

## IV. Corrections to Regulatory Text

On June 3, 2010 and November 22, 2010 we published final rules approving portions of the revised North Dakota SIP for Interstate Transport of Pollution for the 1997 $PM_{2.5}$ and 8–Hour Ozone NAAQS. See 75 FR 31290 and 75 FR 71023. When we published those rules, we included regulatory text that was incorrect. Specifically, we made errors in the "Identification of plan" table contained in 40 CFR 52.1820(e), "EPA-approved nonregulatory provisions." As published in our November 22, 2010 action (which augmented and revised the table contained in our June 3, 2010 action), the first portion of the explanation for item (1) in the table read as follows: "Excluding subsequent revisions, as follows: Chapters 1, 2, 6, 7, 9, 11, and 12; Sections 2.11, 3.7, 6.8, 6.10, 6.11, 6.13, 7.7, and 8.3; subsections 7.8.1.B., 7.8.1.D., and 8.3.1." [2] It should have read, "Excluding subsequent revisions, as follows: Chapters 6, 11, and 12; Sections 2.11, 3.7, 6.10, 6.11, 6.13, and 8.3; and Subsections 3.2.1, 5.2.1, 7.8.1.A, 7.8.1.B, 7.8.1.C, and 8.3.1." We also incorrectly listed the submittal date for items (21) and (22) in the table as 4/09/09 instead

[2] The most recent version of the CFR was current as of July 1, 2010 and does not reflect the regulatory language contained in our November 22, 2010 action. The regulatory language as contained in our November 22, 2010 action does appear in the electronic CFR on the GPOAccess website: *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=4d2eed6d6a2a14bd914c123a19f553c3&rgn=div8&view=text&node=40:4.0.1.1.1.16.1.1&idno=40.*

of 4/06/09. Therefore, we are proposing to correct the identification of plan table in 40 CFR 52.1820(e) accordingly.

**V. Section 110(l)**

Under section 110(l) of the CAA, EPA cannot approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress toward attainment of the NAAQS or any other applicable requirement of the Act. As described in section III, above, most of the revisions we are proposing to approve conform the North Dakota SIP to relevant CAA requirements. In particular, the State revised shutdown and malfunction provisions to comport with CAA requirements. The other changes we are proposing to approve are minor and will not interfere with attainment or reasonable further progress toward attainment of the NAAQS [3] or any other CAA requirements.

**VI. Proposed Action**

EPA is proposing to approve revisions to the North Dakota SIP that the Governor of North Dakota submitted with a letter dated April 6, 2009 and that were State-effective April 1, 2009. Specifically, EPA is proposing to approve North Dakota's revisions to the following portions of the North Dakota Administrative Code: Chapter 33–15–01, "General Provisions," sections 33–15–01–04, 33–15–01–05, and 33–15–01–13; Chapter 33–15–02, "Ambient Air Quality Standards," section 33–15–02, Table 1; Chapter 33–15–05, "Emissions of Particulate Matter Restricted," subsection 33–15–05–03.2.2; Chapter 33–15–14, "Designated Air Contaminant Sources, Permit to Construct, Minor Source Permit to Operate, Title V Permit to Operate," subsection 33–15–14–01.14; and Chapter 33–15–23, "Fees," section 33–15–23–03. See section III of this action, above, for a description of these revisions.

In addition, EPA is proposing administrative corrections to the regulatory text for North Dakota that will appear in the Code of Federal Regulations. Specifically, we are proposing to change the identification of plan table that will appear at 40 CFR 52.1820(e) as follows:

a. We will change the first portion of the explanation for item (1) in the table to read, "Excluding subsequent revisions, as follows: Chapters 6, 11, and 12; Sections 2.11, 3.7, 6.10, 6.11, 6.13, and 8.3; and Subsections 3.2.1, 5.2.1, 7.8.1.A, 7.8.1.B, 7.8.1.C, and 8.3.1."

b. We will change the submittal dates for items (21) and (22) in the table to read, "4/06/09."

See section IV of this action, above, for further information regarding these corrections.

**VII. Statutory and Executive Order Reviews**

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 27, 2011.

**Judith Wong,**

*Acting Regional Administrator, Region 8.*

[FR Doc. 2011–10995 Filed 5–4–11; 8:45 am]

BILLING CODE 6560–50–P

[3] North Dakota has no nonattainment areas. Thus, CAA part D requirements, including the requirement to make reasonable further progress toward attainment, do not apply in North Dakota.

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

## 48 CFR Part 1809

**RIN 2700–AD54**

## Responsibility; Suspension and Debarment

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** NASA is revising the NASA FAR Supplement (NFS) to update internal processing procedures related to suspension and debarment. Although the procedures do not impact the public and will not be codified in the Code of Federal Regulations, one related change does impact the public and that is a new requirement for contracting officers to notify prospective contractors if they are found to be non-responsible. Notification provides the prospective contractor with the opportunity to take corrective action prior to future solicitations.

**DATES:** Interested parties should submit comments to NASA at the address below on or before July 5, 2011 to be considered in formulation of the final rule.

**ADDRESSES:** Interested parties may submit comments, identified by RIN number 2700–AD54, using either of the following methods: (1) Regulations.gov: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking

portal by inputting RIN 2007–AD64 under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "RIN 2007–AD54." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "RIN 2700–AD54" on your attached document. (2) E-mail: *leigh.pomponio@nasa.gov.* Include RIN 2007–AD54 in the subject line of the message.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov* approximately two to three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** Leigh Pomponio, NASA, Office of Procurement, (202) 358–0592; e-mail: *leigh.pomponio@nasa.gov.*

**SUPPLEMENTARY INFORMATION:**

### A. Background

NASA is proposing to amend the NASA FAR Supplement to include a requirement for contracting officers to notify prospective contractors if they are found non-responsible for award. Such notification permits potential contractors to improve their opportunities for future awards by addressing the non-responsibility issues. This proposed rule is consistent with FAR 9.104–6, Federal Awardee Performance and Integrity Information System (FAPIIS). Because contracting officers use FAPIIS to obtain pre-award information, and to enter determinations of non-responsibility for public display, it is a good practice to personally notify contractors of non-responsibility findings and the basis of the finding in an effort to afford potential contractors an opportunity to improve the underlying causes for a non-responsibility determination and to promote maximum competition for future awards.

### B. Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has NOT been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. This is not a major rule under 5 U.S.C. 804.

### C. Regulatory Flexibility Act

This final rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* because it does not impose any new requirements on small entities. This rule only imposes requirements on Government personnel; the impact on the public, including small entities, is the receipt of additional information.

### D. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104–13) is not applicable because the NFS changes do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

### List of Subjects in 48 CFR Part 1809

Government procurement.

**William P. McNally,**

*Assistant Administrator for Procurement.*

Accordingly, 48 CFR Part 1809 is amended as follows:

1. The authority citation for 48 CFR Part 1809 continues to read as follows:

**Authority:** 42 U.S.C. 2455(a), 2473(c)(1)

## PART 1809—CONTRACTOR QUALIFICATIONS

2. Section 1809.105–2 is added to Subpart 1809.1 to read as follows:

**1809.105–2 Determinations and documentation.**

(a) The contracting officer shall provide written notification to a prospective contractor determined not responsible, which includes the basis for the determination. Notification provides the prospective contractor with the opportunity to take corrective action prior to future solicitations.

[FR Doc. 2011–10919 Filed 5–4–11; 8:45 am]

BILLING CODE 7510–01–P

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

## 48 CFR Parts 1812, 1828, and 1852

**RIN 2700–AD55**

## Cross-Waiver of Liability Clauses

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Proposed rule.

**SUMMARY:** NASA proposes to revise the NASA FAR Supplement (NFS) to consolidate and make changes to three currently-existing cross-waiver of liability clauses. The changes include consolidation of the three clauses into two clauses and retitleing the two clauses to more closely align the clauses with current mission programs including International Space Station (ISS) activities, and Science or Space Exploration activities unrelated to the ISS. The existing Expendable Launch Vehicle (ELV) clause will be broadened to apply to contracts and subcontracts related to a launch of any kind other than one involving the International Space Station. The International Space Station (ISS) activities cross-waiver of liability clause is revised and its applicably broadened to include Space Shuttle activities related to the ISS. Accordingly, the Space Shuttle services clause will be deleted in its entirety with all Space Shuttle activity falling under one of the two remaining clauses. These proposed changes to the NFS are being made to align contract clauses with the regulatory authority established by a final rule published February 26, 2008, which established NASA's cross-waiver of liability authority in two categories of NASA agreements.

**DATES:** Interested parties should submit comments on or before July 5, 2011 to be considered in formulation of the final rule.

**ADDRESSES:** Interested parties may submit comments, identified by RIN number 2700–AD55, via the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments may also be submitted to R. Todd Lacks (Mail Stop 5J75), NASA Headquarters, Office of Procurement, Contract Management Division, Washington, DC 20546. Comments may also be submitted by e-mail to *todd.lacks@nasa.gov.*

**FOR FURTHER INFORMATION CONTACT:** R. Todd Lacks, NASA, Office of Procurement, Contract Management Division (Suite 5J75); (202) 358–0799; *e-mail: todd.lacks@nasa.gov.*

**SUPPLEMENTARY INFORMATION:** These proposed changes to the NFS are being made to align contract clauses with the regulatory authority established by the final rule published at 73 FR 10143–50, dated 26 February 2008. The February 2008 rule established NASA's cross-waiver of liability authority in two categories of NASA agreements: (1) Agreements for ISS activities pursuant to the "Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America concerning Cooperation on the Civil International Space Station" (commonly referred to as the ISS Intergovernmental Agreement, or IGA); and (2) launch agreements involving science or space exploration activities unrelated to the ISS. Sections 1812.301(f)(i)(K), (L), and (M) and 1828.371 of the NFS are being changed to reflect the new titles for clauses 1852.228–76 and 1852.228–78 and deletion of 1852.228–72.

### A. Background

NASA has been including cross-waivers of liability in its launch services agreements with U.S. and foreign parties since NASA's original cross-waiver regulations were published in 1991. By incorporating the cross-waivers of liability into agreements for International Space Station (ISS) activities and Science or Space Exploration activities unrelated to the ISS that involve a launch, each Party, as defined in the cross-waiver, agree to waive all claims against any entity or person defined in the cross-waiver for damage to their property arising out of Protected Space Operations. These cross-waivers also require the parties to extend these cross-waivers to their related entities ensuring those related entities also waive all claims against any entity or person defined in the cross-waiver for damages arising out of Protected Space Operations.

### B. Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

### C. Regulatory Flexibility Act

NASA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* because the rule does not impose any additional requirements on small businesses. This proposed rule updates and clarifies already-existing requirements.

### D. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104–13) is not applicable because the NFS changes do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

### List of Subjects in 48 CFR Parts 1812, 1828, and 1852

Government procurement.

**William P. McNally,**

*Assistant Administrator for Procurement.*

Accordingly, 48 CFR parts 1812, 1828, and 1852 are proposed to be amended as follows:

1. The authority citation for 48 CFR parts 1812, 1828, and 1852 continues to read as follows:

**Authority:** 42 U.S.C. 2455(a), 2473(c)(1).

## PART 1812—ACQUISITION OF COMMERCIAL ITEMS

2. In section 1812.301, paragraph (f)(i)(K) is removed and reserved, and paragraphs (f)(i)(L) and (f)(i)(M) are revised to read as follows:

**1812.301 Solicitation provisions and contract clauses for the acquisition of commercial items. (NASA supplements paragraph (f))**

(f)(i) * * *

(L) 1852.228–76, Cross-Waiver of Liability for International Space Station Activities.

(M) 1852.228–78, Cross-Waiver of Liability for Science or Space Exploration Activities unrelated to the International Space Station.

* * * * *

## PART 1828—BONDS AND INSURANCE

3. Section 1828.371 is revised to read as follows:

**1828.371 Clauses incorporating cross-waivers of liability for International Space Station activities and Science or Space Exploration activities unrelated to the International Space Station.**

(a) In contracts covering International Space Station activities, or Science or Space Exploration activities unrelated to the International Space Station that involve a launch, NASA shall require the contractor to agree to waive all claims against any entity or person defined in the clause based on damage arising out of Protected Space Operations. This cross-waiver shall apply only if the person, entity, or property causing the damage is involved in Protected Space Operations and the person, entity, or property damaged is damaged by virtue of its involvement in Protected Space Operations. The cross-waivers will require the contractor to extend the cross-waiver provisions to their subcontractors at any tier and related entities ensuring those subcontractors and related entities also waive all claims against any entity or person defined in the clause for damages arising out of Protected Space Operations. The purpose of the clauses prescribed in this section is to extend the cross-waivers under other agreements to NASA contractors that perform work in support of NASA's obligations under these agreements.

(b) The contracting officer shall insert the clause at 1852.228–78, Cross-Waiver of Liability for Science or Space Exploration Activities unrelated to the International Space Station, in solicitations and contracts above the simplified acquisition threshold for the acquisition of launches for science or space exploration activities unrelated to the International Space Station or for acquisitions for science or space exploration activities that are not related to the International Space Station but involve a launch. If Space Shuttle services under a contract are being conducted in support of science or space exploration activities not related to the International Space Station, the contracting officer shall insert the clause prescribed by this paragraph and designate application of the clause to those particular activities. If a science or space exploration activity is in support of the International Space Station, the contracting officer shall insert the clause prescribed by paragraph (c) of this section and designate its application to that particular launch.

(c) The contracting officer shall insert the clause at 1852.228–76, Cross-Waiver of Liability for International Space Station Activities, in solicitations and contracts above the simplified acquisition threshold when the work to

be performed involves Protected Space Operations, as that term is defined in the clause, relating to the International Space Station. If Space Shuttle services under a contract are being conducted in support of International Space Station activities, the contracting officer shall insert the clause prescribed by this paragraph and designate application of the clause to those particular activities.

(d) At the contracting officer's discretion, the clauses prescribed by paragraphs (b) and (c) of this section may be used in solicitations, contracts, new work modifications, or extensions to existing contracts under the simplified acquisition threshold involving science or space exploration activities unrelated to the International Space Station, or International Space Station activities, respectively, in appropriate circumstances. Examples of such circumstances are when the value of contractor property on a Government installation used in performance of the contract is significant, or when it is likely that the contractor or subcontractor will have its valuable property exposed to risk or damage caused by other participants in the science or space exploration activities unrelated to the International Space Station, or International Space Station activities.

## PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

### 1852.228–72 [Removed]

4. Section 1852.228–72 is removed.

5. Section 1852.228–76 is revised to read as follows:

### 1852.228–76 Cross-Waiver of Liability for International Space Station Activities.

As prescribed in 1828.371(c) and (d), insert the following clause:

## CROSS-WAIVER OF LIABILITY FOR INTERNATIONAL SPACE STATION ACTIVITIES

**[XX/XX]**

(a) The Intergovernmental Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America concerning Cooperation on the Civil International Space Station (IGA) for the International Space Station (ISS) contains a cross-waiver of liability provision to encourage participation in the exploration, exploitation, and use of outer space through the ISS. The objective of this clause is to extend this cross-waiver of liability to NASA contracts in the interest of encouraging participation in the exploration, exploitation, and use of outer space through the International Space Station (ISS). The Parties intend that this cross-waiver of liability be broadly construed to achieve this objective.

(b) As used in this clause, the term:

(1) "*Agreement*" refers to any NASA Space Act agreement that contains the cross-waiver of liability provision authorized by 14 CFR Part 1266.102.

(2) "*Damage*" means:

(i) Bodily injury to, or other impairment of health of, or death of, any person;

(ii) Damage to, loss of, or loss of use of any property;

(iii) Loss of revenue or profits; or

(iv) Other direct, indirect, or consequential Damage.

(3) "*Launch Vehicle*" means an object, or any part thereof, intended for launch, launched from Earth, or returning to Earth which carries Payloads or persons, or both.

(4) "*Partner State*" includes each Contracting Party for which the IGA has entered into force, pursuant to Article 25 of the IGA or pursuant to any successor agreement. A Partner State includes its Cooperating Agency. It also includes any entity specified in the Memorandum of Understanding (MOU) between NASA and the Government of Japan to assist the Government of Japan's Cooperating Agency in the implementation of that MOU.

(5) "*Party*" means a party to a NASA Space Act agreement involving activities in connection with the ISS and a party that is neither the prime contractor under this contract nor a subcontractor at any tier.

(6) "*Payload*" means all property to be flown or used on or in a Launch Vehicle or the ISS.

(7) "*Protected Space Operations*" means all Launch or Transfer Vehicle activities, ISS activities, and Payload activities on Earth, in outer space, or in transit between Earth and outer space in implementation of the IGA, MOUs concluded pursuant to the IGA, implementing arrangements, and contracts to perform work in support of NASA's obligations under these Agreements. It includes, but is not limited to:

(i) Research, design, development, test, manufacture, assembly, integration, operation, or use of Launch or Transfer Vehicles, the ISS, Payloads, or instruments, as well as related support equipment and facilities and services; and

(ii) All activities related to ground support, test, training, simulation, or guidance and control equipment and related facilities or services. "Protected Space Operations" also includes all activities related to evolution of the ISS, as provided for in Article 14 of the IGA. "*Protected Space Operations*" excludes activities on Earth which are conducted on return from the ISS to develop further a Payload's product or process for use other than for ISS-related activities in implementation of the IGA.

(8) "*Related Entity*" means:

(i) A contractor or subcontractor of a Party or a Partner State at any tier;

(ii) A user or customer of a Party or a Partner State at any tier; or

(iii) A contractor or subcontractor of a user or customer of a Party or a Partner State at any tier.

The terms "*contractor*" and "*subcontractor*" include suppliers of any kind.

(9) "*Transfer Vehicle*" means any vehicle that operates in space and transfers Payloads or persons or both between two different space objects, between two different locations on the same space object, or between a space object and the surface of a celestial body. A Transfer Vehicle also includes a vehicle that departs from and returns to the same location on a space object.

(c) Cross-waiver of liability:

(1) The Contractor agrees to a cross-waiver of liability pursuant to which it waives all claims against any of the entities or persons listed in paragraphs (c)(1)(i) through (c)(1)(iv) of this clause based on Damage arising out of Protected Space Operations. This cross-waiver shall apply only if the person, entity, or property causing the Damage is involved in Protected Space Operations and the person, entity, or property damaged is damaged by virtue of its involvement in Protected Space Operations. The cross-waiver shall apply to any claims for Damage, whatever the legal basis for such claims, against:

(i) A Party as defined in (b)(5) of this clause;

(ii) A Partner State other than the United States of America;

(iii) A Related Entity of any entity identified in paragraph (c)(1)(i) or (c)(1)(ii) of this clause; or

(iv) The employees of any of the entities identified in paragraphs (c)(1)(i) through (c)(1)(iii) of this clause.

(2) In addition, the contractor shall, by contract or otherwise, extend the cross-waiver of liability set forth in paragraph (c)(1) of this clause to its subcontractors at any tier by requiring them, by contract or otherwise, to:

(i) Waive all claims against the entities or persons identified in paragraphs (c)(1)(i) through (c)(1)(iv) of this clause; and

(ii) Require that their subcontractors waive all claims against the entities or persons identified in paragraphs (c)(1)(i) through (c)(1)(iv) of this clause.

(3) For avoidance of doubt, this cross-waiver of liability includes a cross-waiver of claims arising from the *Convention on International Liability for Damage Caused by Space Objects,* which entered into force on September 1, 1972, where the person, entity, or property causing the Damage is involved in Protected Space Operations and the person, entity, or property damaged is damaged by virtue of its involvement in Protected Space Operations.

(4) Notwithstanding the other provisions of this clause, this cross-waiver of liability shall not be applicable to:

(i) Claims between the Government and its own contractors or between its own contractors and subcontractors;

(ii) Claims made by a natural person, his/her estate, survivors or subrogees (except when a subrogee is a Party to an Agreement or is otherwise bound by the terms of this cross-waiver) for bodily injury to, or other impairment of health of, or death of, such person;

(iii) Claims for Damage caused by willful misconduct;

(iv) Intellectual property claims;

(v) Claims for Damage resulting from a failure of the contractor to extend the cross-waiver of liability to its subcontractors and related entities, pursuant to paragraph (c)(2) of this clause;

(vi) Claims by the Government arising out of or relating to the contractor's failure to perform its obligations under this contract.

(5) Nothing in this clause shall be construed to create the basis for a claim or suit where none would otherwise exist.

(6) This cross-waiver shall not be applicable when 49 U.S.C. Subtitle IX, Chapter. 701 is applicable.

(End of clause)

6. Section 1852.228–78 is revised to read as follows:

**1852.228–78 Cross-Waiver of Liability for Science or Space Exploration Activities Unrelated to the International Space Station.**

As prescribed in 1828.371(b) and (d), insert the following clause:

**CROSS-WAIVER OF LIABILITY FOR SCIENCE OR SPACE EXPLORATION ACTIVITIES UNRELATED TO THE INTERNATIONAL SPACE STATION**

**[XX/XX]**

(a) The purpose of this clause is to extend a cross-waiver of liability to NASA contracts for work done in support of Agreements between Parties involving Science or Space Exploration activities that are not related to the International Space Station (ISS) but involve a launch. This cross-waiver of liability shall be broadly construed to achieve the objective of furthering participation in space exploration, use, and investment.

(b) As used in this clause, the term:

(1) "*Agreement*" refers to any NASA Space Act agreement that contains the cross-waiver of liability provision authorized in 14 CFR 1266.104.

(2) "*Damage*" means:

(i) Bodily injury to, or other impairment of health of, or death of, any person;

(ii) Damage to, loss of, or loss of use of any property;

(iii) Loss of revenue or profits; or

(iv) Other direct, indirect, or consequential Damage;

(3) "*Launch Vehicle*" means an object, or any part thereof, intended for launch, launched from Earth, or returning to Earth which carries Payloads or persons, or both.

(4) "*Party*" means a party to a NASA Space Act agreement for Science or Space Exploration activities unrelated to the ISS that involve a launch and a party that is neither the prime contractor under this contract nor a subcontractor at any tier hereof.

(5) "*Payload*" means all property to be flown or used on or in a Launch Vehicle.

(6) "*Protected Space Operations*" means all Launch or Transfer Vehicle activities and Payload activities on Earth, in outer space, or in transit between Earth and outer space in implementation of an Agreement for Science or Space Exploration activities unrelated to the ISS that involve a launch. Protected Space Operations begins at the signature of the Agreement and ends when all activities done in implementation of the Agreement are completed. It includes, but is not limited to:

(i) Research, design, development, test, manufacture, assembly, integration, operation, or use of Launch or Transfer Vehicles, Payloads, or instruments, as well as related support equipment and facilities and services; and

(ii) All activities related to ground support, test, training, simulation, or guidance and control equipment, and related facilities or services.

Protected Space Operations excludes activities on Earth which are conducted on return from space to develop further a payload's product or process other than for the activities within the scope of an Agreement.

(7) "*Related entity*" means:

(i) A contractor or subcontractor of a Party at any tier;

(ii) A user or customer of a Party at any tier; or

(iii) A contractor or subcontractor of a user or customer of a Party at any tier.

The terms "contractors" and "subcontractors" include suppliers of any kind.

(8) "*Transfer Vehicle*" means any vehicle that operates in space and transfers Payloads or persons or both between two different space objects, between two different locations on the same space object, or between a space object and the surface of a celestial body. A Transfer Vehicle also includes a vehicle that departs from and returns to the same location on a space object.

(c) Cross-waiver of liability:

(1) The Contractor agrees to a waiver of liability pursuant to which it waives all claims against any of the entities or persons listed in paragraphs (c)(1)(i) through (iv) of this clause based on Damage arising out of Protected Space Operations. This cross-waiver shall apply only if the person, entity, or property causing the Damage is involved in Protected Space Operations and the person, entity, or property damaged is damaged by virtue of its involvement in Protected Space Operations. The waiver shall apply to any claims for Damage, whatever the legal basis for such claims, against:

(i) A Party;

(ii) A Party to another NASA Agreement or contract that includes flight on the same Launch Vehicle;

(iii) A Related Entity of any entity identified in paragraphs (c)(1)(i) or (ii) of this clause; or

(iv) The employees of any of the entities identified in (c)(1)(i) through (iii) of this clause.

(2) The Contractor agrees to extend the cross-waiver of liability as set forth in paragraph (c)(1) of this clause to its own subcontractors at all tiers by requiring them, by contract or otherwise, to:

(i) Waive all claims against the entities or persons identified in paragraphs (c)(1)(i) through (iv) of this clause; and

(ii) Require that their Related Entities waive all claims against the entities or persons identified in paragraphs (c)(1)(i) through (iv) of this clause.

(3) For avoidance of doubt, this cross-waiver of liability includes a cross-waiver of claims arising from the *Convention on International Liability for Damage Caused by Space Objects,* entered into force on 1 September 1972, in which the person, entity, or property causing the Damage is involved in Protected Space Operations and the person, entity, or property damaged is damaged by virtue of its involvement in Protected Space Operations.

(4) Notwithstanding the other provisions of this clause, this cross-waiver of liability shall not be applicable to:

(i) Claims between the Government and its own contractors or between its own contractors and subcontractors;

(ii) Claims made by a natural person, his/her estate, survivors, or subrogees (except when a subrogee is a Party to an Agreement or is otherwise bound by the terms of this cross-waiver) for bodily injury to, or other impairment of health, or death of such person;

(iii) Claims for Damage caused by willful misconduct;

(iv) Intellectual property claims;

(v) Claims for damages resulting from a failure of the contractor to extend the cross-waiver of liability to its subcontractors and related entities, pursuant to paragraph (c)(2) of this clause; or

(vi) Claims by the Government arising out of or relating to a contractor's failure to perform its obligations under this contract.

(5) Nothing in this clause shall be construed to create the basis for a claim or suit where none would otherwise exist.

(6) This cross-waiver shall not be applicable when 49 U.S.C. Subtitle IX, Chapter 701 is applicable.

(End of clause)

[FR Doc. 2011–10903 Filed 5–4–11; 8:45 am]

**BILLING CODE 7510–01–P**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 226

**[Docket No. 110407235–1242–01]**

**RIN 0648–XA349**

## Endangered and Threatened Wildlife; Notice of 90-Day Finding on a Petition to Revise Critical Habitat for the Endangered Leatherback Sea Turtle Under the Endangered Species Act

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

**ACTION:** Notice of 90-day petition finding.

**SUMMARY:** We, NMFS, announce a 90-day finding on a petition to revise critical habitat for the endangered

leatherback sea turtle under the Endangered Species Act (ESA). We find that the petition presents substantial scientific information indicating that the petitioned action may be warranted for leatherback sea turtles and their habitat under our jurisdiction.

**FOR FURTHER INFORMATION CONTACT:** Dennis Klemm, NMFS, Southeast Regional Office, Protected Resources Division, *dennis.klemm@noaa.gov,* (727) 824–5312; or Lisa Manning, NMFS, Office of Protected Resources, *marta.nammack@noaa.gov,* (301) 713–1401.

**SUPPLEMENTARY INFORMATION:**

## Background

On November 3, 2010, we received a petition, dated November 2, 2010, from the Sierra Club asking NMFS and the United States Fish and Wildlife Service (USFWS) to revise, pursuant to the ESA, critical habitat for the endangered leatherback sea turtle. The November 3, 2010, petition is the second petition submitted by the Sierra Club; the first petition submitted by the Sierra Club, dated February 22, 2010, was found not to present substantial scientific information indicating the petitioned revision may be warranted (75 FR 41436, July 16, 2010).

Under the ESA, NMFS, and USFWS each have respective areas of jurisdiction over sea turtles, as clarified by the 1977 "Memorandum of Understanding Defining the Roles of the U.S. Fish and Wildlife Service and the National Marine Fisheries Service in Joint Administration of the Endangered Species Act of 1973 as to Marine Turtles." NMFS has jurisdiction over sea turtles and their associated habitats in the marine environment, while USFWS has jurisdiction when sea turtles are on land. Thus, if Federal agencies are involved in activities that may affect sea turtles involved in nesting behavior, or their nests or their nesting habitats, those Federal agencies are required to consult with the USFWS under section 7 of the ESA to ensure that their activities are not likely to jeopardize the continued existence of the sea turtles. If a Federal action may affect sea turtles while they are in the marine environment, feeding and migrating for example, the Federal agency involved must engage in section 7 consultation with NMFS, to ensure that the action is not likely to jeopardize the continued existence of the sea turtles. Similarly, if critical habitat has been designated, and Federal actions may affect such habitat, an ESA section 7 consultation would be required to ensure that the Federal action is not likely to destroy or adversely modify the critical habitat. If the habitat has been designated on land the consultation would be with USFWS, and if the habitat has been designated in the marine environment, the consultation would be with NMFS.

The petitioner requests that we designate critical habitat for leatherback turtles in the waters off the coastline of the Northeast Ecological Corridor of Puerto Rico,[1] sufficient to protect leatherback turtles using the Northeast Ecological Corridor, and extending at least to the hundred fathom contour, or 9 nautical miles offshore, whichever is further, and including the existing marine extensions of the Espiritu Santo, Cabezas de San Juan, and Arreceifes de la Cordillera Nature Reserves. This portion of the petitioned critical habitat, which falls under NMFS' jurisdiction, is described by the petitioner as having three primary constituent elements: (1) "Migratory pathway conditions to allow for safe and timely passage and access to/from/within nesting sites at San Miguel, Paulinas, and Convento Beaches in the Northeast Ecological Corridor of Puerto Rico;" (2) "Migratory pathway conditions and open ocean conditions to allow for safe and timely passage and access to/from/within breeding sites offshore of the nesting sites at San Miguel, Paulinas, and Convento Beaches in the Northeast Ecological Corridor of Puerto Rico;" and (3) "Water quality to support normal growth, reproduction, development, viability, and health." The petitioner defined the minimum requested boundaries of the critical habitat by the following coordinates:

65.807° W, 18.425° N;
65.697° W, 18.601° N;
65.489° W, 18.581° N;
65.435° W, 18.400° N;
65.631° W, 18.276° N.

As argued in Sierra Club's first petition dated February 22, 2010, this petition asserts, that the beaches of the Northeast Ecological Corridor of Puerto Rico, which fall under USFWS' jurisdiction, are "centrally important to the U.S. Caribbean leatherback population, and should be designated as critical habitat," and that the near-shore coastal waters off those beaches, which fall under NMFS' jurisdiction, "provide room for turtles to mate and access the beaches, and for hatchlings and adults to leave the beaches." The petition also asserts that the coastal zone within the Northeast Ecological Corridor is particularly vulnerable to pressure from development and to the growing impacts of climate change, and so warrants protection as critical habitat. Additional information and details were provided in the Petition to Supplement associated with the Sierra Club's February 22, 2010, petition, which was incorporated by reference.

[1] The Northeast Ecological Corridor is an over 3,000 acre coastal area along Puerto Rico's northeastern shoreline that encompasses nearshore marine habitats as well as forests, wetlands, and one of the most important nesting beaches for leatherback turtles within the United States.

## ESA Statutory Provisions and Policy Considerations

Section 4(b)(3)(D) of the ESA of 1973, as amended (16 U.S.C. 1533 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receiving a petition to revise a critical habitat designation, the Secretary of Commerce (Secretary) make a finding as to whether the petition presents substantial scientific information indicating that the revision may be warranted. The finding is to be published promptly in the **Federal Register**. The Secretary must then determine how he intends to proceed with the requested revision within 12 months after receiving the petition and promptly publish notice of such intention in the **Federal Register**. Joint ESA-implementing regulations issued by NMFS and the USFWS (50 CFR 424.14(b)) define "substantial information" as the amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted. In making this finding on a petition to revise critical habitat to include additional areas, the Secretary must consider whether the petition contains information indicating that areas petitioned to be added to critical habitat contain physical and biological features essential to, and that may require special management to provide for, the conservation of the species involved (50 CFR 424.14(c)(2)(i)). Thus, in reviewing a petition to revise critical habitat we consider the information presented on the following three aspects of critical habitat as defined in the ESA: The physical or biological features identified, the explanation of how such features may be essential to a species' conservation, and how those features may require special management considerations.

## Analysis of Petition

The petition asserts that the revision of leatherback critical habitat to include the waters off the Northeast Ecological Corridor of Puerto Rico is necessary to protect leatherback sea turtles. In contrast to the February 22, 2010, petition, the Sierra Club's second petition proposes three primary constituent elements and specific

boundaries of the critical habitat, as detailed above. The petition also supports the proposed critical habitat revision by reporting what is known from existing accounts of leatherback mating behavior: Mating seems to occur, at least in part, in areas adjacent to nesting beaches. The information from satellite tagging studies of six leatherback turtles indicates heavy use by those turtles of the area described in the petition. The petitioner also cited the proposed Pacific leatherback critical habitat (75 FR 319; January 5, 2010), which has some similarities to the "open space" feature petitioned for designation off Puerto Rico. The petitioner states that the second primary constituent element cited in the proposed Pacific leatherback critical habitat rule (i.e., migratory pathway conditions to allow for safe and timely passage and access to/from/within high use foraging areas) is "for all intents and purposes, identical to the area 'sufficient to protect leatherbacks using the Northeast Ecological Corridor' which the Sierra Club identified." The petition also states that the marine environment in which the proposed critical habitat would be designated is subject to "substantial development and degradation threats." Thus, the additional information presented in this petition supports the required determination that the "areas petitioned to be added to critical habitat contain physical and biological features essential to, and that may require special management to provide for, the conservation of the species involved." 50 CFR 424.14(c)(2)(i).

## Petition Finding

After considering the petition, the information cited by the petitioner, and relevant information readily available in our files, we conclude that, with respect to areas under NMFS' jurisdiction, the petition presents substantial scientific information indicating that the petitioned revision of designated critical habitat for leatherback sea turtles may be warranted.

## Authority

The authority for this action is the ESA, as amended (16 U.S.C. 1533 *et seq.*).

Dated: April 28, 2011.

**Samuel D. Rauch III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

[FR Doc. 2011–10956 Filed 5–4–11; 8:45 am]

**BILLING CODE 3510–22–P**

# Notices

Federal Register
Vol. 76, No. 87
Thursday, May 5, 2011

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

### Agricultural Marketing Service

**[Document No. AMS–ST–11–0032]**

### Notice of Request for an Extension and Revision to a Currently Approved Information Collection

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget, for an extension of and revision to the currently approved information collection for Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides (7 CFR part 110).

**DATES:** Comments received by June 30, 2011 will be considered.

**ADDITIONAL INFORMATION OR COMMENTS:** Contact Jeffery Haynes, Chief, Pesticide Records Staff, Science and Technology Program, Agricultural Marketing Service, Suite 203, 8609 Sudley Road, Manassas, Virginia 20110–4582, Telephone (703) 330–7826, Fax (703) 330–6110.

**SUPPLEMENTARY INFORMATION:**

*Title:* Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides (7 CFR part 110).

*OMB Number:* 0581–0164.

*Expiration Date of Approval:* November 30, 2014.

*Type of Request:* Extension and revision of a currently approved information collection.

*Abstract:* Section 1491 of the Food, Agriculture, Conservation, and Trade Act of 1990, (Pub. L. 101–624; 7 U.S.C. 136i–1), (Act), directs and authorizes the Secretary of Agriculture to require that certified pesticide applicators maintain records of applications of federally restricted use pesticides for a period of two years.

The Act also (1) requires that the pesticide records be made available to Federal or State officials, and to licensed health care professionals who need the records in order to treat an individual who may have been exposed to restricted use pesticides; (2) requires that the Secretary of Agriculture enforce the recordkeeping and access requirements of the Act and promulgate regulations to administer the Act; and (3) establishes civil penalties for violations of the Act. A certified applicator is an individual who is certified by the Environmental Protection Agency (EPA) or a State under cooperative agreement with EPA to use or supervise the use of restricted use pesticides.

The Secretary of Agriculture delegated his responsibilities under the Act to the Agricultural Marketing Service (AMS), which promulgated regulations to administer the Act at 7 CFR part 110 (regulations). In order to enforce these regulations, AMS collects information through personal inspections of the application records of certified applicators of restricted use pesticides.

The information collected by AMS is used only by authorized representatives of AMS (AMS' Science and Technology Program national staff, other designated Federal employees and designated State supervisors and their staffs) who are delegated authority to access the records pursuant to subsection (b) of the Act. The collected information is used to administer the Federal Pesticide Recordkeeping program. AMS is the primary user of this information. The secondary user of the information is each designated State agency which has a cooperative agreement with AMS.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated as follows:

(a) Approximately 292,251 certified private applicators (recordkeepers) apply restricted use pesticides under the Federal regulations. It is estimated that each certified private applicator averages 1.31 hours per year to document their records for a total of 382,849 annual burden hours. This is a 19,519 decrease in burden hours from the previous collection request due to a decrease in the number of certified private applicators and subsequent restricted use pesticide applications. The current data indicates that each certified private applicator makes an average of approximately 16 restricted use pesticide applications per year. Of the 292,251 certified private applicators, approximately 3,591 are selected annually for recordkeeping inspections. It is estimated that a private applicator that is subject to a pesticide record inspection has an additional annual burden of .333 hours, which contributes to an additional annual burden of 1,196 hours.

(b) There are approximately 207,162 certified commercial applicators nationally who are required to provide copies of restricted use pesticide application records to their clients. It is estimated that each certified commercial applicator must provide an average of 616 records to customers. The burden hours for certified commercial applicators to provide a record to each customer averages 0.0080 hour per record. The total annual burden to certified commercial applicators is 1,020,894 hours.

(c) It is estimated that the State agency personnel from 27 States have 30 burden hours per State to equal 810 annual burden hours. State agency personnel from these 27 States conduct an average of 133 certified private applicator inspections at an annual burden of 1.8 hours per inspection to equal 6,464 annual burden hours. The total annual burden for the 27 States to develop a cooperative agreement with AMS and to inspect certified private applicator records have a total annual burden of 7,274 hours.

*Respondents:* Certified private and commercial applicators, State governments or employees, and Federal agencies or employees.

*Estimated Number of Respondents:* 499,467—The total number of respondents include 292,251 certified private applicators (which includes those selected for inspection), 207,162 certified commercial applicators, 27 designated State agency administrative personnel to implement cooperative agreements, and 27 designated State personnel to inspect certified private applicator's records.

*Estimated Number of Responses per Respondent:* The estimated number of responses per respondent is as follows:

(a) It is estimated that certified private applicators (recordkeepers), record on an average 16 restricted use pesticide application records annually.

(b) It is estimated that certified commercial applicators provide 616 copies of restricted use pesticide records to their clients annually.

(c) State agency personnel, who work under cooperative agreements with AMS to conduct restricted use pesticide records inspections, have approximately 3,591 responses annually.

*Estimated Total Annual Burden Hours on Respondents:* 1,412,213. This revision in the Total Annual Burden on Respondents decreases the burden by 385,501 hours due to the decrease in the number of certified applicators and the number of restricted use pesticides applications that certified applicators are making annually.

*Comments are invited on:* (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information 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. Comments should be sent to Jeffery Haynes, Chief, Pesticide Records Staff, Science and Technology Program, Agricultural Marketing Service, Suite 203, 8609 Sudley Road, Manassas, Virginia 20110–4582. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: April 29, 2011.

**Rayne Pegg,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2011–11041 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### North Gifford Pinchot National Forest Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The North Gifford Pinchot Resource Advisory Committee will meet in Salkum, Washington. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to review and recommend fiscal year 2012 Title II project nominations.

**DATES:** The meeting will be held Thursday, June 2, 2011 beginning at 9:30 a.m.

**ADDRESSES:** The meeting will be held at Salkum Timberland Library, 2480 US Highway 12, Salkum, WA 98582. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Gifford Pinchot National Forest Headquarters, 10600 NE. 51st Circle, Vancouver, WA 98682. Please call ahead to 360–891–5001 to facilitate entry into the building to view comments.

**FOR FURTHER INFORMATION CONTACT:** Robert West, Partnership Coordinator, Gifford Pinchot National Forest, 360–891–5068, and *robertwest@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accommodation for access to the facility or proceedings may be made by contacting the person listed For Further Information.

**SUPPLEMENTARY INFORMATION:** The following business will be conducted: Approval of agenda and minutes; public forum opportunity; election of chair and vice chair; update on prior year Title II projects, and review and recommendations of individual fiscal year 2012 Title II project nominations. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by May 1, 2011, to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to Gifford Pinchot National Forest attn: Robert West, 10600 NE. 51st Circle, Vancouver, WA 98682, or by e-mail to *robertwest@fs.fed.us* or via facsimile to 360–891–5045.

Dated: April 27, 2011.

**Ron Freeman,**

*Acting Forest Supervisor.*

[FR Doc. 2011–10873 Filed 5–4–11; 8:45 am]

**BILLING CODE 3410–11–M**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Shasta County Resource Advisory Committee; Meeting

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Shasta County Resource Advisory Committee (RAC) will meet in Redding, California, on April 27, 2011, from 8:30 a.m. to 12 noon. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendation to the Forest Service concerning projects and funding consistent with Title II of the Act. The purpose of this meeting is to discuss project updates and proposals, and information on monitoring efforts.

**DATES:** Wednesday, May 25 at 8:30 a.m.

**ADDRESSES:** The meeting will be held at the Sierra Pacific Industries office, 19794 Riverside Ave, Anderson, California 96007.

**FOR FURTHER INFORMATION CONTACT:** Designated Federal Official, Donna Harmon at (530) 226–2595 or *dharmon@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accommodation for access to the facility or proceedings may be made by contacting the person listed for Further Information.

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public. Public input sessions will be provided and individuals will have the opportunity to

address the Shasta County Resource Advisory Committee.

Dated: April 28, 2011.

**Arlen P. Cravens,**

*Acting Forest Supervisor, Shasta-Trinity National Forest.*

[FR Doc. 2011–10951 Filed 5–4–11; 8:45 am]

**BILLING CODE 3410–11–P**

## AMERICAN BATTLE MONUMENTS COMMISSION

### No Fear Act

**AGENCY:** American Battle Monuments Commission.

**ACTION:** Notice.

**SUMMARY:** The American Battle Monuments Commission (ABMC) is providing notice to its employees, former employees, and applicants for federal employment about the rights and remedies available to them under the Federal antidiscrimination, whistleblower protection, and retaliation laws. This notice fulfills the ABMC's initial notification obligation under the Notification and Federal Employees Antidiscrimination and Retaliation Act (No FEAR Act), as implemented by the Office of Personnel Management (OPM) regulations at 5 CFR part 724.

**FOR FURTHER INFORMATION CONTACT:** Visit the ABMC Web site at *http://www.abmc.gov,* or contact Michael Conley, Director, Equal Employment Opportunity (EEO), by mail at American Battle Monuments Commission, 2300 Clarendon Boulevard, Suite 500, Arlington, VA 22201, or by phone at (703) 696–5177.

**SUPPLEMENTARY INFORMATION:** On May 15, 2002, Congress enacted the "Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002," which is now known as the No FEAR Act. See Public Law 107–174, codified at 5 U.S.C. 2301 note. As stated in the full title of the Act, the Act is intended to "require that Federal agencies be accountable for violations of antidiscrimination and whistleblower protection laws." In support of this purpose, Congress found that "agencies cannot run effectively if those agencies practice or tolerate discrimination." Public Law 107–174, § 101(1).

The Act also requires this agency to provide this notice to its Federal employees, former Federal employees and applicants for Federal employment to inform you of the rights and protections available to you under Federal antidiscrimination, whistleblower protection, and retaliation laws.

**Antidiscrimination Laws**

A Federal agency cannot discriminate against an employee or applicant with respect to the terms, conditions or privileges of employment on the basis of race, color, national origin, religion, sex, age, disability, sexual orientation, parental status or any other non-merit factor. Discrimination on these bases is prohibited by one or more of the following statutes: 5 U.S.C. 2302(b)(1), 29 U.S.C. 206(d), 29 U.S.C. 631, 29 U.S.C. 633a, 29 U.S.C. 791 and 42 U.S.C. 2000e–16.

If you believe that you have been the victim of unlawful discrimination on the basis of race, color, religion, sex, national origin or disability, you must contact an Equal Employment Opportunity (EEO) counselor within 45 calendar days of the alleged discriminatory action, or, in the case of a personnel action, within 45 calendar days of the effective date of the action, before you can file a formal complaint of discrimination with your agency. See, e.g., 29 CFR Part 1614. If you believe that you have been the victim of unlawful discrimination on the basis of age, you must either contact an EEO counselor as noted above or give notice of intent to sue the Equal Employment Opportunity Commission (EEOC) within 180 calendar days of the alleged discriminatory action. If you are alleging discrimination based on marital status or political affiliation, you may file a written complaint with the U.S. Office of Special Counsel (OSC) see contact information below). In the alternative (or in some cases, in addition), you may pursue a discrimination complaint by filing a grievance through the agency's administrative grievance procedures, if such procedures apply and are available.

**Whistleblower Protection Laws**

A Federal employee with authority to take, direct others to take, recommend or approve any personnel action must not use that authority to take or fail to take, or threaten to take or fail to take a personnel action against an employee or applicant because of disclosure of information by that individual that is reasonably believed to evidence violations of law, rule or regulation; gross mismanagement; gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety, unless disclosure of such information is specifically prohibited by law and such information is specifically required by Executive Order to be kept secret in the interest of national defense or the conduct of foreign affairs.

Retaliation against an employee or applicant for making a protected disclosure is prohibited by 5 U.S.C. 2302(b)(8). If you believe that you have been the victim of whistleblower retaliation, you may file a written complaint (Form OSC–11) with the U.S. Office of Special Counsel, 1730 M Street, NW., Suite 218, Washington, DC 20036–4505, or online through the OSC Web site at *http://www.osc.gov.*

**Retaliation for Engaging in Protected Activity**

A Federal agency cannot retaliate against an employee or applicant because that individual exercised his or her rights under any of the Federal antidiscrimination or whistleblower protection laws listed above. If you believe that you are the victim of retaliation for engaging in protected activity, you must follow, as appropriate, the procedures described in the Antidiscrimination Laws and Whistleblower Protection Laws sections or, if applicable, the administrative or negotiated grievance procedures in order to pursue any legal remedy.

**Disciplinary Actions**

Under the existing laws, each agency retains the right, where appropriate, to discipline a Federal employee for conduct that is inconsistent with Federal antidiscrimination and whistleblower protection laws up to and including removal. If OSC has initiated an investigation under 5 U.S.C. 1214, however, according to 5 U.S.C. 1214(f), agencies must seek approval from the Special Counsel to discipline employees for, among other activities, engaging in prohibited retaliation. Nothing in the No FEAR Act alters existing laws or permits an agency to take unfounded disciplinary action against a Federal employee or to violate the procedural rights of a Federal employee who has been accused of discrimination.

**Additional Information**

For further information regarding the No FEAR Act regulations, refer to 5 CFR part 724, as well as the appropriate offices within the ABMC (e.g., EEO or Personnel and Administration). Additional information regarding Federal antidiscrimination, whistleblower protection and retaliation laws can be found on the EEOC Web site at *http://www.eeoc.gov* and on the OSC Web site at *http://www.osc.gov.*

**Existing Rights Unchanged**

Pursuant to section 205 of the No FEAR Act, neither the Act nor this

notice creates, expands or reduces any rights otherwise available to any employee, former employee or applicant under the laws of the United States, including the provisions of law specified in 5 U.S.C. 2302(d).

**Frank A. Manies,**

*Director, Human Resources and Administration.*

[FR Doc. 2011–10984 Filed 5–4–11; 8:45 am]

BILLING CODE P

## COMMISSION ON CIVIL RIGHTS

### Sunshine Act Notice

**AGENCY:** United States Commission on Civil Rights.

**ACTION:** Notice of meeting.

**DATE AND TIME:** Friday, May 13, 2011; 9 a.m. EDT.

**PLACE:** The Washington Marriott at Metro Center, Junior Ballroom Salons 1 and 2, 775 12th Street, NW., Washington, DC 20005.

**Briefing Agenda**

This briefing is open to the public.

**Topic: Peer-to-Peer Violence and Bullying: Examining the Federal Response**

I. Introductory Remarks by Chairman
II. Speakers' Presentations
III. Questions by Commissioners and Staff Director
IV. Adjourn Briefing

**CONTACT PERSON FOR FURTHER INFORMATION:** Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376–8591. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact Pamela Dunston at (202) 376–8105 or at *signlanguage@usccr.gov* at least three business days before the scheduled date of the meeting.

Dated: May 3, 2011.

**Kimberly A. Tolhurst,**

*Senior Attorney-Advisor.*

[FR Doc. 2011–11116 Filed 5–3–11; 4:15 pm]

BILLING CODE 6335–01–P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* National Ocean Recreational Expenditure (NORE) Survey.

*OMB Control Number:* 0648–xxxx.

*Form Number(s):* NA.

*Type of Request:* Regular submission (request for a new information collection).

*Number of Respondents:* 12,701.

*Average Hours per Response:* Non-participants in ocean activities, 2 minutes; Participants in ocean activities, 10 minutes.

*Burden Hours:* 2,449.

*Needs and Uses:* This is a request for a new information collection.

Consistent with Executive Order 13547: Stewardship of our Oceans, our Coasts and our Great Lakes, and NOAA's Next Generation Strategic Plan, the National Marine Fisheries Service (NMFS) plans to collect data to estimate expenditures on recreational activities in the U.S. that interact with marine resources falling within the scope of NMFS' public trust responsibilities. These activities may include but are not limited to: Wildlife watching (for example, whales or dolphins) from a boat or from shore; kayaking or canoeing in fish habitat areas such as estuaries and sloughs; and snorkeling or scuba diving on fish aggregating devices such as ship wrecks. The survey will help enhance NMFS' understanding of the economic implications of its public trust responsibilities as they relate to non-fishing recreational activities. The data collected may also provide information useful for the purposes of marine spatial planning. Measures of economic performance that may be supported by this data collection include the following: (1) Contribution to net national benefit; and (2) contribution to regional economic impacts (income and employment).

*Affected Public:* Individuals or households.

*Frequency:* One time or every two months for up to one year.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: May 2, 2011.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 2011–10954 Filed 5–4–11; 8:45 am]

BILLING CODE 3510–22–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–423–809]**

### Stainless Steel Plate in Coils from Belgium: Final Results of Full Sunset Review and Revocation of the Countervailing Duty Order

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** On June 2, 2010, the Department of Commerce ("the Department") initiated the second sunset review of the countervailing duty ("CVD") order on certain stainless steel plate in coils from Belgium ("SSPC" or "subject merchandise") pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). On the basis of a notice of intent to participate and an adequate substantive response filed on behalf of the domestic interested parties and adequate substantive responses from ArcelorMittal Stainless Belgium N.V. ("AMS") and the Government of Belgium ("GOB"), the Department determined to conduct a full sunset review of the CVD order pursuant to section 751(c) of the Act and 19 CFR 351.218(e)(2). As a result of our analysis, the Department finds that revocation of the CVD order would not likely lead to continuation or recurrence of a countervailable subsidy. Therefore, the Department is revoking this CVD order.

**DATES:** *Effective Date:* May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** Patricia Tran or Jennifer Meek, AD/CVD Operations, Office 1, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1503 or (202) 482–2778.

**SUPPLEMENTARY INFORMATION:**

**Background**

On June 2, 2010, the Department initiated the second sunset review of the CVD order on SSPC from Belgium in accordance with section 751(c) of the Act. *See Initiation of Five-Year ("Sunset") Review,* 75 FR 30777 (June 2, 2010).

Within the deadline specified in 19 CFR 351.218(d)(1)(i), the Department received notices of intent to participate on behalf of Allegheny Ludlum Corporation and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (collectively, "Petitioners"). The submitters claimed interested party status under sections 771(9)(C) and (D) of the Act, as a manufacturer of a domestic like product and as a certified union representing workers in the domestic industry producing certain SSPC, respectively. The Department received a substantive response from Petitioners within the deadline specified in 19 CFR 351.218(d)(3)(i). The Department also received substantive responses in a timely manner from the following respondent interested parties: AMS and the GOB. Timely rebuttal comments were received from Petitioners, AMS and the GOB on July 9, 2010. On July 22, 2010, after analyzing the submissions and rebuttals from interested parties and finding the substantive responses adequate, the Department determined to conduct a full sunset review. *See* Memorandum from Yasmin Nair, International Trade Compliance Analyst, to Susan H. Kuhbach, Director, AD/CVD Operations, Office 1, entitled "Adequacy Determination in Countervailing Duty Sunset Review of Certain Stainless Steel Plate in Coils from Belgium," dated July 22, 2010.

On December 27, 2010, the Department issued the preliminary results of the full sunset review, finding a likelihood of continuation or recurrence of subsidization with a net countervailable subsidy likely to prevail of zero percent for AMS and all other companies. *See Stainless Steel Plate in Coils From Belgium: Preliminary Results of Full Sunset Review,* 75 FR 81217, 81218 (December 27, 2010) ("*Preliminary Results*").

Interested parties were invited to comment on our *Preliminary Results.* The Department received case briefs from Petitioners, the GOB, and AMS within the deadline specified in 19 CFR 351.309(c)(1)(i). On February 16, 2011, the Department returned the case briefs submitted by the GOB and AMS, requesting the briefs to be resubmitted with the removal of certain references to information not on the record of this sunset review. Although both objected to the Department's decision, the GOB and AMS submitted revised versions of their case briefs on February 18, 2011. Timely rebuttal briefs were submitted by Petitioners, the GOB, and AMS.

A public hearing was requested by AMS and was held on Tuesday, March 8, 2011, in accordance with 19 CFR 351.310(c).

On April 7, 2011, the European Union submitted a letter in support of the arguments made by the GOB and AMS.

**Scope of the Order**

The products covered by the order are imports of certain stainless steel plate in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject plate products are flat-rolled products, 254 mm or over in width and 4.75 mm [1] or more in thickness, in coils, and annealed or otherwise heat treated and pickled or otherwise descaled. The subject plate may also be further processed (*e.g.,* cold-rolled, polished, *etc.*) provided that it maintains the specified dimensions of plate following such processing. Excluded from the scope of the order are the following: (1) Plate not in coils, (2) plate that is not annealed or otherwise heat treated and pickled or otherwise descaled, (3) sheet and strip, and (4) flat bars.

The merchandise subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States ("HTSUS") at subheadings: 7219.11.00.30, 7219.11.00.60, 7219.12.00.05, 7219.12.00.06, 7219.12.00.20, 7219.12.00.21, 7219.12.00.25, 7219.12.00.26, 7219.12.00.50, 7219.12.00.51, 7219.12.00.55, 7219.12.00.56, 7219.12.00.65, 7219.12.00.66, 7219.12.00.70, 7219.12.00.71, 7219.12.00.80, 7219.12.00.81, 7219.31.00.10, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.11.00.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, and 7220.90.00.80. Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the scope of the order remains dispositive.

**Analysis of the Comments Received**

All issues raised in this review are addressed in the Issues and Decision Memorandum ("Decision Memorandum") from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Acting Deputy Assistant Secretary for Import Administration, dated concurrently with this notice, which is hereby adopted by this notice. Parties can find this public memorandum in the Central Records Unit, Room 7046 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn.* The paper copy and electronic version of the Decision Memorandum are identical in content.

**Changes From the Preliminary Results**

As a result of the Department's analysis of received comments, we have made certain changes from the *Preliminary Results.* The Department finds that three programs which gave rise to net countervailable subsidies and which were determined not to be terminated in the *Preliminary Results*—Societé Nationale de Crediteà L'Industrie Loans, 1985 Conversion of Sidmar N.V.'s Debt to Equity, and SidInvest—are in fact terminated and that benefit streams from those programs are fully allocated. *See* Decision Memorandum at Comment 1. Because the Department concludes that all programs previously found countervailable have been terminated and that benefit streams from those programs are fully allocated, we determine that revocation of the CVD order on SSPC from Belgium will not likely lead to continuation or recurrence of a countervailable subsidy. *See id.*

**Final Results of Review**

The Department determines that revocation of the CVD order will not likely lead to continuation or recurrence of a countervailable subsidy. As a result, and in accordance with 19 CFR 351.222(i)(2), we are revoking this order effective July 18, 2010, the fifth anniversary of the date of publication in the **Federal Register** of the most recent notice of continuation of this order. *See Continuation of Antidumping Duty*

[1] On May 11, 2007, the Department received a scope inquiry request from U&A Belgium regarding whether the scope of the antidumping ("AD") and CVD orders on SSPC from Belgium excludes stainless steel products with an actual thickness less than 4.75mm, regardless of its nominal thickness. The Department conducted a scope inquiry applicable to all countries subject to the SSPC AD and CVD orders. In the Department's scope ruling, dated December 3, 2008, the Department determined that SSPC with a nominal thickness of 4.75mm, but with an actual thickness less than 4.75mm, and within the dimensional tolerances for this thickness of plate, is included in the scope of the AD orders on SSPC from Belgium, Italy, South Africa, the Republic of Korea, and Taiwan and CVD orders on SSPC from Belgium and South Africa. *See* Memorandum from Melissa G. Skinner to Stephen J. Claeys, entitled "Stainless Steel Plate in Coils from Belgium: Final Scope Ruling,"' dated December 3, 2008.

*Orders on Certain Stainless Steel Plate in Coils From Belgium, Italy, South Korea, South Africa, and Taiwan, and the Countervailing Duty Orders on Certain Stainless Steel Plate in Coils From Belgium, Italy, and South Africa,* 70 FR 41202 (July 18, 2005). We will notify the International Trade Commission of these results.

**Effective Date of Revocation**

Pursuant to section 19 CFR 351.222(i)(2), the Department will instruct U.S. Customs and Border Protection to terminate the suspension of liquidation of the merchandise subject to this order entered, or withdrawn from warehouse, on or after July 18, 2010. Entries of subject merchandise prior to the effective date of revocation will continue to be subject to suspension of liquidation and CVD deposit requirements. The Department will complete any pending administrative reviews of this order and will conduct administrative reviews of subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: April 28, 2011.

**Paul Piquado,**

*Acting Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2011–11002 Filed 5–4–11; 8:45 am]

**BILLING CODE 3510–DS–P**

---

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–201–822]**

### Stainless Steel Sheet and Strip in Coils From Mexico: Final Results of the Five-Year ("Sunset") Review of the Antidumping Duty Order

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** Pursuant to sections 751(c) and 752 of the Tariff Act of 1930, as amended ("the Act"), the Department of Commerce ("Department") finds that revocation of the antidumping duty order on stainless steel sheet and strip ("SSSS") in coils from Mexico would be likely to lead to continuation or recurrence of dumping.

**DATES:** Effective Date: May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** David Cordell or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0408, or (202) 482–3019, respectively.

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 27, 2010, the Department published in the **Federal Register**, a notice of the *Preliminary Results* of the second sunset review of the antidumping duty order on SSSS in coils from Mexico. *See Stainless Steel Sheet and Strip in Coils From Mexico; Preliminary Results of the Five-Year ("Sunset") Review of Antidumping Duty Order,* 75 FR 81221 (December 27, 2010) ("*Preliminary Results*"). In those *Preliminary Results,* we determined that revocation of the order would likely result in continuation or recurrence of dumping. The Department received a case brief from the respondent, ThyssenKrupp Mexinox S.A. de C.V., and its affiliated U.S. importer, Mexinox USA, Inc. (collectively "Mexinox") on February 15, 2011. On February 18, 2011, the Department published the amended final results of the 2008–2009 administrative review, in which it calculated a weighted-average dumping margin of 12.13 percent for Mexinox. *See Stainless Steel Sheet and Strip in Coils From Mexico: Notice of Amended Final Results of Antidumping Duty Administrative Review,* 76 FR 9542 (February 18, 2011). On February 22, 2011, the Department received a rebuttal brief from the domestic interested parties.[1] On February 22, 2011, the Department invited parties to submit comments addressing the issue of whether dumping is likely to continue or recur, if the antidumping duty order is revoked, in light of the amended final results of the 2008–2009 administrative review. On February 23, 2011, Mexinox withdrew its January 23, 2011 request for a hearing. On February 28, 2011, both Mexinox and the domestic interested parties filed comments and both Mexinox and the domestic interested parties filed rebuttal comments on March 4, 2011.

**Scope of the Order**

For purposes of the order, the products covered are certain stainless steel sheet and strip in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.,* cold-rolled, polished, aluminized, coated, *etc.*) provided that it maintains the specific dimensions of sheet and strip following such processing. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States ("HTS") at subheadings: 7219.13.00.31, 7219.13.00.51, 7219.13.00.71, 7219.13.00.81, 7219.14.00.30, 7219.14.00.65, 7219.14.00.90, 7219.32.00.05, 7219.32.00.20, 7219.32.00.25, 7219.32.00.35, 7219.32.00.36, 7219.32.00.38, 7219.32.00.42, 7219.32.00.44, 7219.33.00.05, 7219.33.00.20, 7219.33.00.25, 7219.33.00.35, 7219.33.00.36, 7219.33.00.38, 7219.33.00.42, 7219.33.00.44, 7219.34.00.05, 7219.34.00.20, 7219.34.00.25, 7219.34.00.30, 7219.34.00.35, 7219.35.00.05, 7219.35.00.15, 7219.35.00.30, 7219.35.00.35, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.12.10.00, 7220.12.50.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.20.70.05, 7220.20.70.10, 7220.20.70.15, 7220.20.70.60, 7220.20.70.80, 7220.20.80.00, 7220.20.90.30, 7220.20.90.60, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, 7220.90.00.80.

Although the HTS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise subject to the order is dispositive. Excluded from the scope of the order is the following: (1) Sheet and strip that is not

[1] The domestic SSSS in coils industry includes AK Steel Corporation; Allegheny Ludlum Corporation; North American Stainless; the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial Service Workers International Union; United Auto Workers ("UAW") Local 3303; and UAW Local 4104 (collectively, "domestic interested parties").

annealed or otherwise heat treated and pickled or otherwise descaled; (2) sheet and strip that is cut to length; (3) plate (*i.e.,* flat-rolled stainless steel products of a thickness of 4.75 mm or more); (4) flat wire (*i.e.,* cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm; and (5) razor blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. *See* Chapter 72 of the HTS, "Additional U.S. Note" 1(d). Flapper valve steel is also excluded from the scope of the order. This product is defined as stainless steel strip in coils containing, by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves in compressors. Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length. Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of the order. This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of less than 0.002 or greater than 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron. Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of the order. This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as "Arnokrome III."[2]

Certain electrical resistance alloy steel is also excluded from the scope of the order. This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials (ASTM) specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as "Gilphy 36."[3] Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of the order. This high-strength, ductile stainless steel product is designated under the Unified Numbering System (UNS) as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as "Durphynox 17."[4]

Finally, three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments are also excluded from the scope of the order. These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.,* carpet knives).[5] This steel is similar to AISI grade 420 but containing, by weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as "GIN4 Mo." The second excluded stainless steel strip in coils is similar to AISI 420–J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per 100 square microns. An example of this product is "GIN5" steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37 and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for example, "GIN6."[6] Also excluded from the order is a permanent magnet iron-chromium-cobalt stainless steel strip containing, by weight, 13 percent chromium, 6 percent cobalt, 71 percent iron, 6 percent nickel and 4 percent molybdenum. The product is supplied in widths up to 1.27 cm (12.7 mm), inclusive, with a thickness between 45 and 75 microns, inclusive. This product exhibits magnetic remanence between

[2] "Arnokrome III" is a trademark of the Arnold Engineering Company.

[3] "Gilphy 36" is a trademark of Imphy, S.A.

[4] "Durphynox 17" is a trademark of Imphy, S.A.

[5] This list of uses is illustrative and provided for descriptive purposes only.

[6] "GIN4 Mo," "GIN5" and "GIN6" are the proprietary grades of Hitachi Metals America, Ltd.

400 and 780 nWb, and coercivity of between 60 and 100 oersteds. This product is currently supplied under the trade name "SemiVac 90."

**Analysis of Comments Received**

All issues raised in this review are addressed in the Issues and Decision Memorandum ("Decision Memorandum") from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Acting Deputy Assistant Secretary for Import Administration, dated concurrently with this notice, which is hereby adopted by this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendation in this public memorandum which is on file in the Central Records Unit, Room 7046 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at *http://ia.ita.doc.gov/frn.* The paper copy and electronic version of the Decision Memorandum are identical in content.

**Final Results of Review**

We determine that revocation of the antidumping duty order on SSSS in coils from Mexico would be likely to lead to continuation or recurrence of dumping at the following weighted-average margins:

| Manufacturer/exporter | Margin (percent) |
|---|---|
| Mexinox | 30.69 |
| All Others | 30.69 |

In accordance with section 752(c)(3) of the Act, we will notify the U.S. International Trade Commission of the final results of this sunset review.

**Notification Regarding Administrative Protective Order**

This notice serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary material disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This sunset review and notice are being published in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: April 28, 2011.

**Paul Piquado,**

*Acting Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2011–11005 Filed 5–4–11; 8:45 am]

**BILLING CODE 3510–DS–P**

---

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–475–824]**

### Stainless Steel Sheet and Strip in Coils From Italy: Final Results of the Full Five-Year ("Sunset") Review of the Antidumping Duty Order

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** Pursuant to sections 751(c) and 752 of the Tariff Act of 1930, as amended ("the Act"), the Department of Commerce ("Department") finds, as a result of this review, that revocation of the antidumping duty order on stainless steel sheet and strip ("SSSS") in coils from Italy would be likely to lead to a continuation of dumping.

**DATES:** *Effective Date:* May 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** David Cordell or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0408, or (202) 482–3019, respectively.

**SUPPLEMENTARY INFORMATION**

**Background**

On December 27, 2010, the Department published in the **Federal Register**, a notice of the *Preliminary Results* of the second sunset review of the antidumping duty order on SSSS in coils from Italy. *See Stainless Steel Sheet and Strip in Coils From Italy: Preliminary Results of the Full Second Sunset Review of the Antidumping Duty Order,* 75 FR 81214 (December 27, 2010) ("*Preliminary Results*"). In those *Preliminary Results,* we preliminarily determined that revocation of the order would likely result in continuation or recurrence of dumping. On February 4, 2011, Department officials met with counsel to ThyssenKrupp Acciai Speciali Terni S.p.A. ("TKAST").[1] On February 15, 2011, TKAST submitted a case brief in response to the Department's *Preliminary Results,*[2] and on February 22, 2011, the domestic interested parties[3] submitted a rebuttal brief. A hearing was requested by TKAST on January 24, 2011, and the request was withdrawn on February 23, 2011.

**Scope of the Order**

For purposes of the order, the products covered are certain stainless steel sheet and strip in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.,* cold-rolled, polished, aluminized, coated, *etc.*) provided that it maintains the specific dimensions of sheet and strip following such processing. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States ("HTS") at subheadings: 7219.13.00.31, 7219.13.00.51, 7219.13.00.71, 7219.13.00.81, 7219.14.00.30, 7219.14.00.65, 7219.14.00.90, 7219.32.00.05, 7219.32.00.20, 7219.32.00.25, 7219.32.00.35, 7219.32.00.36, 7219.32.00.38, 7219.32.00.42, 7219.32.00.44, 7219.33.00.05, 7219.33.00.20, 7219.33.00.25, 7219.33.00.35, 7219.33.00.36, 7219.33.00.38, 7219.33.00.42, 7219.33.00.44, 7219.34.00.05, 7219.34.00.20, 7219.34.00.25, 7219.34.00.30, 7219.34.00.35, 7219.35.00.05, 7219.35.00.15, 7219.35.00.30, 7219.35.00.35, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.12.10.00, 7220.12.50.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.20.70.05, 7220.20.70.10, 7220.20.70.15, 7220.20.70.60, 7220.20.70.80, 7220.20.80.00, 7220.20.90.30, 7220.20.90.60, 7220.90.00.10,

[1] *See* Memo to the File from Angelica Mendoza, dated February 8, 2011, in which the Department also placed on the record the Foreign Trade Zone Board ("FTZB") Examiner's Report and the FTZB Determination on the Alabama Mill.

[2] In support of TKAST's positions, the European Union also filed comments on the same day.

[3] AK Steel Corporation; Allegheny Ludlum Corporation; North American Stainless; the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial Service Workers International Union; United Auto Workers ("UAW") Local 3303; and UAW Local 4104 (collectively, "domestic interested parties").

7220.90.00.15, 7220.90.00.60, 7220.90.00.80.

Although the HTS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise subject to the order is dispositive. Excluded from the scope of the order is the following: (1) Sheet and strip that is not annealed or otherwise heat treated and pickled or otherwise descaled; (2) sheet and strip that is cut to length; (3) plate (*i.e.,* flat-rolled stainless steel products of a thickness of 4.75 mm or more); (4) flat wire (*i.e.,* cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm; and (5) razor blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. *See* Chapter 72 of the HTS, "Additional U.S. Note" 1(d). Flapper valve steel is also excluded from the scope of the order. This product is defined as stainless steel strip in coils containing, by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves in compressors. Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length. Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of the order. This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of less than 0.002 or greater than 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron. Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of the order. This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as "Arnokrome III."[4]

Certain electrical resistance alloy steel is also excluded from the scope of the order. This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials (ASTM) specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as "Gilphy 36"[5]

Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of the order. This high-strength, ductile stainless steel product is designated under the Unified Numbering System (UNS) as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as "Durphynox 17."[6]

Finally, three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments are also excluded from the scope of the order. These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.,* carpet knives).[7] This steel is similar to AISI grade 420 but containing, by weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as "GIN4 Mo." The second excluded stainless steel strip in coils is similar to AISI 420–J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per 100 square microns. An example of this product is "GIN5" steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37 and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for

[4] "Arnokrome III" is a trademark of the Arnold Engineering Company.

[5] "Gilphy 36" is a trademark of Imphy, S.A.

[6] "Durphynox 17" is a trademark of Imphy, S.A.

[7] This list of uses is illustrative and provided for descriptive purposes only.

example, "GIN6."[8] Also excluded from the order is a permanent magnet iron-chromium-cobalt stainless steel strip containing, by weight, 13 percent chromium, 6 percent cobalt, 71 percent iron, 6 percent nickel and 4 percent molybdenum. The product is supplied in widths up to 1.27 cm (12.7 mm), inclusive, with a thickness between 45 and 75 microns, inclusive. This product exhibits magnetic remanence between 400 and 780 nWb, and coercivity of between 60 and 100 oersteds. This product is currently supplied under the trade name "SemiVac 90."

**Analysis of Comments Received**

All issues raised in this review are addressed in the Issues and Decision Memorandum ("Decision Memorandum") from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Acting Deputy Assistant Secretary for Import Administration, dated concurrently with this notice, which is hereby adopted by this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendation in this public memorandum, which is on file in the Central Records Unit, Room 7046 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at *http://ia.ita.doc.gov/frn.* The paper copy and electronic version of the Decision Memorandum are identical in content.

**Final Results of Review**

We determine that revocation of the antidumping duty order on SSSS in coils from Italy would be likely to lead to continuation or recurrence of dumping at the following weighted-average margins:

| Manufacturer/exporter | Margin (percent) |
|---|---|
| TKAST | 2.11 |
| All Others | 2.11 |

In accordance with section 752(c)(3) of the Act, we will notify the U.S. International Trade Commission of the final results of this full sunset review.

**Notification Regarding Administrative Protective Order**

This sunset review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act. This notice serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary material disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Dated: April 28, 2011.

**Paul Piquado,**

*Acting Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2011–11004 Filed 5–4–11; 8:45 am]

**BILLING CODE 3510–DS–P**

[8] "GIN4 Mo," "GIN5" and "GIN6" are the proprietary grades of Hitachi Metals America, Ltd.

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Proposed Information Collection; Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (hereinafter the "Corporation"), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning its proposed renewal of its Interest Payment Form. This form is the official document AmeriCorps members and institutions use to collect information necessary for disbursing interest payments, as detailed in 42 U.S.C. 12602 through 12604. Copies of the information collection request can be obtained by contacting the office listed in the **ADDRESSES**section of this notice.

**DATES:** Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by July 5, 2011.

**ADDRESSES:** You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, National Service Trust; Attention Bruce Kellogg; 1201 New York Avenue, NW., Washington, DC 20525.

(2) By hand delivery or by courier to the Corporation's mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

(3) *By fax to:* (202) 606–3492, *Attention:* Bruce Kellogg.

(4) *Electronically through the Corporation's e-mail address system: bkellogg@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 606–3472 between 8:30 a.m. and 5 p.m. Eastern time, Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Bruce Kellogg, (202) 606–6954, or by e-mail at *bkellogg@cns.gov.*

**SUPPLEMENTARY INFORMATION:** The Corporation is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, 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 expected 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 submissions of responses).

**Background**

This form or its electronic equivalent is used by AmeriCorps members to request interest payments, by schools and lenders to verify eligibility for the payments, and by both parties to verify certain legal requirements.

**Current Action**

The Corporation seeks to renew the current information collection. The Interest Payment Form is unchanged.

The information collection will be used in the same manner as the existing application. The Corporation also seeks to continue using the current

application until the revised application is approved by OMB. The current application is due to expire on 9/30/2011.

*Type of Review:* Renewal.

*Agency:* Corporation for National and Community Service.

*Title:* Interest Payment Form, OMB Payment Form, OMB Number: 3045–0053.

*Agency Number:* None.

*Affected Public:* Individuals who have successfully completed a term of national service who wish to request payment of interest accruing on qualified student loans during the member's term of service in AmeriCorps.

*Total Respondents:* Paper Interest Payment Form, 4,000 responses annually.

*Frequency:* Some members do not have qualified student loans while others have several. Currently, about two-thirds of the interest payments are processed electronically. The Corporation expects the use of paper forms to continue to decrease.

*Average Time per Response:* 10 minutes for member and institution.

*Estimated Total Burden Hours:* 667 hours.

*Total Burden Cost (capital/startup):* None.

*Total Burden Cost (operating/maintenance):* None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: April 27, 2011.

**Maggie Taylor-Coates,**

*Manager, National Service Trust.*

[FR Doc. 2011–10916 Filed 5–4–11; 8:45 am]

**BILLING CODE 6050–$$–P**

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Proposed Information Collection; Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (hereinafter the "Corporation"), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning its proposed renewal of its Forbearance Request for National Service Form. This form is the official document AmeriCorps members and institutions use to collect information necessary for processing forbearance requests, as detailed in 42 U.S.C. 12602 through 12604. Copies of the information collection request can be obtained by contacting the office listed in the addresses section of this notice.

**DATES:** Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by July 5, 2011.

**ADDRESSES:** You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, National Service Trust; Attention Bruce Kellogg; 1201 New York Avenue, NW., Washington, DC 20525.

(2) By hand delivery or by courier to the Corporation's mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

(3) By fax to: (202) 606–3492, Attention: Bruce Kellogg.

(4) Electronically through the Corporation's e-mail address system: *bkellogg@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 606–3472 between 8:30 a.m. and 5 p.m. Eastern Time, Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Bruce Kellogg, (202) 606–6954, or by e-mail at *bkellogg@cns.gov.*

**SUPPLEMENTARY INFORMATION:**

The Corporation is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, 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 expected 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 submissions of responses).

**Background**

This form or its electronic equivalent is used by AmeriCorps members to request a forbearance based on national service, by schools and lenders to verify eligibility for the forbearance, and by both parties to verify certain legal requirements.

**Current Action**

The Corporation seeks to renew and revise the current information collection. Except for minor edits, the Forbearance Request Form is unchanged.

The information collection will be used in the same manner as the existing application. The Corporation also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on 9/30/2011.

*Type of Review:* Renewal.

*Agency:* Corporation for National and Community Service.

*Title:* Forbearance Request for National Service Form, OMB Number: 3045–0030.

*Agency Number:* None.

*Affected Public:* Individuals who have enrolled in a term of national service who wish to postpone loan payments on qualified student loans while they serve.

*Total Respondents:* Paper Forbearance Request Form, 1,200 responses annually.

*Frequency:* Some members do not have qualified student loans while others have several. Currently, about three-quarters of the forbearance requests are processed electronically. The Corporation expects the use of paper forms to continue to decrease.

*Average Time per Response:* 10 minutes for member and institution.

*Estimated Total Burden Hours:* 200 hours.

*Total Burden Cost (capital/startup):* None.

*Total Burden Cost (operating/maintenance):* None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the

information collection request; they will also become a matter of public record.

Dated: April 27, 2011.

**Maggie Taylor-Coates,**

*Manager, National Service Trust.*

[FR Doc. 2011–10918 Filed 5–4–11; 8:45 am]

**BILLING CODE 6050–$$–P**

## DEPARTMENT OF EDUCATION

### Notice of Submission for OMB Review

**AGENCY:** Department of Education.

**ACTION:** Comment Request.

**SUMMARY:** The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

**DATES:** Interested persons are invited to submit comments on or before June 6, 2011.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, *Attention:* Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or emailed to *oira_submission@omb.eop.gov* with a cc: To *ICDocketMgr@ed.gov.* Please note that written comments received in response to this notice will be considered public records.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The OMB is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 29, 2011.

**Darrin A. King,**

*Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.*

### Institute of Education Sciences

*Type of Review:* Extension.

*Title of Collection:* Conversion Magnet Schools Evaluation.

*OMB Control Number:* 1850–0832.

*Agency Form Number(s):* N/A.

*Frequency of Responses:* On Occasion.

*Affected Public:* Not-for-profit institutions.

*Total Estimated Number of Annual Responses:* 20.

*Total Estimated Annual Burden Hours:* 280.

*Abstract:* The Conversion Magnet Schools Evaluation is being conducted to determine if efforts to turn around low-performing schools through converting to a Magnet Schools Assistance Program supported magnet school are associated with improved student achievement and the reduction in minority group isolation. The Institute of Education Sciences, in collaboration with the Office of Innovation and Improvement, initiated the study due to the popularity and persistence of magnet programs and the inconclusive research on the relationship of these programs to important student outcomes. The study will use quasi-experimental designs to explore the relationship between magnet programs and student achievement both for "resident" students who attend magnet schools as their neighborhood schools and, if possible, for non-resident students. Data collection includes student records data, principal surveys, and project director interviews. The U.S. Department of Education has commissioned American Institutes for Research to conduct this study.

An OMB clearance request that (1) described the study design and full data collection activities and (2) requested approval for the burden associated with the first three years of data collection was approved in 2007 (OMB Number 1850–0832 approval 7/13/07; expiration 7/31/10). In 2010, we requested clearance for the burden associated with the fourth and fifth year of data collection necessary for the rigorous comparative interrupted time series design including student records data collection for the 2009–2010 school year (OMB Number 1850–0832 approval 6/14/10; expiration 6/30/13). We are now requesting clearance for the burden associated with one additional round of student records data collection (student records data from the 2010–2011 school year) from participating districts due to the later than expected implementation of the magnet programs in the 2007 grantee cohort.

Copies of the information collection submission for OMB review may be accessed from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4516. When you access the information collection, click on "Download Attachments " to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–10957 Filed 5–4–11; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

### Notice of Submission for OMB Review

**AGENCY:** Department of Education.

**ACTION:** Comment Request.

**SUMMARY:** The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L 104–13).

**DATES:** Interested persons are invited to submit comments on or before June 6, 2011.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, *attention:* Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or e-mailed to *oira_submission@omb.eop.gov* with a cc: To *ICDocketMgr@ed.gov.* Please note that written comments received in response to this notice will be considered public records.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of

1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The OMB is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 29, 2011.

**Darrin A. King,**

*Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.*

**Office of Special Education and Rehabilitative Services**

*Type of Review:* Revision.

*Title of Collection:* Annual Performance Report of Independent Living for Older Individuals Who are Blind.

*OMB Control Number:* 1820–0608.

*Agency Form Number(s):* RSA–7–OB.

*Frequency of Responses:* Annually.

*Affected Public:* State, Local, or Tribal Government, State Educational Agencies or Local Educational Agencies.

*Total Estimated Number of Annual Responses:* 56.

*Total Estimated Annual Burden Hours:* 336.

*Abstract:* This data collection instrument is being submitted to obtain approval for information collection on the Independent Living Services for Older Individuals Who Are Blind program. Through this program, grants are made to states to support services for individuals age 55 or older whose severe visual impairment makes competitive employment difficult to obtain but for whom independent living goals are feasible. This data will be used to evaluate and construct a profile for the program nationwide. The respondents will be the managers of the Independent Living Services for Older Individuals Who Are blind program in each of the 56 states and territories. The revisions to this instrument consist of 2 additional items in Part I to capture the amount of other federal funds made available to the program, and the carryover for those funds. In Part III, rearrangement in the order of requested information to avoid double counting of consumers in the race and ethnicity categories; an additional item to capture the number of consumers served who are homeless; additional items to capture the number of consumers referred from nursing homes, assisted living facilities, government/social service agencies, and self referrals. In Part IV, section C was revised to omit "assistive technology" and avoid the overlap with section B—specifically B2 and C2 which asked for the same information. The word "regained" was changed to "maintained" or "gained" wherever it appeared in the document as appropriate. Finally, in Part VI, we added language to link the information requested to that already provided in Part IV, and added items to capture the number of consumers who died while receiving services.

Copies of the information collection submission for OMB review may be accessed from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4519. When you access the information collection, click on "Download Attachments " to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–10966 Filed 5–4–11; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF EDUCATION

### Notice of Submission for OMB Review

**AGENCY:** Department of Education.

**ACTION:** Comment request.

**SUMMARY:** The Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

**DATES:** Interested persons are invited to submit comments on or before June 6, 2011.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503, be faxed to (202) 395–5806 or e-mailed to *oira_submission@omb.eop.gov* with a cc: to *ICDocketMgr@ed.gov.* Please note that written comments received in response to this notice will be considered public records.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The OMB is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 29, 2011.

**Darrin A. King,**

*Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.*

**Office of Special Education and Rehabilitative Services**

*Type of Review:* Extension.

*Title of Collection:* Client Assistance Program Report.

*OMB Control Number:* 1820–0528.

*Agency Form Number(s):* RSA–227.

*Frequency of Responses:* Annually.

*Affected Public:* Not-for-profit institutions.

*Total Estimated Number of Annual Responses:* 56.

*Total Estimated Annual Burden Hours:* 896.

*Abstract:* Form RSA–227 is used to meet specific data collection requirements contained in Section 112 of the Rehabilitation Act of 1973, as amended, and its implementing Federal Regulations at 34 CFR part 370. Data from the form have been used to evaluate individual programs. These data also have been used to indicate trends in the provision of services from year to year. In addition, Form RSA–227 will be used to analyze and evaluate the effectiveness of individual Client Assistance Program grantees. These agencies provide services to individuals seeking or receiving services from programs and projects authorized by the Rehabilitation Act of 1973, as amended. Form RSA–227 has enabled the Rehabilitation Services Administration (RSA) to furnish the President and Congress with data on the provision of advocacy services and has helped to establish a sound basis for future funding requests.

Copies of the information collection submission for OMB review may be accessed from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4520. When you access the information collection, click on "Download Attachments " to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to the Internet address *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–10982 Filed 5–4–11; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

### Applications for New Awards; Technology and Media Services for Individuals With Disabilities—Center on Online Learning and Students With Disabilities

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice.

*Overview Information:*

Technology and Media Services for Individuals with Disabilities—Center on Online Learning and Students with Disabilities; Notice inviting applications for new awards for fiscal year (FY) 2011.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.327U.

*Dates:*

Applications Available: May 5, 2011.

Deadline for Transmittal of Applications: June 20, 2011.

Deadline for Intergovernmental Review: August 18, 2011.

**Full Text of Announcement**

**I. Funding Opportunity Description**

*Purpose of Program:* The purposes of the Technology and Media Services for Individuals with Disabilities program are to: (1) Improve results for children with disabilities by promoting the development, demonstration, and use of technology; (2) support educational media services activities designed to be of educational value in the classroom setting to children with disabilities; and (3) provide support for captioning and video description that are appropriate for use in the classroom setting.

*Priority:* In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute, or otherwise authorized in the statute (see sections 674(c) and 681(d) of the Individuals with Disabilities Education Act (IDEA)).

*Absolute Priority:* For FY 2011 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

*Center on Online Learning and Students With Disabilities (84.327U)*

*Background:*

Online learning is growing rapidly in this country and is likely to become an essential component of the educational system as usage increases and more advanced forms of online learning emerge. By one estimate, 1.5 million students in kindergarten through grade 12 (K–12) were engaged in some form of online learning during the 2009–2010 school year, and this number is expected to increase dramatically in future years (Wicks, 2010; Picciano & Seaman, 2007; U.S. Department of Education, 2010). The expanded use of online learning offers potential benefits to children with disabilities but also poses significant challenges (Keeler, *et al.,* 2007).

"Online learning," as used in this notice, refers to learning that takes place partially or entirely over the Internet (U.S. Department of Education, 2009). Online learning can have different forms and take place in different contexts. For example, online learning may take place in a traditional school as a regular part of the school day, or it may take place in a full-time online "virtual school" in which the student participates from home, a community setting, or a workplace. The pedagogy of online learning may be "expository" in which the technology is used to transmit educational content in a manner similar to a traditional lecture. The pedagogy may be "active" in which the technology allows learners to access content through interactive simulations, games, or other online resources, or the pedagogy may be "interactive" in which learning emerges from human interactions that take place via online learning communities, virtual worlds, etc. Online learning can be largely text-based; video and audio may also may be used to provide content. Content may be delivered on a desktop computer, laptop computer, or a mobile device like a smart phone or electronic tablet. Finally, online learning may involve "synchronous" communication in which students and teachers interact concurrently, for example, through online chats or webcasts, or it may involve "asynchronous" communication with delayed interactions using e-mail, threaded discussions, etc. (U.S. Department of Education, 2009; Barbour & Reeves, 2009). Online learning is expected to evolve in future years with increased use of multimedia, games, and social networking; increased mobility of and expansion into informal learning environments; infusion of competencies in emerging technologies; and more personalized learning (U.S. Department of Education, 2010).

When asked why they have chosen to use online learning resources for instruction, school administrators cite several reasons, including that these resources allow schools to offer courses not otherwise available in particular school settings (e.g., rural schools, under-resourced schools); meet the needs of specific groups of students (e.g., homebound students, English learners); offer advanced or college-level courses; reduce scheduling conflicts; and that the resources permit students who failed courses to take them again. Cost advantages are sometimes cited also, but less frequently (Picciano & Seaman, 2007; Barbour & Reeves, 2009).

Online learning can have a number of potential benefits for children with disabilities. Use of online technology can allow for individualized instruction, flexible presentation of content,

frequent and immediate feedback, better monitoring of student progress, and increased student control. Additionally, flexible online learning may increase access for homebound or hospital-bound children. Online learning in the home increases the potential for parental involvement. Finally, online learning may help reduce the impact of shortages of related services providers and other specialists in rural and under-resourced areas (e.g., through online speech therapy, academic remediation, etc.) (Smith & Meyen, 2003; Barbour & Reeves, 2009; Keeler, *et al.,* 2007; Muller, 2010).

Research suggests that online learning can be at least as effective as in-person instruction in many circumstances, but that characteristics of the students and instructional content may influence its effectiveness (U.S. Department of Education, 2009; Figlio, Rush & Yin, 2010). Most of the research on the effectiveness of online learning to date has focused on postsecondary students, and few studies have examined the effectiveness of online learning for students with disabilities. Research on the potential effectiveness of online learning is needed, particularly for K–12 students and students with disabilities.

Before all children with disabilities can benefit from online learning, the materials and delivery platforms (web, mobile devices, computers, etc.) must be fully accessible. Current efforts to help ensure accessibility include the Web Accessibility Initiative (*http://www.w3.org/WAI*), development of accessibility standards by the United States Access Board (*http://www.access-board.gov*), development and application of the National Instructional Materials Accessibility Standard (NIMAS) (*http://aim.cast.org/collaborate/NIMASCtr*), and the "Access for All" accessibility initiative of the IMS Global Learning Consortium (*http://www.imsglobal.org/accessibility*). These efforts have led to the establishment and implementation of accessibility standards for the World Wide Web, information technologies, and instructional materials in printed and digital forms. Research, however, is needed on the degree to which these efforts are sufficiently comprehensive and effective in ensuring accessibility of online learning for individuals with disabilities.

Online learning not only must be accessible, but also must be effective in supporting learning for children with disabilities by providing learning supports and being "universally designed" to meet the needs of all learners (Keeler, *et al.,* 2007; Grabinger, Aplin, & Ponnappa-Brenner, 2008). Archambault, *et al.* (2010) conducted a survey of online learning programs to identify challenges and strategies for serving "at-risk" students, including children with disabilities, enrolled in these online programs. Among the main challenges reported were difficulty in establishing and maintaining student engagement and motivation, and student difficulties related to managing time and navigating assignments. The programs reported using a variety of strategies to address these challenges, including early identification and intervention for at-risk learners; personal learning plans; individualized instruction using supplementary tools (e.g., technology-based reading programs and online study tools); connecting learning activities to real life; increasing communication among teachers, mentors, learning coaches, students, and families; and extended time to complete online work. While the programs reported that using these strategies was helpful, additional research is needed to study their effects on student learning outcomes.

Online learning is expanding and evolving dramatically in the United States, offering new opportunities for the education of children with disabilities but also presenting challenges related to accessibility and effectiveness. Research is needed to: (1) Determine the extent to which current online learning opportunities are available, accessible, and potentially effective in improving outcomes for children with disabilities, and (2) identify promising approaches for improving the accessibility and potential effectiveness of online learning for children with disabilities.

*Priority:*

The purpose of this priority is to fund a cooperative agreement to support the establishment and operation of a Center on Online Learning and Students with Disabilities (Center). The Center will conduct a program of research to study: (1) Current and emerging trends and issues related to the participation of all children with disabilities in online learning from kindergarten through grade 12 (K–12); (2) potential positive outcomes and negative consequences of online learning for children with disabilities; and (3) promising approaches for effectively including children with disabilities in online learning.

To be considered for funding under this absolute priority, applicants must meet the application requirements contained in this priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

*Application Requirements.* An applicant must include in its application—

(a) A logic model that depicts, at a minimum, the goals, activities, outputs, and outcomes of the proposed project. A logic model communicates how a project will achieve its outcomes and provides a framework for both the formative and summative evaluations of the project;

**Note:** The following two Web sites provide more information on logic models and list multiple online resources: *http://www.researchutilization.org/matrix/logicmodel_resource3c.html,* and *http://www.tadnet.org/model_and_performance.*

(b) A plan to implement the activities described in the *Project Activities* section of this priority;

(c) A plan, linked to the proposed project's logic model, for a formative evaluation of the proposed project's activities. The plan must describe how the formative evaluation will use clear performance objectives to ensure continuous improvement in the operation of the proposed project, including objective measures of progress in implementing the project and ensuring the quality of products and services;

(d) A budget for a summative evaluation to be conducted by an independent third party;

(e) A budget for attendance at the following:

(1) A one and one half-day kick-off meeting to be held in Washington, DC, within four weeks after receipt of the award, and an annual planning meeting held in Washington, DC, with the Office of Special Education Programs (OSEP) Project Officer during each subsequent year of the project period.

(2) A three-day Project Directors' Conference in Washington, DC, during each year of the project period.

(3) Two additional two-day trips annually to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP.

*Project Activities.* To meet the requirements of this priority, the Center, at a minimum, must—

(a) Establish and maintain a technical work group (TWG) to review the research and development plans and activities of the Center and to provide technical advice throughout the project period. At a minimum the TWG must convene annually, whether in person, by phone, or through other means. The TWG must include individuals with expertise in online learning, effective instructional approaches for children

with disabilities, and research methods, including the research methodologies employed by the Center;

(b) Plan and conduct a systematic program of research and development using methods that may include analyses of extant literature, data, and documents from other sources; collection of data via surveys, focus groups, interviews, and observations; analysis of instructional artifacts; design research; quasi-experimental research; and other appropriate methods. The program of research and development must accomplish the following four tasks:

(1) Identify and verify trends and issues related to the participation of children with disabilities in K–12 online learning in a range of forms and contexts (e.g., virtual schools, online courses, expository, interactive, etc.). Research topics must include: Accessibility and delivery of content, patterns of student participation, learning needs and supports, and emerging forms of online learning and their potential impact on accessibility and outcomes for children with disabilities;

(2) Identify and describe major potential positive outcomes and negative consequences of participation in online learning for children with disabilities, and analyze the available evidence on these outcomes and consequences. Positive outcomes may include a range of academic, social, career, and functional achievements associated with college- and career-readiness. Negative consequences may include reduced access to social or extra-curricular activities, a narrowed curriculum, or reduced alignment of instruction with academic standards;

(3) Identify and develop promising approaches for increasing the accessibility and potential effectiveness of online learning for children with disabilities. These approaches may involve designing accessibility and support features for online learning, providing supplementary off-line resources, individualizing online learning, identifying and addressing student learning problems as soon as possible, and training students, teachers, tutors, parents, and others involved in online learning on ways to support student learning.

(4) Test the feasibility, usability, and potential effectiveness (or promise) of one or more key approaches identified in paragraph (3) using appropriate research designs such as quasi-experimental, single-subject, qualitative, and experimental research. This research must involve actual try-outs of the approach(es) with the intended populations in authentic settings. The research must produce detailed descriptions of the approaches and their key components, evidence that the approaches can be successfully implemented in authentic settings, and evidence of the promise of the approaches for achieving their intended outcomes;

(c) Maintain a Web site that meets government and industry-recognized standards for accessibility.

(d) Disseminate information on the activities and findings of the project regionally and nationally through the use of Web sites and other electronic media, publications, presentations, and communities of practice.

(e) Maintain ongoing communication with the OSEP Project Officer through monthly phone conversations and e-mail communication.

(f) Communicate and collaborate, on an ongoing basis, with OSEP-funded projects and other projects engaged in relevant activities. This collaboration may include the coordination of research, joint dissemination of findings, and planning and carrying out meetings and events.

(g) Participate in a summative evaluation of the Center conducted by an independent third party.

*Extending the Project for a Fourth and Fifth Year*

The Secretary may extend the Center for up to two additional years beyond its original project period of 36 months if the grantee is achieving the intended outcomes of the grant.

*References*

Archambault, L.; Diamond, D.; Brown, R.; Cavanaugh, C.; Coffey, M.; Foures-Aalbu, D.; Richardson, J. & Zygouris-Coe, V. (2010). Research committee issues brief: An exploration of at-risk learners and online education. Vienna VA: International Association for K–12 Online Learning.

Barbour, M. K. & Reeves, T. C. (2009). The reality of virtual schools: A review of the literature. Computers & Education, 52, 402–416.

Figlio, D.N., Rush, M. & Yin, L. (2010). Is it live or is it Internet? Experimental estimates of the effects of online instruction on student learning (NBER Working Paper 16089). Cambridge, MA: National Bureau of Economic Research. (*http://www.nber.org/papers/w16089*)

Grabinger, S. R., Aplin, C. & Ponnappa-Brenner, G. (2008). Supporting learners with cognitive impairments in online environments. TechTrends, 52(1), 63–69.

Keeler, C. G., Richter, J., Anderson-Inman, L., Horney, M. A., Ditson, M. (2007). Exceptional Learners: Differentiated Instruction Online. In C. Cavanaugh & R. Blomeyer (Eds.), What works in K–12 online learning (pp. 125 – 178). Eugene, OR: International Society for Technology in Education.

Müller, E. (2010). Virtual K–12 public school programs and students with disabilities: Issues and recommendations—A Policy Forum proceedings document. Alexandria, VA: Project Forum at the National Association of State Directors of Special Education.

Picciano, A. G., & Seaman, J. (2007). K–12 online learning: A survey of U.S. school district administrators. Newburyport, MA: Sloan Consortium.

Smith, S. J. & Meyen, E. L. (2003). Applications of online instruction: An overview for teachers, students with mild disabilities, and their parents. Focus on Exceptional Children. 35(6), 1–15.

U.S. Department of Education, Office of Innovation and Improvement. (2008). Evaluating Online Learning: Challenges and Strategies for Success, Washington, DC.

U.S. Department of Education, Office of Planning, Evaluation, and Policy Development. (2009). Evaluation of Evidence-Based Practices in Online Learning: A Meta-Analysis and Review of Online Learning Studies, Washington, DC.

U.S. Department of Education, Office of Educational Technology. (2010). Transforming American Education: Learning Powered by Technology, Washington, DC, 2010.

Wicks, M. (2010). A national primer on K–12 online learning, Version 2. Vienna, VA: International Association for K–12 Online Learning.

*Waiver of Proposed Rulemaking:* Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

*Program Authority:* 20 U.S.C. 1474 and 1481(d).

*Applicable Regulations:* The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

**Note:** The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

## II. Award Information

*Type of Award:* Cooperative agreement.

*Estimated Available Funds:* $1,497,000. Contingent upon the availability of funds and the quality of applications, we may make additional

awards in FY 2012 from the list of unfunded applicants from the competition.

*Maximum Award:* We will reject any application that proposes a budget exceeding $1,497,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

*Number of Awards:* 1.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 36 months with an optional additional 24 months based on performance.

## III. Eligibility Information

1. *Eligible Applicants:* State educational agencies (SEAs); local educational agencies (LEAs), including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants and grant recipients funded under this competition must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the projects (see section 682(a)(1)(A) of IDEA).

## IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office.

To obtain a copy via the Internet, use the following address: *http://www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.EDPubs.gov* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.327U.

To obtain a copy from the program office, contact the person listed under *For Further Information Contact* in section VII of this notice.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 50 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the references, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: May 5, 2011.

Deadline for Transmittal of Applications: June 20, 2011.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under *For Further Information Contact* in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice. Deadline for Intergovernmental Review: August 18, 2011.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any

changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf*).

7. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.*

We are participating as a partner in the Governmentwide Grants.gov Apply site. The Center on Online Learning and Students with Disabilities competition, CFDA number 84.327U, is included in this project. We request your participation in Grants.gov.

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *http://www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

You may access the electronic grant application for the Center on Online Learning and Students with Disabilities competition, CFDA number 84.327U, at *http://www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.327, not 84.327U).

Please note the following:

- Your participation in Grants.gov is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *http://www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- If you submit your application electronically, you must upload any narrative sections and all other attachments to your application as files in a .PDF (Portable Document) format only. If you upload a file type other than a .PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System:* If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under *For Further Information Contact* in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the

Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.327U) LBJ Basement Level 1, 400 Maryland Avenue, SW, Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.327U) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

**Note for Mail or Hand Delivery of Paper Applications:** If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:*

In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers, by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

## VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technology and Media Services for Individuals with Disabilities program. These measures focus on the extent to which projects are of high quality, are relevant to improving outcomes of

children with disabilities, and contribute to improving outcomes for children with disabilities. We will collect data on these measures from the project funded under this competition.

The grantee will be required to report information on its project's performance in annual performance reports to the Department (34 CFR 75.590).

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

**VII. Agency Contact**

*For Further Information Contact:* David Malouf, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4114, Potomac Center Plaza (PCP), Washington, DC 20202–2550. Telephone: (202) 245–6253.

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

**VIII. Other Information**

*Accessible Format:* Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

*Electronic Access to This Document:* The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *http://www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *http://www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 2, 2011.

**Alexa Posny,**

*Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 2011–10990 Filed 5–4–11; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Savannah River Site

**AGENCY:** Department of Energy.

**ACTION:** Notice of Open Meeting.

**SUMMARY:** This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

**DATES:** Monday, May 23, 2011, 1 p.m.–5 p.m., Tuesday, May 24, 2011, 8:30 a.m.–4:30 p.m.

**ADDRESSES:** Hyatt Regency Savannah, Two West Bay Street, Savannah, GA 31402.

**FOR FURTHER INFORMATION CONTACT:** Gerri Flemming, Office of External Affairs, Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; *Phone:* (803) 952–7886.

**SUPPLEMENTARY INFORMATION:**

*Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

**Tentative Agenda**

*Monday, May 23, 2011*

1 p.m.—Combined Committee Session
5 p.m.—Adjourn

*Tuesday, May 24, 2011*

8:30 a.m.—Approval of Minutes, Chair Update, Public Comment Session, Agency Updates, Administrative Committee Report, Strategic and Legacy Management Committee Report, Facility Disposition and Site Remediation Committee Report, Public Comment Session
12 p.m.—Lunch Break
1 p.m.—Waste Management Committee Report, Nuclear Materials Committee Report, Public Comment Session
4:30 p.m.—Adjourn

If needed, time will be allotted after public comments for items added to the agenda.

*Public Participation:* The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gerri Flemming at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gerri Flemming's office at the address or telephone listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

*Minutes:* Minutes will be available by writing or calling Gerri Flemming at the address or phone number listed above. Minutes will also be available at the following Web site: *http://www.srs.gov/general/outreach/srs-cab/meeting_summaries_2011.html.*

Issued at Washington, DC, on May 2, 2011.

**LaTanya R. Butler,**

*Acting Deputy Committee Management Officer.*

[FR Doc. 2011–10971 Filed 5–4–11; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Idaho National Laboratory

**AGENCY:** Department of Energy.

**ACTION:** Notice of Open Meeting.

**SUMMARY:** This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho National

Laboratory. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Wednesday, May 18, 2011 8 a.m.–5 p.m.

Opportunities for public participation will be from 10:15 a.m. to 10:30 a.m. and from 2:15 p.m. to 2:30 p.m.

These times are subject to change; please contact the Federal Coordinator (below) for confirmation of times prior to the meeting.

**ADDRESSES:** Hilton Garden Inn, 700 Lindsey Boulevard, Idaho Falls, Idaho 83402.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Pence, Federal Coordinator, Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, MS–1203, Idaho Falls, Idaho 83415. Phone (208) 526–6518; Fax (208) 526–8789 or e-mail: *pencerl@id.doe.gov* or visit the Board's Internet home page at: *http://www.inlemcab.org*.

**SUPPLEMENTARY INFORMATION:**

*Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Topics (agenda topics may change up to the day of the meeting; please contact Robert L. Pence for the most current agenda):

- Recent Public Involvement and Outreach.
- Idaho EM Cleanup Status.
- Advanced Mixed Waste Treatment Project Overview.
- Idaho Cleanup Project Overview.
- Deactivation and Decommissioning Overview and Update.
- Idaho Nuclear Technology and Engineering Center—Spent Nuclear Fuel/Calcine Overview.
- Subsurface Disposal Area Progress.
- CH2M–WG Idaho, LLC—Safety Record.

*Public Participation:* The EM SSAB, Idaho National Laboratory, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Robert L. Pence at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Robert L. Pence at the address or telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. This notice is being published less than 15 days prior to the meeting date due to programmatic issues that had to be resolved prior to the meeting date.

*Minutes:* Minutes will be available by writing or calling Robert L. Pence, Federal Coordinator, at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.inlemcab.org/meetings.html.*

Issued at Washington, DC on May 2, 2011.

**LaTanya R. Butler,**

*Acting Deputy Committee Management Officer.*

[FR Doc. 2011–10972 Filed 5–4–11; 8:45 am]

BILLING CODE P

## DEPARTMENT OF ENERGY

### Energy Efficiency and Renewable Energy

### State Energy Advisory Board (STEAB); Meeting

**AGENCY:** Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Notice of Open Meeting.

**SUMMARY:** This notice announces an open meeting of the State Energy Advisory Board (STEAB). The Federal Advisory Committee Act (Pub. L. 92–463; 86 Stat.770) requires that public notice of these meetings be announced in the **Federal Register**.

**DATES:** June 7–8, 2011, 9 a.m.–5 p.m., June 9, 2011, 9 a.m.–12 p.m.

**ADDRESSES:** Capital Hilton, 1001 16th Street, NW., Washington, DC 20036.

**FOR FURTHER INFORMATION CONTACT:** Gil Sperling, STEAB Designated Federal Officer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue, SW., Washington DC 20585; or *e-mail: gil.sperling@ee.doe.gov.*

**SUPPLEMENTARY INFORMATION:** *Purpose of the Board:* To make recommendations to the Assistant Secretary for the Office of Energy Efficiency and Renewable Energy regarding goals and objectives, programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

*Tentative Agenda:* Review and update of task force and Subcommittee accomplishments, meet with key staff of the Office of Energy Efficiency and Renewable Energy to discuss new initiatives and programs coming out of each program office, meet with National laboratory directors and staff to gain a better understanding of deployment efforts, and update to the Board on routine business matters and other topics of interest.

*Public Participation:* The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Gil Sperling at the address or email listed above. Requests to make oral comments must be received five days prior to the meeting; reasonable provision will be made to include requested topic(s) on the agenda. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

*Minutes:* The minutes of the meeting will be available for public review and copying within 60 days on the STEAB Web site: *http://www.steab.org.*

Issued at Washington, DC, on April 29, 2011.

**LaTanya Butler,**

*Acting Deputy Committee Management Officer.*

[FR Doc. 2011–10975 Filed 5–4–11; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Energy Information Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** U.S. Energy Information Administration (EIA), Department of Energy (DOE).

**ACTION:** Agency information collection activities: Proposed collection; comment request.

**SUMMARY:** The EIA is soliciting comments on the proposed three-year extension to the EIA–22M, "Monthly Biodiesel Production Survey."

**DATES:** Comments must be filed by July 5, 2011. If you anticipate difficulty in submitting comments within that

period, contact the person listed below as soon as possible.

**ADDRESSES:** Send comments to Chris Buckner. To ensure receipt of the comments by the due date, submission by FAX (202–586–1076) or e-mail (*chris.buckner@eia.gov*) is recommended. The mailing address is Office of Petroleum and Biofuels Statistics, EI–25, Forrestal Building, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585. Alternatively, Chris Buckner may be contacted by telephone at 202–586–6670.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of any forms and instructions should be directed to Chris Buckner at the address listed above. The proposed forms and changes in definitions and instructions are also available on the Internet at: *http://www.eia.doe.gov/survey/#eia-22m*.

**SUPPLEMENTARY INFORMATION:**

I. Background
II. Current Actions
III. Request for Comments

## I. Background

The Federal Energy Administration (FEA) Act of 1974 (15 U.S.C. 772(b), Pub. L. 93–275), requires the EIA to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer term domestic demands.

Section 503 of the Energy Policy Act of 1992, Public Law 102–486 (EPACT1992), (42 U.S.C. 13253) directs DOE to estimate consumption of alternative and replacement fuels annually. Since 1994, EIA has published replacement fuel consumption data annually in *Alternatives to Traditional Transportation Fuels*.[1] Biodiesel consumption (estimated by EIA based on secondary sources) has been included since 2000.

The Energy Policy Act of 2005 (EPACT2005), Public Law 109–058 (42 U.S.C. 15801) specifies in greater detail how EIA should monitor biodiesel. Section 42 U.S.C. 7135(m)(1) states:

"In order to improve the ability to evaluate the effectiveness of the Nation's renewable fuels mandate, the [Administrator] shall conduct and publish the results of a survey of renewable fuels demand in the motor vehicle fuels market in the United States monthly, and in a manner designed to protect the confidentiality of individual responses. In conducting the survey, the Administrator shall collect information both on a national and regional basis, including each of the following:"

(A) The quantity of renewable fuels produced
(B) The quantity of renewable fuels blended
(C) The quantity of renewable fuels imported
(D) The quantity of renewable fuels demanded
(E) Market price data
(F) Such other analyses or evaluations as the Administrator finds necessary to achieve the purposes of this section.

42 U.S.C. 7135(m)(2) also provides:

"The Administrator shall also collect or estimate information both on a national and regional basis, pursuant to subparagraphs (A) through (F) of paragraph (1), for the 5 years prior to implementation of this subsection."

The EIA, as part of its effort to comply with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35), provides the general public and other Federal agencies with opportunities to comment on collections of energy information conducted by or in conjunction with the EIA. Any comments received help the EIA prepare data requests that maximize the utility of the information collected, and to assess the impact of collection requirements on the public. Also, the EIA will later seek approval for this collection by the Office of Management and Budget (OMB) under Section 3507(a) of the Paperwork Reduction Act of 1995.

Please refer to the proposed forms and instructions for more information about the purpose, who must report, when to report, where to submit, the elements to be reported, detailed instructions, provisions for confidentiality, and uses (including possible nonstatistical uses) of the information. For instructions on obtaining materials, see the **FOR FURTHER INFORMATION CONTACT** section.

## II. Current Actions

The EIA proposes a three-year extension to the EIA–22M, "Biodiesel Production Survey" with no changes.

## III. Request for Comments

Prospective respondents and other interested parties should comment on the actions discussed in item II. The following guidelines are provided to assist in the preparation of comments.

*As a Potential Respondent to the Request for Information*

A. Is the proposed collection of information necessary for the proper performance of the functions of the agency and does the information have practical utility?

B. What actions could be taken to help ensure and maximize the quality, objectivity, utility, and integrity of the information to be collected?

C. Are the instructions and definitions clear and sufficient? If not, which instructions need clarification?

D. Can the information be submitted by the respondent by the due date?

E. Public reporting burden for this collection is estimated to average:

*Estimated hours per response:* 3 hours. The estimated burden includes the total time necessary to provide the requested information. In your opinion, how accurate is this estimate?

F. The agency estimates that the only cost to a respondent is for the time it will take to complete the collection. Will a respondent incur any start-up costs for reporting, or any recurring annual costs for operation, maintenance, and purchase of services associated with the information collection?

G. Does any other Federal, State, or local agency collect similar information? If so, specify the agency, the data element(s), and the methods of collection.

*As a Potential User of the Information To Be Collected*

A. Is the proposed collection of information necessary for the proper performance of the functions of the agency and does the information have practical utility?

B. What actions could be taken to help ensure and maximize the quality, objectivity, utility, and integrity of the information disseminated?

C. Is the information useful at the levels of detail to be collected?

D. For what purpose(s) would the information be used? Be specific.

E. Are there alternate sources for the information and are they useful? If so, what are their weaknesses and/or strengths?

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the forms. They also will become a matter of public record.

**Statutory Authority:** Section 3507(h)(1) of the Paperwork Reduction Act of 1995, Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*), and the DOE Organization Act (42 U.S.C. 7101 *et seq.*).

[1] *http://www.eia.doe.gov/cneaf/alternate/page/atftables/afvtransfuel_II.html*

Issued in Washington, DC, April 28, 2011.

**Stephanie Brown,**

*Director, Office of Survey Development & Statistical Integration, U.S. Energy Information Administration.*

[FR Doc. 2011–10977 Filed 5–4–11; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2784–004]**

### Pacific Gas and Electric Company; Notice of Application Tendered for Filing With the Commission, and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following transmission line only project application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent License—Transmission Line Only.

b. *Project No:* P–2784–004.

c. *Date Filed:* April 18, 2011.

d. *Applicant:* Pacific Gas and Electric Company (PG&E).

e. *Name of Project:* Rollins Transmission Line Project.

f. *Location:* The Rollins Transmission Line Project is located in Placer and Nevada counties, California.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Forrest Sullivan, Senior Project Manager, Pacific Gas and Electric Company, 5555 Florin Perkins Road, Sacramento, CA, 95826. Tel: (916) 386–5580.

i. *FERC Contact:* Mary Greene, (202) 502–8865 or *mary.greene@ferc.gov.*

j. *Status:* This application is not ready for environmental analysis at this time.

k. *Description of Project:* The Project is connected with the Yuba-Bear Hydroelectric Project, FERC Project No. 2266, owned and operated by the Nevada Irrigation District (NID). The Project consists of a single circuit, 3-phase, 60-kilovolt, wood-pole transmission line extending 0.72 mile from NID's Rollins powerhouse switchyard to PG&E's interconnected transmission grid. The project is within a 40 foot corridor. PG&E proposes to remove from the project, an access road that is 1,867 feet in length, with project widths between 20 and 60 feet. The project occupies a total of 3.46 acres, all of which is under private ownership.

PG&E is not proposing to modify the existing Project and does not plan any changes to the operation or maintenance of the transmission line.

l. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the three digits in the docket number field to access the document. 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. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. With this notice, we are initiating consultation with the California State Historic Preservation Officer (SHPO), as required by section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

n. Procedural schedule and final amendments: This application will be processed according to the following Licensing Schedule. Revisions to the schedule will be made if the Commission determines it necessary to do so.

| Milestone | Tentative date |
|---|---|
| Notice of Acceptance/Notice of Ready for Environmental Analysis | June 2011. |
| Filing of recommendations, preliminary terms and conditions, and fishway prescriptions | August 2011. |
| Commission issues Draft EIS | February 2012. |
| Comments on Draft EIS | March 2012. |
| Modified Terms and Conditions | May 2012. |
| Commission Issues Final EIS | September 2012. |

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice soliciting final terms and conditions.

Dated: April 29, 2011.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2011–10958 Filed 5–4–11; 8:45 am]

BILLING CODE P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. NJ11–12–000]**

### Orlando Utilities Commission; Notice of Filing

Take notice that on April 15, 2011, Orlando Utilities Commission submitted its tariff filing per 35.25(e): Order 890 compliance to be effective 4/15/2011.

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 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 May 20, 2011.

Dated: April 29, 2011.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2011–10960 Filed 5–4–11; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP11–213–000]**

### ANR Pipeline Company; Notice of Request Under Blanket Authorization

Take notice that on April 18, 2011, ANR Pipeline Company (ANR), 717 Texas Street, Suite 2400, Houston, TX 77002–2761, filed in Docket No. CP11–213–000, an application pursuant to sections 157.205 and 157.208(b) of the Commission's Regulations under the Natural Gas Act (NGA) as amended, to offset and replace portions of its 24-inch natural gas pipeline located in Federal waters, offshore Louisiana, under ANR's blanket certificate issued in Docket No. CP82–480–000, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also 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, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Rene Staeb, Director, Certificates & Regulatory Administration, ANR Pipeline Company, 717 Texas Street, Suite 2400, Houston, TX 77002–2761 at telephone (832) 320–5215, fax (832) 320–6215 or e-mail: *rene_staeb@transcanada.com* or to M. Catharine Davis, Vice President U.S. Pipelines Law, ANR Pipeline Company, 717 Texas Street, Suite 2400, Houston, TX 77002–2761, telephone (832) 320–5509, fax (832) 320–6509 or e-mail: *catharine_davis@transcanada.com* or to Robert D. Jackson, Director, Certificates and Regulatory Administration, ANR Pipeline Company, 717 Texas Street, Suite 2400, Houston, TX 77002–2761, telephone (832) 320–5487, fax (832) 320–6487 or e-mail: *robert_jackson@transcanada.com.*

Specifically, ANR proposes to offset and replace 2200 feet of its 24-inch natural gas pipeline, Line No. 614, located in Federal waters, offshore Louisiana, South Marsh Island Blocks 114, 122, 132 and 137. ANR states as a result of forces from Hurricane Ike in 2008 a portion of ANR's Line No. 614 has shifted as much as 1,800 feet to the west from its original position to within 7 feet of a production platform located in South Marsh Island Block No. 122. ANR is proposing to offset the 24-inch line a minimum of 500 feet in all directions from the platform to provide appropriate clearance for production activities. The estimated cost for this project is $23,783,000.

Any person or the Commission's staff may, within 60 days after 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 regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, 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 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Dated: April 29, 2011.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2011–10959 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–ORD–2011–0418; FRL–9302–4]**

### Human Studies Review Board (HSRB); Notification of a Public Teleconference

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

**ACTION:** Notice.

**SUMMARY:** The U. S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a public teleconference of the HSRB to discuss its draft report from the April 13–14, 2011 HSRB meeting, and consider a draft letter from an HSRB workgroup on providing research participants with individualized study results measuring the amount of antimicrobial cleaning products on participants' skin and the amount they breathe in while mopping floors.

**DATES:** The teleconference will be held on Tuesday, May 24, 2011 from approximately 1 p.m. to approximately 3 p.m. Eastern Time.

**ADDRESSES:** Submit your written comments, identified by Docket ID No. EPA–HQ–ORD–2011–0418, by one of the following methods:

*Internet: http://www.regulations.gov:* Follow the Web site instructions for submitting comments.

*E-mail: ORD.Docket@epa.gov.*

*Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), ORD Docket, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

*Hand Delivery:* The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW., Washington, DC 20460. The hours of operation are 8:30 a.m. to 4:30 p.m.

Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566–1744 or e-mail the ORD Docket at *ord.docket@epa.gov* for instructions. Updates to Public Reading Room access are available online at *http://www.epa.gov/epahome/dockets.htm.*

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–ORD–2011–0418. 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 comments includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which 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 comments 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.

**FOR FURTHER INFORMATION CONTACT:** Any members of the public who wish to receive further information should contact Jim Downing at *telephone number:* (202) 564–2468; *fax:* (202) 564–2070; *e-mail address: downing.jim@epa.gov,* or Lu-Ann Kleibacker at *telephone number:* (202) 564–7189; *fax:* (202) 564–2070; *e-mail address: kleibacker.lu-ann@epa.gov; mailing address:* Environmental Protection Agency, Office of the Science Advisor, 8105R, 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at *http://www.epa.gov/osa/hsrb.*

**SUPPLEMENTARY INFORMATION:**

*Location:* The meeting will take place via telephone only.

*Meeting access:* For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT,** so that appropriate arrangements can be made.

*Procedures for providing public input:* Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in section I, "Public Meeting," under subsection D, "How May I Participate in this Meeting?" of this notice.

## I. Public Meeting

### *A. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT.**

### *B. How can I access electronic copies of this document and other related information?*

In addition to using *http://www.regulations.gov,* you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.*

*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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the ORD Docket, EPA/DC Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW., Washington, DC 20460. The hours of operation are 8:30 a.m to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566–1744, or e-mail the ORD Docket at *ord.docket@epa.gov* for instructions. Updates to the Public Reading Room access are available on the Web site (*http://www.epa.gov/epahome/dockets.htm*).

### *C. What should I consider as I prepare my comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you use that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

### *D. How may I participate in this meeting?*

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA–HQ–ORD–2011–0418 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments will be accepted up to Tuesday, May 17, 2011. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments during the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to Jim Downing or Lu-Ann Kleibacker under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Tuesday, May 17, 2011, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official (DFO) to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of

the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. Written comments. Submit written comments prior to the meeting. For the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, Tuesday, May 17, 2011. You should submit your comments using the instructions in section I, under subsection C, "What Should I Consider as I Prepare My Comments for EPA?" In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT.** There is no limit on the length of written comments for consideration by the HSRB.

*E. Background*

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App.2 section 9. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the EPA Science Advisor.

1. Topics for Discussion. The HSRB will be reviewing its draft report from the April 13–14, 2011 HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the April 13–14, 2011 HSRB meeting can be found at **Federal Register** Volume 76, Number 59 (Monday, March 28, 2011), pages 17121–17123) and at the HSRB Web site *http://www.epa.gov/osa/hsrb/.* The April 13–14, 2011 meeting draft report is now available. You may obtain electronic copies of this document and certain other related documents that might be available electronically from the *http://www.regulations.gov* Web site and the HSRB Internet home page at *http://www.epa.gov/osa/hsrb.* The HSRB will also review and consider a draft letter providing participants with individualized study results that was provided at a previous HSRB meeting. The HSRB was asked to provide feedback on the letter that will be sent to the participants from the Antimicrobial Exposure Assessment Task Force II that measured the amount of antimicrobial cleaning products on participants' skin and the amount they breathe in while mopping floors.

For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: April 29, 2011.

**Paul T. Anastas,**

*EPA Science Advisor.*

[FR Doc. 2011–11001 Filed 5–4–11; 8:45 am]

**BILLING CODE 6560–50–P**

---

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9301–9]**

## Proposed Settlement Agreement, Clean Air Act Citizen Suit

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

**ACTION:** Notice of Proposed Settlement Agreement; Request for Public Comment.

**SUMMARY:** In accordance with section 113(g) of the Clean Air Act, as amended ("CAA"), 42 U.S.C. 7413(g), notice is hereby given of a proposed settlement agreement to resolve a lawsuit filed by the Sierra Club, the National Parks Conservation Association, and the Northwest Environmental Defense Center (collectively "Plaintiffs") in the United States District Court for the Western District of Washington: *Sierra Club, et al.* v. *U.S. Environmental Protection Agency,* No. 2:10-cv-01872–RSL (W.D. Wash.). Plaintiffs filed a deadline suit to compel the Administrator to respond to an administrative petition seeking EPA's objection to a CAA Title V operating permit issued by the Southwest Clean Air Agency to Transalta Centralia Generation L.L.C. ("Transalta") for its coal-fired power plant in Centralia, Washington. The proposed settlement agreement states that EPA intends to respond to the petition by April 29, 2011.

**DATES:** Written comments on the proposed settlement agreement must be received by *June 6, 2011.*

**ADDRESSES:** Submit your comments, identified by Docket ID number EPA–HQ–OGC–2011–0348, online at *http://www.regulations.gov* (EPA's preferred method); by e-mail to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, *Mailcode:* 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

**FOR FURTHER INFORMATION CONTACT:** Sara Froikin, Office of General Counsel (Mail Code 2322A), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone:* (202) 564–3187; fax number (202) 564–5603; *e-mail address: froikin.sara@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Additional Information About the Proposed Settlement Agreement

This proposed settlement agreement would resolve a lawsuit alleging that the Administrator failed to perform a nondiscretionary duty to grant or deny, within 60 days of submission, an administrative petition to object to a CAA Title V permit issued by the Southwest Clean Air Agency to Transalta Centralia Generation L.L.C. for its coal-fired power plant in Centralia, Washington. The proposed settlement agreement states that EPA intends to respond to the petition by April 29, 2011, and the Plaintiffs have agreed to file a motion for voluntary dismissal of the lawsuit (except for the claim for

costs of litigation) with prejudice within 5 business days after EPA issues a response to the petition. EPA has also agreed to pay specified attorneys fees to the Plaintiffs, and the Plaintiffs have agreed to file a motion for dismissal of Plaintiffs' claims for costs of litigation within 5 days after receiving payment.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed settlement agreement from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this settlement agreement should be withdrawn, the terms of the settlement agreement will be affirmed.

**II. Additional Information About Commenting on the Proposed Settlement Agreement**

*A. How can I get a copy of the settlement agreement?*

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2011–0348) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *http://www.regulations.gov.* You may use the *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *http://www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

*B. How and to whom do I submit comments?*

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through *http://www.regulations.gov,* your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: April 27, 2011.

**Richard B. Ossias,**

*Associate General Counsel.*

[FR Doc. 2011–11023 Filed 5–4–11; 8:45 am]

BILLING CODE 6560–50–P

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 9:15 a.m. on Tuesday, May 10, 2011, to consider the following matters:

*Summary Agenda:* No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Final Rule Amending Part 335 to Conform with Requirements of the Securities and Exchange Commission.

Memorandum and resolution re: Amendments to the Statement of Policy for Section 19 of the FDI Act.

Memorandum and resolutions re: 35–Year Employee Service Resolutions.

*Discussion Agenda:*

Memorandum and resolution re: Notice of Proposed Rulemaking Pursuant to § 742(c) of the Dodd-Frank Wall Street Reform and Consumer Protection Act for the Purpose of Adding 12 CFR part 349 to Regulate FDIC–Supervised Entities Engaged in Retail Forex Transactions.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *http://www.vodium.com/goto/fdic/boardmeetings.asp* to view the event. If

you need any technical assistance, please visit our Video Help page at: *http://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: May 3, 2011.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2011–11153 Filed 5–3–11; 4:15 pm]

BILLING CODE P

## FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

**[Docket No. AS11–15]**

### Appraisal Subcommittee Notice of Meeting

**AGENCY:** Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

**ACTION:** Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC, 250 E Street, SW., Room 6C, Washington, DC 20219.

Date: May 11, 2011.

Time: 10:30 a.m.

Status: Open.

Matters to be Considered:

**Summary Agenda**

April 13, 2011 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

**Discussion Agenda**

West Virginia Compliance Review.

**How To Attend and Observe an ASC Meeting**

E-mail your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street, NW., Ste 760, Washington, DC 20005. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. If that Monday is a Federal holiday, then your request must be received 4:30 p.m., ET on the previous Friday. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: May 2, 2011.

**James R. Park,**

*Executive Director.*

[FR Doc. 2011–10985 Filed 5–4–11; 8:45 am]

BILLING CODE P

## FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

**[Docket No. AS11–16]**

### Appraisal Subcommittee Notice of Meeting

**AGENCY:** Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

**ACTION:** Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC, 250 E Street, SW., Room 6C, Washington, DC 20219.

Date: May 11, 2011.

Time: Immediately following the ASC open session.

Status: Closed.

Matters to be Considered:

April 13, 2011 minutes—Closed Session.

Preliminary discussion of State Compliance Reviews.

Dated: May 2, 2011.

**James R. Park,**

*Executive Director.*

[FR Doc. 2011–10986 Filed 5–4–11; 8:45 am]

BILLING CODE P

## FEDERAL MARITIME COMMISSION

### Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR part 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by e-mail at *OTI@fmc.gov*.

A & J Cargo Logistics Inc. (OFF), 8245 NW 36th Street, Ste. 5, Miami, FL 33166, Officer: Jose L. Iglesias, President/Secretary/Treasurer, (Qualifying Individual), Application Type: New OFF License.

A.J. Arango, Inc. (OFF), 1516 E. 8th Avenue, Tampa, FL 33605, Officers: Roslyn A. McKenna, Vice President, (Qualifying Individual), James Alberdi, President, Application Type: QI Change.

American Red Ball International, Inc. (NVO & OFF), 9750 3rd Avenue NE, Suite #200, Seattle, WA 98115, Officers: John Griffin, President, (Qualifying Individual), Jim Gaw, Vice President, Application Type: QI Change.

American Vanpac Carriers, Inc. (NVO & OFF), 9750 3rd Avenue NE, Seattle, WA 98115, Officers: John Griffin, President, (Qualifying Individual), Jim Gaw, Vice President, Application Type: QI Change.

Atlas Van Lines International Corp. (OFF), 9750 3rd Avenue NE, #200, Seattle, WA 98115, Officers: John Griffin, President, (Qualifying Individual), Jim Gaw, Vice President, Application Type: QI Change.

Capital Logistics CHB Corp. (NVO & OFF), 6000 NW 97th Avenue, #9–10, Miami, FL 33178, Officers: Manuel G. Viegas, President, (Qualifying Individual), Francisco A. Neves, Vice President, Application Type: Name Change.

Cargo Infinity USA, Inc. (NVO & OFF), 9420 Telstar Avenue, Suite 108, El Monte, CA 91731, Officers: Jean L. Niu, President, (Qualifying Individual), Ada Lai Y. Lee, Director, Application Type: Add NVO Service.

Cargonauts USA Corp. (NVO & OFF), 10913 NW 30th Street, Suite 107, Doral,

FL 33172, Officer: Miguel O. Gonzalez, President/Secretary, (Qualifying Individual), Application Type: New NVO & OFF License.

Coco's International Movers Inc. (OFF), 12606 NW 115th Avenue, Miami, FL 33178, Officers: Macarena L. Scalia, Director, (Qualifying Individual),Monica P. Pauley, Director, Application Type: New OFF License.

Eastern Express Cargo Inc. dba Eastern Express (NVO), 10717 Camino Ruiz, #119, San Diego, CA 92126, Officers: Alex O. De Guzman, President, (Qualifying Individual), Abraham B. Lanuzga, Vice President, Application Type: Business Structure Change.

Embarque Bandera Shipping, Inc. (NVO), 421 Audubon Avenue, New York, NY 10033, Officer: Amelio De Jesus Cabrera, President/Secretary, (Qualifying Individual), Application Type: New NVO License.

Embarque La Espanola Corp. (NVO), 31–01 102nd Street, East Elmhurst, NY 11369, Officers: Jose L. Jorge, Secretary, (Qualifying Individual), Juan A. Peralta, President, Application Type: New NVO License.

Genex Logistics, LLC (NVO & OFF), 169 Crown Avenue, Staten Island, NY 10312, Officers: Genevieve Fortunato, Managing Member, (Qualifying Individual), Stewart A. Fortunato, Managing Member, Application Type: License Transfer.

Headwin Global Logistics (USA) Inc. (NVO), 11222 S. La Cienega Blvd., Suite 148, Inglewood, CA 90304, Officers: Bing S. Jiang, CFO, Joanne Gong, Secretary/Treasurer, (Qualifying Individuals), Application Type: QI Change.

JDB Logistics, Inc. (NVO & OFF), 780–A Apex Road, Sarasota, FL 34240, Officers: Karen L. Ambrosia, President, (Qualifying Individual), Richard Glanz, Vice President/Secretary, Application Type: License Transfer.

JP Forwarding Inc. (NVO & OFF), 407 Berry Street, Suite 5L, Brooklyn, NY 11211, Officer: Joel Parnes, President/Secretary/Treasurer, (Qualifying Individual), Application Type: New NVO & OFF License.

Mitsubishi Corporation LT USA (NVO & OFF), 1515 E. Woodfield Road, Suite 365, Schaumburg, IL 60173, Officer: Keiju Yamazaki, President, (Qualifying Individual), Mark Boulware, Secretary, Application Type: QI Change.

Ocean Wave, Inc (NVO), 3415 39th Avenue CT. NW, Gig Harbor, WA 98335, Officer: Karen M. Teng-Raine, President/VP/Treas./Sec., (Qualifying Individual), Application Type: New OFF License.

Sterling Relocation Americas Inc (OFF), 187 Danbury Road, Wilton, CT 06897, Officers: Timothy M. Trout, Vice President Transportation Services, (Qualifying Individual), Rupert O. Morley, CEO, Application Type: New OFF License.

SDS Trans Inc. (NVO & OFF), 145–38 157th Street, 1st Floor, Jamaica, NY 11434, Officer: Si Yual An, President, (Qualifying Individual), Application Type: Name Change.

Tatra Shipping Co. (OFF), 8904 S. Harlem Avenue, Unit C, Bridgeview, IL 60455, Officers: Peter Mincik, President, (Qualifying Individual), Zuzana Fidrikova, Secretary, Application Type: New OFF License.

Trans Knights Inc. (NVO & OFF), 20955 Pathfinder Road, Suite 222, Diamond Bar, CA 91765, Officer: Rachel Zhu, President, (Qualifying Individual), Application Type: Add OFF Service.

Unifreight Logistics, Inc. (NVO & OFF), 9133 S. La Cienega Blvd., #245, Inglewood, CA 90301, Officer: John C. Chang, President/CFO/Secretary, (Qualifying Individual), Application Type: New NVO & OFF License.

V R Logistics Incorporated (NVO & OFF), 30 Sheryl Drive, Edison, NJ 08820, Officers: Govind (Gary) Bhagat, Vice President/Treasurer, (Qualifying Individual), Vanita G. Bhagat, President, Application Type: New NVO & OFF License.

VIP Cargo Services Limited Liability Company (NVO), 14 Mountain Avenue, North Plainfield, NJ 07060–4127, Officer: Raja E. Ahmed, President, (Qualifying Individual), Application Type: New NVO License.

Wilson Transportation, Inc. (NVO & OFF), 16226 Foster Street, Overland Park, KS 66085, Officers: Jerry G. Owen, Vice President, (Qualifying Individual), Mark A. Wilson, President/Treasurer/Secretary, Application Type: Add NVO Service.

World Wide Express LLC (NVO), 6000 NW 32 Ct., Miami, FL 33142, Officers: Marius Marcinkevicius, Manager, (Qualifying Individual), Jonas Vencius, Manager, Application Type: New OFF License.

Dated: April 29, 2011.

**Rachel E. Dickon,**

*Assistant Secretary.*

[FR Doc. 2011–10933 Filed 5–4–11; 8:45 am]

BILLING CODE 6730–01–P

## FEDERAL MARITIME COMMISSION

### Ocean Transportation Intermediary License; Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary license has been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

| License No. | Name/address | Date reissued |
|---|---|---|
| 019288N | Kairos Logistics LLC, 1447 West 178th Street, Suite 305, Gardena, CA 90248 | February 15, 2011. |

**Sandra L. Kusumoto,**

*Director, Bureau of Certification and Licensing.*

[FR Doc. 2011–10934 Filed 5–4–11; 8:45 am]

BILLING CODE 6730–01–P

## FEDERAL MARITIME COMMISSION

### Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following licenses are being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

*License Number:* 018977N.

*Name:* Alas Cargo LLC.

*Address:* 228–236 Star of India Lane, Main Street, Carson, CA 90746.

*Order Published:* FR: 3/23/11 (Volume 76, No. 56, Pg. 16422).

*License Number:* 021901F.

*Name:* Magusa Logistics, Corp.

*Address:* 11222 NW. 53rd Lane, Doral, FL 33178.

*Order Published:* FR: 3/23/11 (Volume 76, No. 56, Pg. 16422).

**Sandra L. Kusumoto,**

*Director, Bureau of Certification and Licensing.*

[FR Doc. 2011–10935 Filed 5–4–11; 8:45 am]

BILLING CODE 6730–01–P

## FEDERAL MARITIME COMMISSION

### Ocean Transportation Intermediary License; Revocation

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR Part 515, effective on the corresponding date shown below:

*License Number:* 1072F.
*Name:* D. Lee Kraus & Company, Ltd.
*Address:* 713 W. Pratt Street, Baltimore, MD 21201.
*Date Revoked:* March 18, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 0453F.
*Name* : Competent Shipping Corporation.
*Address* : 271 Route 46 West, Suite C–205, Fairfield, NJ 07006.
*Date Revoked:* March 4, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 1821F.
*Name* : Eastern Export Company, Inc.
*Address* : 966 Norfolk Square, Norfolk, VA 23502.
*Date Revoked:* March 30, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 003069NF.
*Name* : A. H. Carter & Associates, Inc.
*Address:* 25706 74th Avenue S., Kent, WA 98032.
*Date Revoked:* March 26, 2011.
*Reason:* Failed to maintain valid bonds.

*License Number:* 3165F.
*Name* : Woodbridge International Forwarding, Inc.
*Address:* 9009 North Loop East, Suite 235, Houston, TX 77029.
*Date Revoked:* March 2, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 4358NF.
*Name:* Orion International Freight Forwarders, Inc.
*Address:* 2129 NW 86th Avenue, Miami, FL 33122.
*Date Revoked:* March 11, 2011.
*Reason:* Surrendered license voluntarily.

*License Number:* 4422F.
*Name* : C & C Group, Inc.
*Address:* 1928 NE. 82nd Avenue, Miami, FL 33126.
*Date Revoked:* March 24, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 015083F.
*Name:* Gandhi International Shipping, Inc.
*Address* : 2358 W. Devon Avenue, Chicago, IL 60659.
*Date Revoked:* March 31, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 16604N.
*Name:* Pisces Shipping, Inc. dba Pisces Container Lines.
*Address:* 175 North Highland Avenue, Elmhurst, IL 60126.
*Date Revoked:* March 3, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 169094N.
*Name* : Trans Port Agencies, Inc.
*Address:* 1790 Yardley-Langhorne Road, Suite 202, Yardley, PA 19067.
*Date Revoked:* March 26, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 017051N.
*Name* : Worldwide Shipping Corporation,
*Address* : 17800 Castleton Street, Suite 235, City of Industry, CA 91748.
*Date Revoked:* March 13, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 17511N.
*Name:* Royal Cargo Line Inc.
*Address:* 1928 NW. 82nd Avenue, Miami, FL 33126.
*Date Revoked:* March 24, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 019278N
*Name* : Nelcon Cargo Corp.
*Address:* 1970 NW. 82nd Avenue, Miami, FL 33126.
*Date Revoked:* March 29, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 019787N.
*Name:* Jam'n International Cargo Inc.
*Address* : 2140 East University Drive, Rancho Dominguez, CA 90220.
*Date Revoked:* March 4, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 020335N.
*Name:* Intercontinental Cargo Enterprises, Inc.
*Address:* 8501 NW. 17th Street, Suite 120, Miami, FL 33126.
*Date Revoked:* March 16, 2011.
*Reason* : Failed to maintain a valid bond.

*License Number:* 020339N.
*Name:* Coastal Maritime, Ltd.
*Address:* 1204 Water Birch Court, Chesapeake, VA 23323.
*Date Revoked:* March 30, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 020507F.
*Name* : World Appliances, Inc.
*Address* : 2822 Juniper Street, Fairfax, VA 22031.
*Date Revoked:* March 4, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 020653NF.
*Name:* Mainfreight International, Inc.
*Address:* 1400 Glenn Curtiss Street, Carson, CA 90746.
*Date Revoked:* March 29, 2011.
*Reason* : Failed to maintain valid bonds.

*License Number:* 021932N.
*Name:* Cargolinx Inc.
*Address:* 6405 NW. 36th Street, Suite 107, Miami, FL 33166.
*Date Revoked:* March 4, 2011.
*Reason:* Failed to maintain a valid bond.

*License Number:* 022296N.
*Name* : Batista Cargo Inc.
*Address* : 4963 Broadway, New York, NY 10034.
*Date Revoked:* March 26, 2011.
*Reason:* Failed to maintain a valid bond.

**Sandra L. Kusumoto,**
*Director, Bureau of Certification and Licensing.*

[FR Doc. 2011–10932 Filed 5–4–11; 8:45 am]
BILLING CODE 6730–01–P

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 20, 2011.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *The Lawton Partners Trust, with Robert A. Lawton as trustee,* Central City, Kentucky; to retain control of First

United, Inc., and thereby indirectly retain control of First National Bank of Muhlenberg County, Kentucky, both in Central City, Kentucky.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The O. Jay Tomson Revocable Trust, Ollie Jay Tomson, trustee,* Mason City, Iowa; to retain control of FBHC Holding Company, and thereby indirectly retain control of Flatirons Bank, both in Boulder, Colorado.

Board of Governors of the Federal Reserve System, May 2, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–10968 Filed 5–4–11; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 31, 2011.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106–2204:

1. *Newburyport Five Cents Bancorp, MHC and Newburyport Five Cents Bancorp, Inc.,* both in Newburyport, Massachusetts; to become a mutual bank holding company and a stock bank holding company, respectively, by acquiring 100 percent of the voting shares of Newburyport Five Cents Savings Bank, Newburyport, Massachusetts.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Palco Bankshares, Inc.,* Palco, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of Midwest Community Bank, Plainville, Kansas.

Board of Governors of the Federal Reserve System, May 2, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–10970 Filed 5–4–11; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 20, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Marshall & Ilsley Corporation,* Milwaukee, Wisconsin; to acquire up to an additional 4 percent equity interest, for a total ownership of up to 88 percent, of Taplin, Canida & Habacht, LLC, Miami, Florida, and thereby continue to engage in financial and investment advisory services and securities brokerage services, pursuant to sections 225.28(b)(6)(i) and (ii) of Regulation Y.

Board of Governors of the Federal Reserve System, May 2, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–10969 Filed 5–4–11; 8:45 am]

**BILLING CODE 6210–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**AGENCY:** U.S. Department of Health and Human Services.

**ACTION:** 30-day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

**SUMMARY:** As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, U.S. Department of Health and Human Services has submitted a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

**DATES:** Comments must be submitted June 6, 2011.

**ADDRESSES:** Written comments may be submitted to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Sherrette Funn-Coleman

**SUPPLEMENTARY INFORMATION:**

*Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

*Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study.

The Agency received 0 comments were received in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide U.S. Department of Health and Human Services projected average estimates for the next three years: [1]

*Current Actions:* New collection of information.

*Type of Review:* New collection

*Affected Public:* Individuals and households, businesses and organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities:

*Respondents:* 3,000,000 over 3 years

*Annual Responses:* 1,000,000 annually

*Frequency of Response:* Once per request

*Average Minutes per Response:* 4

*Burden Hours:* 670,000 hours annually

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

**Mary Forbes,**

*Office of the Secretary, Paperwork Reduction Act Clearance Officer.*

[FR Doc. 2011–10952 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

[1] The 60-day notice included the following estimate of the aggregate burden hours for this generic clearance federal-wide:

*Average Expected Annual Number of Activities:* 25,000.

*Average Number of Respondents per Activity:* 200.

*Annual Responses:* 5,000,000.

*Frequency of Response:* Once per request.

*Average Minutes per Response:* 30.

*Burden Hours:* 2,500,000.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the President's Council on Fitness, Sports, and Nutrition; Correction

**AGENCY:** Office of the President's Council on Fitness, Sports, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice; Correction.

**SUMMARY:** The Department of Health and Human Services published a notice in the **Federal Register** of April 21, 2011 to announce a meeting of the President's Council on Fitness, Sports, and Nutrition that will be held on May 10, 2011, from 11 a.m. to 2:30 p.m., in the U.S. Capitol Visitor Center, East Capitol and First Streets, NE., Washington, DC 20001. The meeting location has changed.

**FOR FURTHER INFORMATION CONTACT:** Ms. Shellie Pfohl, Executive Director, President's Council on Fitness, Sports, and Nutrition, Phone: (240) 276–9866 or (240) 276–9567.

**Correction**

In the **Federal Register** of April 21, 2011, FR Doc. 2011–9665, on page 22398, in the first column, correct the **ADDRESSES** caption to read:

**ADDRESSES:** Russell Senate Office Building, The Kennedy Caucus Room; Constitution Avenue and First Street, NE., Washington, DC 20002.

Dated: April 28, 2011.

**Shellie Y. Pfohl,**

*Executive Director, President's Council on Fitness, Sports, and Nutrition.*

[FR Doc. 2011–10973 Filed 5–4–11; 8:45 am]

**BILLING CODE 4150–35–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Partnerships To Advance the National Occupational Research Agenda (NORA)

**AGENCY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public meeting.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting: "Partnerships to Advance the National Occupational Research Agenda (NORA)".

*Public Meeting Time and Date:* 10 a.m.–3:30 p.m. EDT, June 29, 2011.

*Place:* Patriots Plaza, 395 E Street, SW., Conference Room 9000, Washington, DC 20201.

*Purpose of the Meeting:* The National Occupational Research Agenda (NORA) has been structured to engage partners with each other and/or with NIOSH to advance NORA priorities. The NORA Liaison Committee continues to be an opportunity for representatives from organizations with national scope to learn about NORA progress and to suggest possible partnerships based on their organization's mission and contacts. This opportunity is now structured as a public meeting via the Internet to attract participation by a larger number of organizations and to further enhance the success of NORA. Some of the types of organizations of national scope that are especially encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome.

This meeting will include updates from NIOSH leadership on NORA as

well as updates from approximately half of the NORA Sector Councils on their progress, priorities, and implementation plans to date, including the NORA Manufacturing, Public Safety, Services, and Wholesale and Retail Trade Sector Councils. Updates will also be given on the Mid-Decade Review of NORA, the NORA Symposium 2011, and at least one NIOSH Program that is working on several NORA priorities, e.g., the NIOSH Economics Program. After each update, there will be time to discuss partnership opportunities.

*Status:* The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to *noracoordinator@cdc.gov* containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation by Web meeting (requirements include: Computer, Internet connection, and telephone, preferably with 'mute' capability) or in person. An e-mail confirming registration will include the details needed to participate in the Web meeting. Non-U.S. citizens are encouraged to participate in the Web meeting. Non-U.S. citizens who do not register to attend in person on or before June 6, 2011, will not be granted access to the meeting site and will not be able to attend the meeting in-person due to mandatory security clearance procedures at the Patriots Plaza facility.

*Background:* NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see *http://www.cdc.gov/niosh/nora/about.html.*

Since 2006, NORA has been structured according to industrial sectors. Ten major sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, ten NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008–10, most of these Councils posted draft strategic plans for public comment and eight have posted finalized National Sector Agendas after considering comments on the drafts. For the National Sector Agendas, see *http://www.cdc.gov/niosh/nora/.*

**FOR FURTHER INFORMATION CONTACT:** Sidney C. Soderholm, PhD, NORA Coordinator, e-mail *noracoordinator@cdc.gov,* telephone (202) 245–0665.

Dated: April 27, 2011.

**Tanja Popovic,**

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2011–10950 Filed 5–4–11; 8:45 am]

**BILLING CODE 4163–19–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Docket No. CDC–2011–0004]**

### Public Health Information Network (PHIN) Messaging Guide for Syndromic Surveillance

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is requesting public comment on the draft *PHIN Messaging Guide for Syndromic Surveillance.* The document translates the business requirement recommendations from the International Society for Disease Surveillance to technical specifications to support meaningful use of electronic health records for syndromic surveillance. Comments will be used to inform and finalize the Messaging Guide.

**DATES:** Written comments must be received on or before June 20, 2011. See Addresses for instructions to submit comment.

**ADDRESSES:** You may submit written comments to the following address: Public Health Informatics and Technology Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–76, Atlanta, Georgia 30329. *Attn:* PHIN Syndromic Surveillance Messaging Guide Comments (Docket No. CDC–2011–0004),

You may also submit written comments electronically to *http://www.regulations.gov.* Comments must be identified by Docket No. CDC–2011–0004. Please follow directions at *http://wwww.regulations.gov* to submit comments.

All relevant comments received will be posted publicly without change, including any personal or proprietary information provided. An electronic version of the draft is available to download at *http://www.regulations.gov* and *http://www.cdc.gov/phin/library/2011/guides/Syndromic_Surveillance_Implementation_Guide_Release_1_4.pdf.*

Written comments, identified by Docket No. CDC–2011–0004, will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Daylight Time, at 1600 Clifton Road, NE., Atlanta, Georgia 30333. Please call ahead to (404) 639–6100 and ask for a representative from the Public Health Informatics and Technology Program Office to schedule your visit. Comments may also be viewed at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Nikolay Lipskiy, Centers for Disease Control and Prevention, Public Health Informatics and Technology Program Office; l600 Clifton Road, NE., Mailstop E–76, Atlanta, Georgia 30329, phone 404–498–6100.

**SUPPLEMENTARY INFORMATION:** The International Society for Disease Surveillance (ISDS), with the support of CDC, convened a Meaningful Use Workgroup to define current syndromic surveillance business standards and data requirements. The goal of the ISDS workgroup is to ensure that public health authorities, health care professionals, Electronic Health Record (EHR) technology developers, and the HHS Office of the National Coordinator for Health Information Technology have business standards that will best support meaningful use of EHRs for syndromic surveillance. The Final Recommendation from ISDS (available at *http://www.syndromic.org/uploads/files/ISDSRecommendation_FINAL.pdf)* was published in early January 2011. As the ISDS workgroup developed recommendations, the CDC Public Health Informatics and Technology Program Office, worked to translate the business requirement recommendations to technical specifications. This notice announces a draft *PHIN Messaging*

*Guide for Syndromic Surveillance* available for public comment at *http://www.regulations.gov* and *http://www.cdc.gov/phin/library/2011/guides/Syndromic_Surveillance_Implementation_Guide_Release_1_4.pdf*

Dated: April 27, 2011.

**Tanja Popovic,**

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2011–10949 Filed 5–4–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0322]**

### Guidance for Industry on Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." This document is intended to provide guidance to firms that are manufacturing, marketing, or distributing orally ingested over-the-counter (OTC) liquid drug products packaged with dosage delivery devices (e.g., calibrated cups, droppers, syringes, or spoons). FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for orally ingested OTC liquid drug products.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Spencer Salis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, rm. 5216, Silver Spring, MD 20993–0002, 301–796–3327.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a guidance for industry entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." The Agency has determined that many orally ingested OTC liquid drug products in the marketplace are packaged with dosage delivery devices that bear markings that are inconsistent with the labeled dosage directions, contain superfluous markings, or are missing necessary markings. FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for orally ingested OTC drug products. FDA recommends that dosage delivery devices be included for all orally ingested OTC drug products that are liquid formulations, that they should bear markings that are consistent with the labeled dosage directions, and that they should be labeled in a manner that attempts to ensure that they are used only with the products with which they are included.

In the **Federal Register** of November 5, 2009 (74 FR 57319), FDA announced the availability of a draft guidance for industry entitled "Dosage Delivery Devices for Over-the-Counter Liquid Drug Products." The notice gave interested persons an opportunity to comment by February 2, 2010. We received a number of comments from individuals, firms, and consumer groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on dosage delivery devices for orally ingested OTC liquid drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 28, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–10965 Filed 5–4–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its sixty-seventh meeting.

*Name:* National Advisory Committee on Rural Health and Human Services.

*Dates and Times:* June 15, 2011, 9 a.m.–4:45 p.m., June 16, 2011, 9 a.m.–4:45 p.m., June 17, 2011, 8:45 a.m.–10:30 a.m.

*Place:* Park Place Hotel, 300 East State Street, Traverse City, MI 49684. (231) 946–5000.

*Status:* The meeting will be open to the public.

*Purpose:* The National Advisory Committee on Rural Health and Human Services provides advice and recommendations of health and human services in rural areas.

*Agenda:* Wednesday morning, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The first three presentations will be overviews of rural Michigan and the relevant health indicators. The remainder of the day the Committee will hear presentations on two of the chosen

Subcommittee topics. The first panel will focus on the impact of Value-Based Purchasing Demonstrations. The second panel will focus on primary care training and placement. The Subcommittees will then move into breakout sessions to further discuss these topics. After the panel discussions, the Committee Chair will give an overview of the site visits. This will be followed by a call for public comment. The Wednesday meeting will close at 4:45 p.m.

Thursday morning, at 9 a.m., the Committee will travel to Munson Medical Center for a briefing on its role in serving the region. At 10 a.m. the Committee will break into Subcommittees and depart to the site visits. The Value-Based Purchasing Demonstrations Subcommittee will meet at Mercy Cadillac Hospital in Cadillac, MI. The Primary Care Training and Placement Subcommittee will meet at Kalkaska Rural Health Clinic in Kalkaska, MI. The Subcommittees will return to the Park Place Hotel in Traverse City at 4 p.m. Transportation to the site visits will not be provided to the public. The Thursday meeting will close at 4:45 p.m.

The Final session will be convened on Friday morning at 8:45 am. The meeting will open with a review of the Subcommittee site visits. The Committee will draft a letter to the Secretary or Designee and discuss the September 2011 meeting. The meeting will adjourn at 10:30 a.m.

*For Further Information Contact:* Thomas Morris, MPA, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 10B–45, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Deborah DeMasse-Snell at the Office of Rural Health Policy (ORHP) via Telephone at (301) 443–0835 or by e-mail at *ddemasse-snell@hrsa.gov*. The committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: April 28, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2011–10983 Filed 5–4–11; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Improved Standard for Immune System Recovery Assay**

*Description of Invention:* Monitoring an immune system that has been depleted by infection (*e.g.,* HIV), chemotherapy, or progenitor cell transplantation is vital to assessing individual's recovery status. This technology provides a new plasmid standard to be used as part of the existing TREC assay. This new plasmid has a shorter insert than the commercially available one, which means it now matches the PCR product generated in the qPCR reaction in the TREC assay. Additionally, the new plasmid is easier to grow up than the existing standard.

*Applications:* TREC assay for T-cell concentration measurements.

*Advantages:*

- The insert of standard plasmid is shorter and directly matches the PCR product generated in the qPCR reaction.
- The standard plasmid is easy to grow up.

*Development Status:* Fully developed.

*Inventors:* Daniel C. Douek, Richard A. Koup, Brenna J. Hill (NIAID.)

*Relevant Publications:*

1. Douek *et al.* Changes in thymic function with age and during the treatment of HIV infection. Nature 1998 Dec 17;396(6712):690–695. [*PubMed:* 9872319.]

2. Douek *et al.* Assessment of thymic output in adults after haematopoietic stem-cell transplantation and prediction of T-cell reconstitution. Lancet 2000 May 27;355(9218):1875–1881. [*PubMed:* 10866444.]

*Patent Status:* HHS Reference No. E–067–2011/0—Research Material. Patent protection is not being pursued for this technology.

*Licensing Status:* Research tool available for non-exclusive licensing.

*Licensing Contact:* Susan Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov.*

**Glucocerebrosidase Activators as a Treatment for Gaucher Disease**

*Description of Invention:* This technology is a collection of small molecule activators of a genetically defective version of the enzyme called glucocerebrosidase (GCase), which causes Gaucher disease. Gaucher disease is a rare disease affecting 1 in 40,000 babies born. Ashkenazi Jews of eastern European descent (about 1 in 800 live births) are at particular risk of carrying this genetic defect. It is caused by inherited genetic mutations in the gene that encodes GCase, which result in reduced activity of the enzyme. This enzyme is normally made and then transported to an organelle called a lysosome, which is dedicated to the degradation and disposal of molecules the cell no longer needs. GCase is responsible for the breakdown of a fatty material called glucocerebroside (or glucosylceramide). The accumulation of this lipid occurs inside specific cells called macrophages and macrophage-derived cells. The disease has been categorized into three types: neuronopathic (types 2, 3) and non-neuronopathic (type 1) with mild to severe symptoms that can appear at anytime from infancy to adulthood. Clinical manifestations can include an enlarged spleen and liver, anemia, decreased platelets, bone disease and neurodegeneration, with varying severity depending on the type of disease and time of diagnosis. The deficient GCase activity has been attributed to insufficient GCase enzyme in the lysosome. After production in the endoplasmic reticulum (ER), defective GCase does not fold properly and is therefore degraded in the ER and not transported to the lysosome where it would hydrolyze glucocerebroside. The small molecule activators may act by increasing the concentration of GCase that reaches the lysosome by facilitating the proper folding of GCase so that it can be released from the ER and transported to lysosomes. Thus, these small molecules could be acting like "chaperones," because they facilitate proper folding which results in some active enzyme. Prior failed attempts to use small molecule chaperones to improve GCase folding and transport were made with inhibitors of GCase, which ironically properly folded active GCase that was subsequently transported to the lysosome, but the molecule also inhibited the GCase co that it could not break down glucocerebroside. On the other hand, these proposed small molecules were

screened for their ability to activate defective GCase in the presence of a fluorogenic mimic of glucocerebroside, and their ability to facilitate translocation of defective GCase to lysosomes as well. This creates the opportunity to induce proper folding, while avoiding inhibition of enzyme function.

*Application:* Treatment of Gaucher Disease.

*Development Status:* Early development.

*Inventors:* Juan Marugan, Noel T. Southall, Ehud M. Goldin, Wei Zheng, Samarjit Patnaik, Ellen Sidransky, Omid Motabar, Wendy Westbroek (NHGRI.)

*Related Publications:* None.

*Patent Status:* U.S. Provisional Application No. 61/420,946, filed December 8, 2010, (HHS Reference No. E–257–2010/0–US–01.)

*Licensing Status:* Available for licensing.

*Licensing Contact:* Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*

**A Novel Strategy for Development of an Effective HIV/AIDS Vaccine**

*Description of Invention:* The invention offered for licensing and commercial development relates to the field of HIV/AIDS Vaccines. More specifically, the invention describes a novel strategy that can be useful in effective vaccination and treatment of HIV/AIDS infected persons. In this strategy (called 'trigger-and-neutralize' strategy) the infected subject is primed with HIV trimeric gp 120 immunogen to induce the production of CD4i (CD4-induced) antibodies. The patient is then treated with a compound that stabilizes the 'open' conformation of the gp120 of the HIV virus, at which conformation the gp120 epitope is better exposed and effectively neutralized by the CD4i antibodies.

*Applications:* Vaccination and treatment of HIV/AIDS infected patients.

*Advantages:* The unique strategy of eliciting CD4i antibodies *in vivo* and ensuring their neutralizing effect by stabilizing the gp120 open conformation, will provide more effective treatment compared to other published methods that utilize neutralizing antibodies to treat HIV/AIDS.

*Development Status:* The subject matter of the invention continues to be researched. Proof-of-principle of some of the aspects of the invention have been demonstrated.

*Market:* Although there are currently many commercial drugs available for treatment of HIV/AIDS, there still exists an urgent need to develop vaccines against the disease. This need (no approved vaccine is available yet) is particularly important because of the resistance developed by many patients to commercial drugs and thus the need for the use of drug cocktails, as well as the severe side effects that many of the drugs exhibit. At present, the World Health Organization estimates that over 30 million people are infected with HIV and that over 25 million individuals have died from AIDS-related illnesses. The potential market for HIV vaccines is therefore huge and thus this invention may be commercially attractive for vaccine and drug manufacturers.

*Inventors:* Sriram Subramaniam (NCI.)

*Relevant Publications:*

1. Liu J, Bartesaghi A, Borgnia MJ, Sapiro G, Subramaniam S. Molecular architecture of native HIV–1 gp120 trimers. Nature. 2008 Sep 4;455(7209):109–113. [*PubMed:* 18668044.]

2. White TA, Bartesaghi A, Borgnia MJ, Meyerson JR, M. de la Cruz MJ, Bess JW, Nandwani R, Hoxie JA, Lifson JD, Milne JL, Subramaniam S. Molecular architectures of trimeric SIV and HIV–1 envelope glycoproteins on intact viruses: strain dependent variation in quaternary structure. PLoS Pathog. 2010 Dec 23;6(12):e1001249. [*PubMed:* 21203482.]

3. Felts RL, Narayan K, Estes JD, Shi D, Trubey CM, Fu J, Hartnell LM, Ruthel GT, Schneider DK, Nagashima K, Bess JW Jr, Bavari S, Lowekamp BC, Bliss D, Lifson JD, Subramaniam S. 3D visualization of HIV transfer at the virological synapse between dendritic cells and T-cells. Proc Natl Acad Sci U S A. 2010 Jul 27;107(30):13336–13341. [*PubMed:* 20624966.]

*Patent Status:* U.S. Provisional Application No. 61/356,326 filed 18 Jun 2010 (HHS Reference No. E–201–2010/0–US–01), entitled "Immunogenic Compositions Derived from Structural Alteration of HIV Envelope Proteins."

*Licensing Status:* Available for licensing and commercial development.

*Licensing Contacts:*

- Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*
- John Stansberry, PhD; 301–435–5236; *js852e@nih.gov.*

*Collaborative Research Opportunity:* The Center for Cancer Research, NCI/NIH is seeking statements of capability or interest from parties interested in collaborative research to further develop, produce, evaluate, or commercialize trimeric gp120 immunogens. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

**Epoxy-guaiane Cancer Inhibitors: New Class of Natural Products Isolated From the African Plant** *Phyllanthus englerii*

*Description of Invention:* The present invention involves the observation of renal selective inhibitory activity by the extracts of the African plant *Phyllanthus englerii.* Bioassay-guided fractionation of the purified extracts revealed a series of novel chemical entities which are named Englerin A–F. The englerins and their derivatives are useful in the treatment of a number of cancers, particularly renal cancer. The englerins exhibit selective and potent renal cell inhibitory activity *in vitro.*

These compounds are recoverable in reasonable yield from natural product extracts and are considered to be reasonably tractable for synthetic chemistry schemes. Sufficient supply of several analogs had been extracted from repository samples for identification and initial biological characterization. Subsequent five-dose testing in the NCI60 screening panel indicated and confirmed impressive renal-selective activity.

*Applications:* The new chemical entities can be potential cancer therapeutics, especially for renal cancer.

*Advantages:*

- There is reasonable yield and recovery of the compounds from the natural product extracts.
- The synthetic chemistry schemes for synthesis of these compounds are considered to be reasonably tractable.

*Development Status:* Proof of concept *in vitro* studies have been completed and further *in vitro* and *in vivo* animal model studies are ongoing.

*Inventors:* John A. Beutler *et al.* (NCI)

*Relevant Publication:* S. Sutthivaiyakit *et al.* A novel 29-*nor*-3,4-seco-friedelane triterpene and a new guaiane sesquiterpene from the roots of *Phyllanthus oxyphyllus.* Tetrahedron 2003 Dec 8; 59(50):9991–9995.

*Patent Status:* U.S. Patent Application No. 12/811,245 filed 29 Jul 2010 (HHS Reference No. E–064–2008/2–US–06) and related international filings.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov.*

*Collaborative Research Opportunity:* The National Cancer Institute Molecular Targets Development Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize epoxy-guaiane cancer inhibitors. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

**Imidazoacridones With Anti-Tumor Activity**

*Description of Invention:* The present invention relates to novel bifunctional molecules with potent and selective activity against colon, liver and pancreatic tumors. Compounds have low animal toxicity, excellent PK/PD characteristics and proved to be very effective in several preclinical animal models of cancer. Extensive mechanistic studies have demonstrated that compounds inhibit tumor growth through a novel mechanism. These agents are composed of an imidazoacridone moiety linked by a nitrogen containing aliphatic chain of various length and rigidity to another aromatic ring system capable of intercalation to DNA.

Previous studies on related symmetrical bis-imidazoacridones revealed that only one planar imidazoacridone moiety intercalates into DNA. The second aromatic moiety, which is crucial for biological activity, along with the linker resides in DNA minor groove, and is believed to interact with DNA-binding proteins (most likely, transcription factors and/or repair proteins). The symmetrical bis-imidazoacridones arrest the growth of sensitive cancers (especially colon cancers) but do not kill the tumors. It was hypothesized that the growth arrest was due to the inability of the affected tumor cells to repair DNA damage caused by the compounds. Remarkably, bis-imidazoacridones are very well tolerated, are very tissue selective and do not appear to damage normal tissues.

Since the binding of the symmetrical bis-imidazoacridones to DNA was unsymmetrical, the inventors have developed unsymmetrical compounds in which one imidazoacridone moieties was replaced by other intercalating groups, with the expectation that this would enhance biological activity while retaining the remarkable tissue selectivity and low systemic toxicity. The new compounds contain intercalating moieties such as 3-chloro-7-methoxyacridine or naphthalimide along with the original imidazoacridones.

These new compounds, especially those containing naphthalimide moiety, are extremely cytotoxic against a variety of tumor cells in vitro (IC50 at low nanomolar range) and kill tumor cells by inducing apoptosis. In vivo, in nude mice xenografted with human tumors, the compounds significantly inhibited the growth of such tumors as colon tumor HCT116 and Colo205 as well as pancreatic tumors (lines 6.03 and 10.05 freshly established from a patient). These compounds are extremely potent agents against hepatocellular carcinoma as evidenced by their ability to eradicate liver cancer in an orthotopic liver cancer model in rats. Remarkably, no toxicity was observed at the therapeutic doses. These are among the most potent agents known against cancers of the GI tract and appear to be tolerated very well.

*Inventors:* Wieslaw M. Cholody *et al.* (NCI)

*Patent Status:*

- U.S. Patent 6,664,263 issued 16 Dec 2003 (HHS Reference No. E–289–1999/0–US–07) and related international patents/patent applications.
- U.S. Patent 6,541,483 issued 01 Apr 2003 (HHS Reference No. E–065–1996/2–US–25) and related international patents/patent applications.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Betty B. Tong, PhD; 301–594–6565; *tongb@mail.nih.gov.*

*Collaborative Research Opportunity:* The National Cancer Institute, Center for Cancer Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize imidazoacridones as therapeutic agents for cancer treatment. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: April 29, 2011.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 2011–11055 Filed 5–4–11; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Child Health and Human Development Council.

*Date:* June 2, 2011.

*Open:* 8 a.m. to 12:20 p.m.

*Agenda:* (1) A report by the Director, NICHD; (2) Report of the Subcommittee on Planning and Policy; (3) NICHD Scientific Visioning update; and other business of the Council.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

*Closed:* 12:20 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Yvonne T. Maddox, PhD, Deputy Director, National Institute of Child Health, and Human Development, NIH, 9000 Rockville Pike MSC 7510, Building 31, Room 2A03, Bethesda, MD 20892, (301) 496–1848.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://ww.nichd.nih.gov/about/nachhd.htm,* where an agenda and any additional information for the meeting will be posted when available.

In order to facilitate public attendance at the open session of Council, reserve seating will be made available to the first five individuals reserving seats in the main meeting room, Conference Room 6. Please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation. Additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access

instructions at: *http://www.nichd.nih.gov/about/overview/advisory/nachhd/virtual-meeting.cfm* The meeting is partially closed to the public.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS)

Dated: April 29, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11034 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, PAR–09–247: NIDDK Ancillary Studies to Major Ongoing Clinical Research Studies in CKD (R01).

*Date:* May 27, 2011.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call.)

*Contact Person:* Najma Begum, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452. (301) 594–8894. *begumn@niddk.nih.gov.*

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Periodontitis and Glycemic Control.

*Date:* June 15, 2011.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call.)

*Contact Person:* D. G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452. (301) 594–7682. *pateldg@niddk.nih.gov.*

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Studies Related to Diabetes.

*Date:* June 17, 2011.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call.)

*Contact Person:* D. G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452. (301) 594–7682. *pateldg@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 29, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11037 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Initial Review Group, Comparative Medicine Review Committee.

*Date:* June 7–8, 2011.

*Time:* 8 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Marriott, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Bonnie B. Dunn, PhD, Scientific Review Officer, National Center For Research Resources, or National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1074, MSC 4874, Bethesda, Md 20892–4874, 301–435–0824, *dunnbo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards., National Institutes of Health, HHS)

Dated: April 29, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11040 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* AIDS Research Advisory Committee, NIAID, AIDS Vaccine Research Subcommittee.

*Date:* May 24–25, 2011.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* Presenting and discussing data on recombinant chimpanzee adenovirus vectors for malaria and AIDS vaccines and discussing future clinical trial plans for AIDS vaccine testing.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1 and E2, Bethesda, MD 20892.

*Contact Person:* James A. Bradac, PhD, Program Official, Preclinical Research and Development Branch, Division of AIDS, Room 5116, National Institutes of Health/NIAID, 6700B Rockledge Drive, Bethesda, MD 20892–7628, 301–435–3754, *jbradac@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 29, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11039 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, Heart Pumps for Clinical Trials for Children.

*Date:* May 23, 2011.

*Time:* 8:30 a.m. to 1 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Chang Sook Kim, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov.*

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, Assay Platforms for Biomarkers of Cardiovascular Disease.

*Date:* May 25, 2011.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call.)

*Contact Person:* Kristin Goltry, PhD, Scientific Review Officer, Review Branch, DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive Room 7198, Bethesda, MD 20892, 301–435–0297, *goltrykl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 28, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11036 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Biomedical Imaging Technology—A.

*Date:* June 2–3, 2011.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Valencia Riverwalk, 140 East Houston Street, San Antonio, TX 78205.

*Contact Person:* Behrouz Shabestari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5126, MSC 7854, Bethesda, MD 20892, (301) 435–2409, *shabestb@csr.nih.gov.*

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

*Date:* June 2–3, 2011.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

*Contact Person:* Jonathan K Ivins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: Innovations in Molecular Probes.

*Date:* June 2, 2011.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Valencia, 150 East Houston Street, San Antonio, TX 78205.

*Contact Person:* David L Williams, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301) 435–1174, *williamsdl2@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Psychosocial Risk and Disease Prevention.

*Date:* June 2, 2011.

*Time:* 2 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Martha M Faraday, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, 301–435–3575, *faradaym@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Lung Diseases.

*Date:* June 7–8, 2011.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* George M Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuropharmacology.

*Date:* June 14–15, 2011.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Christine L. Melchior, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1713, *melchioc@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Immune Mechanism.

*Date:* June 15–16, 2011.

*Time:* 8 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Scott Jakes, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, *jakesse@mail.nih.gov.*

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review

Group; Instrumentation and Systems Development Study Section.

*Date:* June 15–16, 2011.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

*Contact Person:* Raymond Jacobson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, MSC 7849, Bethesda, MD 20892, 301–435–0483, *jacobsonrh@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 28, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11033 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders A.

*Date:* June 22–23, 2011.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Carlyle Suites Hotel, 1731 New Hampshire Ave., NW., Washington, DC 20009.

*Contact Person:* Richard D. Crosland, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529 Bethesda, MD 20892–9529 301–496–9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 27, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11024 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 26, 2011, 8 a.m. to May 26, 2011, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 22, 2011, 76 FR 22716.

The meeting title has been changed to "Member Conflict: Kidney and Urology". The meeting is closed to the public.

Dated: April 28, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–11031 Filed 5–4–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[USCG–2011–0310]**

### National Maritime Security Advisory Committee; Meeting

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of teleconference meeting.

**SUMMARY:** The National Maritime Security Advisory Committee (NMSAC) will meet by teleconference to discuss the results of the Seafarer Access to Shore Leave Working Group. This meeting will be open to the public.

**DATES:** The teleconference meeting will take place on Friday, May 20, 2011, from 11 a.m. to 1 p.m. EST. Please note that the meeting may close early if the committee has completed its business.

**ADDRESSES:** The Committee will meet via telephone conference, on May 20, 2011. As there are only 100 teleconference lines, public participation will be on a first come basis.

For information on facilities or services for individuals with disabilities or to request special assistance at the teleconference, contact Mr. Ryan Owens as soon as possible.

To facilitate public participation we are inviting public comment on the issues to be considered by the committee as listed in the "Agenda" section below. Comments must be submitted in writing no later than May 16, 2011, and must be identified by USCG–2011–0310 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: Ryan.F.Owens@uscg.mil.* Include the docket number in the subject line of the message.
- *Fax:* (202) 372–1990.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9239.

*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. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

*Docket:* For access to the docket to read documents or comments related to this notice, go to *http://www/regulations.gov.*

A public comment period will be held during the meeting on May 20, 2011 from 12:30–1 p.m. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this teleconference, please contact Mr. Ryan F. Owens, Alternate Designated Federal Officer (DFO) of NMSAC, telephone 202–372–1108, fax 202–372–1990. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager,

Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. (Pub. L. 92–463).

NOSAC provides advice and makes recommendations to the Coast Guard on safety and other concerns affecting the offshore oil and gas industry and assists the Coast Guard in formulating U.S. positions for discussion and presentation at the International Maritime Organization (IMO).

## Agenda

(1) Results of Seafarer Access Working Group's review and recommendations of Section 811 of the Coast Guard Authorization Act of 2010 which requires facility security plans to make accommodations for shore side access for seaman.

(2) Period for public comment. Public comment period will be held from 12:30–1 p.m. Speakers' comments are limited to 3 minutes.

(3) Committee discussion and consensus recommendation.

Dated: May 2, 2011.

**K.C. Kiefer,**

*Captain, U.S. Coast Guard, Office of Port and Facility Activities.*

[FR Doc. 2011–10993 Filed 5–4–11; 8:45 am]

**BILLING CODE 9110–04–P**

---

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5486–N–11]**

## Notice of Proposed Information Collection for Public Comment on the Assessment of Native American, Alaska Native and Native Hawaiian Housing Needs

**AGENCY:** Office of Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments Due Date: July 5, 2011.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 8230, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Stoloff, Department of Housing and Urban Development, Office of Policy Development and Research, 451 7th Street, SW., Room 8120, Washington DC 20401; telephone (202) 402–5723, (this is not a toll free number). Copies of the proposed data collection instruments and other available documents may be obtained from Dr. Stoloff.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including if the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

*Title of Proposal:* Assessment of Native American, Alaska Native and Native Hawaiian Housing Needs

*Description of the need for information and proposed use:*

The Department is conducting this study under contract with The Urban Institute and its subcontractors, NORC, Econometrica and SSI. The project is a housing needs assessment that will produce national level estimates of housing needs in tribal areas in the United States. Under the Native American Housing and Self Determination Act of 1996 (NAHASDA), HUD provides funding though several programs to Native American and Alaskan Native populations. The level of housing need is of particular interest to HUD and the Congress has mandated this study (see Senate Report 111–69). HUD has not published a study on housing needs, in general, for this population since 1996. The surveys covered by this data collection include a household survey of tribal members, a telephone, web, and in-person survey of tribes and/or Tribally Designated Housing Entities (TDHEs), an interview guide for tribal leaders, a survey of lenders working in tribal areas, an interview guide for organizations and leaders in Hawaii, and an interview guide for staff at Urban Indian Centers.

*Members of the affected public:*

TDHE/tribal housing staff: 80 phone surveys, 24 in-person interviews, and 449 web-based surveys

Household survey: Approximately 1,280 households

Lender survey: 30–35 lenders, primarily Section 184 Program approved lenders, but also including tribe-owned credit unions, Native CDFIs, and lenders using state HFA initiatives.

Urban study telephone interviews: 25 Indian Community Center Directors in urban areas

In-person interviews for urban study (5 locations): other Indian community center staff; housing agency, homeless shelter, and social service agency staff.

Group discussions: Native Americans residents in urban areas served by the above agencies in 5 locations. Hawaii study: telephone interviews with Native Hawaiian agency staff and stakeholders; homestead associations.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:*

| Respondents | Number of respondents | Number responses per respondent | Average burden/response (in hours) | Total burden hours |
|---|---|---|---|---|
| Household Survey | 1280 | 1 | 45 minutes (.75 hour) | 960 |
| TDHE Telephone Survey | 80 | 1 | 45 minutes (.75 hour) | 60 |
| TDHE on-site interviews | 24 | 1 | 1 hour | 24 |
| TDHE web-based surveys | 449 | 1 | 30 minutes | 224.5 |
| Lender Telephone Interviews | 35 | 1 | 45 minutes (.75 hours) | 26.25 |

| Respondents | Number of respondents | Number responses per respondent | Average burden/response (in hours) | Total burden hours |
|---|---|---|---|---|
| On-site interviews with Tribal Leaders, Program Staff. | 96 (24 sites × 4 per site) | 1 | 1 hour | 96 |
| Telephone Interviews of Indian Community Center Directors. | 25 | 1 | 30 minutes (.5 hours) | 12.5 |
| On-site interviews for Urban Indian case studies | 25 (5 × 5 per site) | 1 | 1.5 hours | 37.5 |
| On-site group discussions for Urban Indian case studies. | 40 (5 × 8 per group) | 1 | 2 hours | 80 |
| Telephone interviews with Native Hawaiian agency staff/stakeholders. | 24 | 1 | 45 minutes (.75 hours) | 18 |
| Structured telephone interviews with homestead associations. | 50 | 1 | 30 minutes (.5 hours) | 25 |
| Total | | | | 1,563.75 |

*Status of the proposed information collection:* Pending OMB approval.

*Authority:* Title 13 U.S.C. 9(a), and Title 12, U.S.C., Section 1701z–1 *et seq.*

Dated: April 27, 2011.

**Raphael W. Bostic,**

*Assistant Secretary for Policy Development and Research.*

[FR Doc. 2011–10994 Filed 5–4–11; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5415–FA–28]**

## Announcement of Funding Awards for the Emergency Capital Repair Grant Program; Fiscal Year 2010

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice of funding awards.

**SUMMARY:** In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of Emergency Capital Repair Grant funding decisions made by the Department in FY 2011. This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

**FOR FURTHER INFORMATION CONTACT:** Mr. Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, 451 7th Street, SW., Washington, DC 20410; telephone (202) 708–3000 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, visit the HUD Web site at *http://www.hud.gov.*

**SUPPLEMENTARY INFORMATION:** The Emergency Capital Repair Grants Program is authorized by Section 202(b) of the Housing Act of 1959 (12 U.S.C. 1701q–2). Section 202b was amended to provide grants for 'substantial capital repairs to eligible multifamily projects with elderly tenants that are needed to rehabilitate, modernize, or retrofit aging structures, common areas or individual dwelling units.' HUD accepted applications on a first-come, first-serve basis and awarded emergency capital repair grants until available amounts were expended.

The Catalog of Federal Domestic Assistance number for this program is 14.315.

The Emergency Capital Repair Grant is designed to provide funds to make emergency capital repairs to eligible multifamily projects owned by private nonprofit entities designated for occupancy by elderly tenants. The capital repair needs must relate to items that present an immediate threat to the health, safety, and quality of life of the tenants. The intent of these grants is to provide one-time assistance for emergency items that could not be absorbed within the project's operating budget and other project resources.

A total of $4,893,248 was awarded to 16 projects and 1,809 units. In accordance with section 102(a)4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987. 42 U.S.C. 3545), the Department is publishing the grantees and amounts of the awards in Appendix A of this document.

Dated: April 26, 2011.

**Robert C. Ryan,**

*Acting Assistant Secretary for Housing—Federal Housing Commissioner.*

### APPENDIX A—EMERGENCY CAPITAL REPAIR GRANT AWARDEES FY 2010

| Name of development | Name of owner/sponsor | City | State | Number of units | Dollar amount awarded | Repairs funded |
|---|---|---|---|---|---|---|
| Baptist Towers | Baptist Towers, Inc | Louisville | KY | 199 | $220,774 | Replace elevators. |
| Cheshire House | Cheshire House, Inc | Philadelphia | PA | 12 | 251,953 | Replace windows, emergency call system, elevators and roof. |
| Culpepper Garden I | Culpepper Garden I, Inc | Arlington | VA | 204 | 447,071 | Replace the convertor system tees and piping. |
| DePaul House Apartments. | Associated Catholic Charities, Inc. | Baltimore | MD | 109 | 53,448 | Replace the failing roof. |
| Four Freedoms House of Seattle. | Four Freedoms House of Seattle, Inc. | Seattle | WA | 302 | 431,113 | Replace the brick canopy and canopy posts over the main entrance. |
| Four Freedoms House of Miami Beach. | Four Freedoms House of Miami Beach, Inc. | Miami Beach | FL | 210 | 229,430 | Replace the windows. |

APPENDIX A—EMERGENCY CAPITAL REPAIR GRANT AWARDEES FY 2010—Continued

| Name of development | Name of owner/sponsor | City | State | Number of units | Dollar amount awarded | Repairs funded |
|---|---|---|---|---|---|---|
| Friendship House—Hopkinsville. | Friendship House—Hopkinsville, Inc. | Hopkinsville | KY | 61 | 500,000 | Correct major foundation issues. |
| Friendship Manor | Friendship Homes, Inc | Morgantown | WV | 49 | 351,114 | Repair the elevators and replace the windows, cooling chassis units in the through-wall combination heating, ventilation and air conditioning units. |
| Givens Estates | Given Housing Corporation | Ashville | NC | 78 | 101,178 | Replace 20 decaying raised walkways. |
| Glover Plaza | Glover Plaza, Inc | Wilmington | NC | 75 | 272,210 | Replace the roofs and correct the failed drainage system. |
| Highlands Manor | National Church Residences of Daytona Beach, Florida, Inc. | Dayton Beach | FL | 63 | 410,074 | Repair and replace the existing exterior insulation finishing systems. |
| Riverside Apartments | Riverside Apartments | New Castle | PA | 128 | 294,265 | Replace the roof and grinder pump. |
| Sandpiper Run | National Church Residences of Florida @ McGregor Lake, Inc. | Ft. Myers | FL | 60 | 500,000 | Repair and replace the existing exterior insulation finishing system. |
| Steel Plaza | Senior Citizens Housing Development Corporation of Los Angeles. | Los Angeles | CA | 66 | 258,002 | Replace the common area and individual tenant HVAC units. |
| Steelworkers Tower | NCSC/USA Housing Development Corporation. | Pittsburgh | PA | 80 | 406,967 | Replace the roof, elevator and windows. |
| Village of Brush Manor | Brush Park Senior Housing Development Corporation. | Detroit | MI | 113 | 165,649 | Replace the windows. |

[FR Doc. 2011–10987 Filed 5–4–11; 8:45 am]
BILLING CODE 4210–67–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5374–N–30]**

## Buy American Exceptions Under the American Recovery and Reinvestment Act of 2009

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** In accordance with the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–05, approved February 17, 2009) (Recovery Act), and implementing guidance of the Office of Management and Budget (OMB), this notice advises that certain exceptions to the Buy American requirement of the Recovery Act have been determined applicable for work using Capital Fund Recovery Formula and Competition (CFRFC) grant funds. Specifically, exceptions were granted to the Denver Housing Authority for the purchase and installation of Underwriter Laboratory-listed (UL-Listed) drop in anchor materials for the Osage Apartments project, the Luzerne County Housing Authority of Luzerne County, PA, for the purchase and installation of through-the-wall air-conditioning units for the Frank Crossin Towers project, and to the Dakota County Community Development Agency of Dakota County, MN, for the purchase and installation of a ductless split air conditioning unit at the Colleen Loney Manor project.

**FOR FURTHER INFORMATION CONTACT:** Donald J. LaVoy, Deputy Assistant Secretary for Office of Field Operations, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4112, Washington, DC 20410–4000, telephone number 202–402–8500 (this is not a toll-free number); or Dominique G. Blom, Deputy Assistant Secretary for Public Housing Investments, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4130, Washington, DC 20410–4000, telephone number 202–402–8500 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

**SUPPLEMENTARY INFORMATION:** Section 1605(a) of the Recovery Act provides that none of the funds appropriated or made available by the Recovery Act may be used for a project for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States. Section 1605(b) provides that the Buy American requirement shall not apply in any case or category in which the head of a Federal department or agency finds that: (1) Applying the Buy American requirement would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality, or (3) inclusion of iron, steel, and manufactured goods will increase the cost of the overall project by more than 25 percent. Section 1605(c) provides that if the head of a Federal department or agency makes a determination pursuant to section 1605(b), the head of the department or agency shall publish a detailed written justification in the **Federal Register**.

In accordance with section 1605(c) of the Recovery Act and OMB's implementing guidance published on April 23, 2009 (74 FR 18449), this notice advises the public that, on April 25, 2011, the following exceptions were granted:

1. *Denver Housing Authority.* Upon request of the Denver Housing Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Osage Apartments project. The exception was granted by HUD on the basis that the relevant manufactured goods (UL-Listed drop in anchor materials) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

2. *Luzerne County Housing Authority.* Upon request of the Luzerne County Housing Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Frank Crossin Towers project. The exception was granted by HUD on the basis that the relevant manufactured goods (through-the-wall air conditioning systems) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

3. *Dakota County Community Development Agency.* Upon request of the Dakota County Community Development Agency, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC funds, in connection with the Colleen Loney project. The exception was granted by HUD on the basis that the relevant manufactured goods (ductless split air conditioning units) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

Dated: April 28, 2011.

**Sandra B. Henriquez,**

*Assistant Secretary for Public and Indian Housing.*

[FR Doc. 2011–10991 Filed 5–4–11; 8:45 am]

**BILLING CODE 4210–67–P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Electronic Devices Having a Digital Television Receiver and Components Thereof,* DN 2801; the Commission is soliciting comments on any public interest issues raised by the complaint.

**FOR FURTHER INFORMATION CONTACT:** James R. Holbein, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint filed on Zenith Electronics LLC on April 29, 2011. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic devices having a digital television receiver and components thereof. The complaint names as respondents Sony Corporation of Tokyo, Japan, Sony Corporation of America of New York, NY and Sony Electronics, Inc. of San Diego, CA.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number ("Docket No. 2801") in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: April 29, 2011.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. 2011–10947 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–694]**

### In The Matter of Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same; Notice of Commission Determination To Extend the Supplemental Briefing Schedule

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to extend the supplemental briefing schedule identified in its prior notice issued April 18, 2011 by seven (7) days.

**FOR FURTHER INFORMATION CONTACT:** Daniel E. Valencia, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–1999. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E. Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted the instant investigation on December 16, 2009, based on a complaint filed by Pioneer Corporation of Tokyo, Japan and Pioneer Electronics (USA) Inc. of Long Beach, California (collectively, "Pioneer"). 74 FR 66676 (Dec. 16, 2009). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain multimedia display and navigation devices and systems, components thereof, and products containing same by reason of infringement of various claims of United States Patent Nos. 5,365,448 ("the '448 patent"), 5,424,951 ("the '951 patent"), and 6,122,592 ("the '592 patent"). The complaint named Garmin International, Inc. of Olathe, Kansas, Garmin Corporation of Taiwan (collectively, "Garmin") and Honeywell International Inc. of Morristown, New Jersey ("Honeywell") as the proposed respondents. Honeywell was subsequently terminated from the investigation.

On December 16, 2010, the ALJ issued his final initial determination ("ID"). In his final ID, the ALJ found no violation of section 337 by Garmin. Specifically, the ALJ found that the accused products do not infringe claims 1 and 2 of the '448 patent, claims 1 and 2 of the '951 patent, or claims 1 and 2 of the '592 patent. The ALJ found that the '592 patent was not proven to be invalid and that Pioneer has established a domestic industry under 19 U.S.C. 1337(a)(3)(C). On February 23, 2011, the Commission determined to review the final ID in part.

On April 18, 2011, the Commission issued a notice indicating that it had determined to extend the target date and request supplemental briefing from the private parties and the public. On April 22, 2011, the Commission investigative attorney ("IA") filed an unopposed motion for an extension of the briefing schedule set forth in the Commission's April 18, 2011 notice. The IA's motion is granted.

The Commission has determined to extend all submission dates set forth in its prior notice by seven (7) days. In particular, opening submissions of the parties to the investigation are due no later than May 10, 2011. A public version of these submissions must be filed with the Secretary no later than May 17, 2011. Reply submissions of the parties to the investigation are due no later than May 24, 2011. Written submissions from members of the public will be accepted anytime on or before May 24, 2011. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR 210).

By order of the Commission.

Issued: April 29, 2011.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. 2011–10945 Filed 5–4–11; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

**[Inv. No. 337–TA–685]**

### In the Matter of Certain Flash Memory and Products Containing Same; Notice of Commission Decision To Review in Part a Final Determination Finding a Violation of Section 337; Request for Written Submissions

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review in part the presiding administrative law judge's ("ALJ") final initial determination ("ID") issued on February 28, 2011, finding a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337 in the above-captioned investigation.

**FOR FURTHER INFORMATION CONTACT:** Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted Inv. No. 337–TA–685 on September 9, 2009, based on a complaint filed by Samsung Electronics Co. ("Samsung") of Suwon City, South Korea on August 21, 2009. 74 FR 45469 (Sept. 2, 2009). The complaint, as amended, alleged violations of Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain flash memory and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 6,930,050 ("the '050 patent") and 5,740,065 ("the '065 patent"). The

Commission's notice of investigation named numerous respondents, including Spansion, Inc. and Spansion, LLC of Sunnyvale, California (collectively, "Spansion") and D–Link Corporation of Taipei City, Taiwan and D–Link Systems, Inc. of Fountain View, California (collectively "D–Link"). Respondents Spansion and D–Link are herein referred to collectively as "Respondents."

On February 28, 2011, the ALJ issued his final ID, finding a violation of Section 337. The ID included the ALJ's recommended determination ("RD") on remedy and bonding. In his ID, the ALJ found that asserted claims 8 and 12 of the '065 patent are infringed. The ALJ also found that claims 1, 8, and 12 of the '065 patent are not invalid under 35 U.S.C. 102 for anticipation. The ALJ also found that the asserted claims of the '065 patent are not invalid for failing to satisfy the written description requirement of 35 U.S.C. 112 ¶ 1. The ALJ further found that the asserted claims of the '065 patent are not invalid as indefinite under 35 U.S.C. 112 ¶ 2. The ALJ also found that there is a domestic industry with respect to claim 1 of the '065 patent as required by 19 U.S.C. 1337(a)(2) and (3). In his RD, the ALJ recommended that the appropriate remedy is a limited exclusion order barring entry of infringing flash memory devices or products containing same and that it would also be appropriate to issue cease and desist orders against both Spansion and D–Link. The ALJ also recommended that Respondents be required to post a bond equal to 2.4 percent of the entered value of any accused product that they seek to import during the period of Presidential review.

On March 14, 2011, Respondents filed a petition seeking review of the ALJ's determination concerning the ALJ's findings on claim construction, infringement, invalidity, and domestic industry. Also on March 14, 2011, the Commission investigative attorney ("IA") filed a petition seeking review of the ALJ's determination concerning the ALJ's findings on claim construction, infringement, validity, and the domestic industry. On March 22, 2011, Samsung filed an opposition to Respondents' and the IA's petitions for review. Also on March 22, 2011, the IA filed a response to Respondents' petition for review on the issue of invalidity under 35 U.S.C. 102 for anticipation. On March 25, 2011, the IA filed an unopposed motion for leave to file a public version of its petition for review out of time. The Commission hereby determines to grant the motion.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, the Commission has determined to review the ID's construction of the limitation "extracting an optimal working condition by accumulatively averaging working conditions of lots previously processed" of claim 8 of the '065 patent. In particular, the Commission has determined to review the ID's construction of "extracting an optimal working condition by accumulatively averaging" as not being limited to Equation (1) of the '065 patent. The Commission has also determined to review the ID's construction of the "extracting" limitation of claim 8 as including the phrase "suitable lots." The Commission has further determined to review the ID's construction of the claim limitation "accumulatively averaging working conditions of lots previously processed" of claim 8 of the '065 patent. In particular, the Commission has determined to review the ID's construction of the claim limitations "accumulatively averaging" and "working conditions."

The Commission has also determined to review the ID's finding that Spansion's accused run-to-run alignment and exposure controllers infringe claims 8 and 12 of the '065 patent. The Commission has further determined to review the ID's finding that Japanese Unexamined Patent Application Publication H5–47893, entitled "Adjustment Method for Semiconductor Manufacturing Apparatus" does not anticipate claim 8 of the '065 patent. The Commission has also determined to review the ID's finding that claim 8 is not invalid for failing to satisfy the written description requirement. The Commission has further determined to review the ID's finding that claims 1, 8, and 12 are not invalid as indefinite. The Commission has also determined to review the ID's finding that Samsung's Exposure Parameter Optimization System practices claim 1 of the '065 patent. The Commission has determined not to review the remaining issues decided in the ID.

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

1. Please address whether it is appropriate to apply a plain, ordinary meaning analysis in construing the claim term "accumulatively averaging" even though this term is admittedly a "coined term." In discussing this issue, please address the following questions:

a. If an ordinary meaning analysis of "accumulatively averaging" is appropriate, does the experts' testimony concerning the understanding of one of ordinary skill in the art in any way conflict with the meaning of the claim language as informed by the intrinsic evidence?

b. If an ordinary meaning analysis is appropriate, what is the definition of the word "accumulatively" and how does the meaning of the word "accumulatively" affect the correct construction of "accumulatively averaging?"

c. If an ordinary meaning analysis is appropriate, how does the definition of "accumulatively" fit into the context of the purpose of the '065 invention in terms of effective automatic process control.

d. If "accumulatively averaging" should be construed according to its ordinary meaning, how would such an analysis affect the validity of claim 1?

2. Please address Samsung's expert, Dr. Watts', admission that, under Samsung's broad interpretation of "accumulatively averaging" as encompassing all types of averaging, the limitation could read on averaging operations that are not useful for the process control procedure disclosed in the '065 patent. *See* Watts, Tr. 861:16–862:3.

3. With respect to the claim construction of the "working conditions" limitation, please address the following questions:

a. Should the "process parameter values" recited in claim 11 be read into claim 8?

b. How does the meaning of the phrase "according to" in col. 5, ln. 46 of the '065 specification inform the interpretation of the phrase "based on" recited in claim 8?

c. Are there any specific examples available from the evidence of record that may shed light on when a process parameter variable that is not specifically a machine setting may be used in a semiconductor manufacturing process as disclosed in the '065 patent? In considering this question, please also address how such a parameter might then be converted to the proper units or axis for a particular piece of processing equipment.

4. Please address in depth whether the particular type of averaging used in Spansion's accused process satisfies the "accumulatively averaging" limitation under the doctrine of equivalents.

5. Please address whether claim 8 satisfies the written description requirement if the claim limitation "extracting an optimal working condition by accumulatively averaging" is limited to Equation (1) disclosed in the '065 patent, where Equation (1) may represent to one of ordinary skill in the art a moving average or a weighted or unweighted average.

6. Please address whether claims 1, 8, and 12 of the '065 patent are indefinite if the "accumulatively averaging" limitation is construed to include a moving average or a weighted or unweighted average.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see In the Matter of Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

*Written Submissions:* The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

Complainants and the IA are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the dates that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on Monday, May 16, 2011. Reply submissions must be filed no later than the close of business on Monday, May 23, 2011. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–46 and 210.50).

Issued: April 29, 2011.

By order of the Commission.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. 2011–10946 Filed 5–4–11; 8:45 am]

BILLING CODE P

## INTERNATIONAL TRADE COMMISSION

**[USITC SE–11–011]**

## Government in the Sunshine Act Meeting Notice

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** May 13, 2011 at 11 a.m.

**PLACE:** Room 110, 500 E Street, SW., Washington, DC 20436, *Telephone:* (202) 205–2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agendas for future meetings: None.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701–TA–477 and 731–TA–1180–1181 (Preliminary) (Bottom Mount Combination Refrigerator-Freezers from Korea and Mexico). The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before May 16, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before May 23, 2011.

5. Vote in Inv. Nos. 701–TA–478 and 731–TA–1182 (Preliminary) (Certain Steel Wheels from China). The Commission is currently scheduled to transmit it determinations to the Secretary of Commerce on or before May 16, 2011; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before May 23, 2011.

6. Outstanding action jackets: None.

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.

By order of the Commission.

Issued: May 3, 2011.

**William R. Bishop,**

*Hearings and Meetings Coordinator.*

[FR Doc. 2011–11092 Filed 5–3–11; 4:15 pm]

BILLING CODE 7020–02–P

## DEPARTMENT OF JUSTICE

### Notice of Lodging of a Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on April 27, 2011, a proposed Consent Decree in *United States* v. *Bunting Bearings, LLC,* Civil Action No. 3:10–CV–01527, was lodged with the United States District Court for the Northern District of Ohio.

In this action the United States alleges that Bunting Bearings, LLC is liable under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. 9607, for the recovery of response costs incurred by the United States at the Eagle-Picher Superfund Site in Delta, Ohio. Under the proposed Consent Decree, Bunting Bearings, LLC will reimburse the United States $450,000 in past response costs.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044–7611, and should refer to *United States* v. *Bunting Bearings, LLC,* D.J. Ref. 90–11–3–09684.

The proposed Consent Decree may be examined at the U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, IL 60604–3590 (contact Associate Regional Counsel Craig Melodia (312/886–2870)). During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed consent decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $5.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the stated address.

**Maureen Katz,**

*Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2011–10900 Filed 5–4–11; 8:45 am]

**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States of America* v. *Richard D. Kor, Wesley D. Kor, and KOR Ethanol, Inc.,* Case No. 10–4086, was lodged with the United States District Court for the District of South Dakota, Southern Division, on April 28, 2011.

This proposed Consent Decree concerns a complaint filed by the United States against Richard D. Kor, Wesley D. Kor, and Kor Ethanol, Inc., pursuant to Sections 301, 309, 311 and 404 of the Clean Water Act, 33 U.S.C. 1311, 1319, 1321 and 1344, to obtain injunctive relief from and impose civil penalties against the Defendants for violating the Clean Water Act by, among other things, discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations by requiring the Defendants to restore the impacted areas and perform mitigation and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to David A. Carson, United States Department of Justice, Environment and Natural Resources Division, 999 18th Street, South Terrace, Suite 370, Denver, Colorado 80202, and refer to *United States* v. *Richard D. Kor, et al.,* DJ # 90–5–1–1–17529.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of South Dakota, Southern Division, 400 S. Phillips Avenue, Sioux Falls, South Dakota 57104. In addition, the proposed Consent Decree may be viewed at *http://www.usdoj.gov/enrd/Consent_Decrees.html.*

**Cherie L. Rogers,**

*Assistant Section Chief, Environmental Defense Section, Environment & Natural Resources Division.*

[FR Doc. 2011–10989 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF LABOR

### Comment Request for Information Collection for Employment and Training (ET) Handbook 336, 18th Edition: "Unemployment Insurance (UI) State Quality Service Plan Planning (SQSP) and Reporting Guidelines," Extension of Current Collection

**AGENCY:** Employment and Training Administration, Labor Department.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the collection of data about the proposed extension to ET Handbook 336, 18th Edition: "Unemployment Insurance (UI) State Quality Service Plan Planning (SQSP) and Reporting Guidelines" which expires August 31, 2011. S:OUI\OMB\1205–0132\2011\1205–0132SQSP 60 day FRN.doc A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

**DATES:** Written comments must be submitted to the office listed in the addressee's section below on or before July 5, 2011.

**ADDRESSES:** Submit written comments to the Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue, NW., Room S4220, Washington, DC 20210, *Attention:* Delores Mackall. *Telephone number:* 202–693–3183 (this is not a toll-free number). *Fax:* 202–693–3975. *E-mail: Mackall.Delores@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The SQSP represents an approach to the unemployment insurance performance management and planning process that allows for an exchange of

information between the federal and state partners to enhance the ability of the program to reflect the joint commitment to performance excellence and client-centered services. As part of UI Performs, a comprehensive performance management system implemented in 1995 for the UI program, the SQSP is the principal vehicle that state UI agencies use to plan, record and manage program improvement efforts as they strive for excellence in service. The SQSP, which serves as the State Plan for the UI program, also serves as the grant document through which states receive federal UI administrative funding. The statutory basis for the SQSP is Title III, Section 302 of the Social Security Act, which authorizes the Secretary of Labor to provide funds to administer the UI programs, and Sections 303 (a) (8) and (9) which govern the expenditures of those funds. The SQSP represents an approach to tie program performance with the budget and planning process.

**II. Review Focus**

The Department of Labor is particularly interested in comments which:

- 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 submissions of responses.

ETA proposes to extend this information collection. The Department's information collection authority for SQSP is under Office of Management and Budget (OMB) number 1205–0132. Currently, the Employment and Training Administration is soliciting comments concerning the extension of and modification to the ET Handbook No. 336.

States will continue to use the State Plan Narrative to provide a general summary of the UI program in the state. Additionally, states are to include in the Narrative: (1) Performance in comparison to the Government Performance and Results Act (GPRA) goals; (2) results of customer satisfaction surveys (optional); and (3) actions planned to correct deficiencies regarding UI programs and reporting requirements. Actions planned to correct deficiencies for Secretary Standards, Core Measures, and the Data Validation (DV) program are expected to be addressed in corrective action plans.

On April 13, 2011, OMB approved a non-substantive change to 1205–0132, requiring that all states include in their SQSP submissions a corrective action plan to reduce and recover improper payments. Comment is encouraged on this recent change as well as on the 1205–0132 data requirements in general.

The Department will provide each state workforce agency with its state-specific root causes for its improper payments, based on BAM survey results. The SQSP Handbook No. 336 includes an action plan for each state to complete. The state action plan will include the following items:

- Strategies to reduce root causes, including recovery of these improper payments;
- Timeline, expected targets and measures; and
- Type and source of resources dedicated to accomplish the action plan.

**III. Current Actions**

*Type of Review:* extension of current collection.

*Title:* Unemployment Insurance State Quality Service Plan (SQSP).

*OMB Number:* 1205–0132.

*Affected Public:* State Workforce Agencies.

*Total Annual Respondents:* 53.

*Reporting Frequency:* 13 annual reports and 4 quarterly reports per year per respondent.

*Total Annual Responses:* 901.

*Average Time per Response:* 3.37 hours.

*Estimated Total Annual Burden Hours:* 3036 hours.

*Total Annual Burden Cost for Respondents:* $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Signed at Washington, DC, this 29th day of April 2011.

**Jane Oates,**

*Assistant Secretary, Employment and Training Administration.*

[FR Doc. 2011–10937 Filed 5–4–11; 8:45 am]

BILLING CODE 4510–FW–P

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

### Proposed Exemptions from Certain Prohibited Transaction Restrictions

**AGENCY:** Employee Benefits Security Administration, Labor

**ACTION:** Notice of Proposed Exemptions.

**SUMMARY:** This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). This notice includes the following proposed exemptions: D–11513, North Trust Corporation; D–11634, The United Brotherhood of Carpenters Pension Fund (the Fund); D–11639, Wolverine Bronze Profit Sharing Plan and Trust (the Plan); and L–11651 and L–11652, Verizon Communications, Inc. (Verizon and Cellco Partnership, doing business as Verizon Wireless (Verizon Wireless; collectively, the Applicants) *et al.*]

**DATES:** All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice.

**ADDRESSES:** Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N–5700, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. _____, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via e-mail or FAX. Any such comments or requests should be sent either by e-mail to: *moffitt.betty@dol.gov,* or by FAX to (202) 219–0204 by the end of the scheduled comment period. The

applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC 20210.

**Warning:** If you submit written comments or hearing requests, do not include any personally-identifiable or confidential business information that you do not want to be publicly-disclosed. All comments and hearing requests are posted on the Internet exactly as they are received, and they can be retrieved by most Internet search engines. The Department will make no deletions, modifications or redactions to the comments or hearing requests received, as they are public records.

**SUPPLEMENTARY INFORMATION:**

**Notice to Interested Persons**

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Northern Trust Corporation
Located in Chicago, IL
[Application No. D–11513]

**Proposed Exemption**

The Department is considering granting an exemption under the authority of section 408(a) of ERISA and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

*Section I. Transactions*

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) and (D) and section 406(b)(1) and (2) of ERISA and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), (D), and (E) of the Code, shall not apply, effective October 31, 2008, to the sale (the Sale) by a Plan (as defined in Section III(e)) of an Auction Rate Security (ARS, as defined in Section III(c)) to Northern Trust Corporation or an affiliate thereof (Northern), if the conditions of Section II are met.[1]

*Section II. Conditions*

(a) The Plan acquired the ARS in connection with brokerage or advisory services provided by Northern to the Plan;

(b) The last auction for the ARS was unsuccessful;

(c) The Sale is made pursuant to a written offer by Northern (the Offer) containing all of the material terms of the Sale, in which the Plan would have the opportunity to sell the ARS but would be under no obligation to do so, and would include but is not limited to the following:

(i) Northern will distribute each Offer to its eligible customers, marked, or otherwise prepared in a manner reasonably designed to prominently indicate to the recipient the subject matter, importance, and time-sensitivity of the information provided;

(ii) Acceptance of an Offer would cause Northern to purchase the eligible ARS at the next applicable coupon interest payment date as described therein. Purchase dates may vary depending on when an Offer is accepted and when the next coupon interest payment date for such eligible ARS occurs;

(iii) Acceptance of the Offer could be withdrawn at any time until three business days prior to the payment date; and

(iv) The Offer will comply with "plain English" standards and will include: A reference to a Web site containing a description of the eligibility criteria used by Northern; a reference to where the Plan fiduciary can find a list of eligible ARS held in the account (including the amount and other identifying information); the background of the Offer; the methods and timing by which eligible customers may accept the Offer; the manner of determining the purchase dates for eligible ARS pursuant to the Offer; the timing of payment for eligible ARS purchased pursuant to the Offer; the methods and timing by which a customer may elect to withdraw its acceptance of the Offer; the expiration date of the Offer; a suggestion that eligible customers consult their tax advisors to determine the tax consequences, if any, of accepting the Offer and to ensure that accounting and financial reporting complies with applicable accounting guidance; and how to obtain additional information concerning the Offer;

(d) The Sale is a one-time transaction for no consideration other than cash payment against prompt delivery of the ARS;

(e) The sales price for the ARS is equal to the par value of the ARS, plus any accrued but unpaid interest or dividends as applicable, as of the date of the Sale;

(f) The Plan does not waive any rights or claims in connection with the Sale;

(g) The decision to accept the Offer or retain the ARS is made by an Independent Fiduciary (as defined in Section III(d)).[2] Notwithstanding the foregoing, in the case of an individual retirement account (IRA) which is beneficially owned by an employee, officer, director or partner of Northern, the decision to accept the Offer or retain the ARS may be made by such employee, officer, director, or partner;

(h) Neither Northern nor an affiliate thereof exercises investment discretion or renders investment advice, within the meaning of 29 CFR 2510.3–21(c), in connection with the decision to sell or retain the ARS;

(i) The Plan does not pay any commissions or any other transaction costs with respect to the Sale;

(j) The Sale is not part of an arrangement, agreement, or understanding designed to benefit a party in interest or disqualified person to the Plan;

[1] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer also to the corresponding provisions of section 4975 of the Code.

[2] The Department notes that ERISA's general standards of fiduciary conduct would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things, the decision to sell the ARS to Northern for the par value of the ARS. The Department further emphasizes that it expects plan fiduciaries, prior to entering into any of the transactions, to fully understand the risks associated with this type of transaction, following disclosure by Northern of all the relevant information.

(k) Northern maintains, or causes to be maintained, for a period of six (6) years from the date of the Sale such records as are necessary to enable the persons described below in paragraph (l)(i), to determine whether the conditions of this proposed exemption, if granted, have been met, except that—

(i) No party in interest or disqualified person with respect to a Plan which engages in a Sale, other than Northern and its affiliates, as applicable, shall be subject to a civil penalty under section 502(i) of ERISA or the taxes imposed by section 4975(a) and (b) of the Code, if such records are not maintained, or not available for examination, as required, below by paragraph (l)(i); and

(ii) A separate prohibited transaction shall not be considered to have occurred solely because, due to circumstances beyond the control of Northern or its affiliates, as applicable, such records are lost or destroyed prior to the end of the six-year period; and

(l)(i) Except as provided below in paragraph (l)(ii), and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of ERISA, the records referred to above in paragraph (k) are unconditionally available at their customary location for examination during normal business hours by—

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service, or the U.S. Securities and Exchange Commission; or

(B) Any fiduciary of any Plan, including an IRA owner, that engages in a Sale, or any duly authorized employee or representative of such fiduciary; or

(C) Any employer of participants and beneficiaries and any employee organization whose members are covered by a Plan that engages in the Sale, or any authorized employee or representative of these entities;

(ii) None of the persons described above in paragraph (l)(i)(B)–(C) shall be authorized to examine trade secrets of Northern, or commercial or financial information which is privileged or confidential; and

(iii) Should Northern refuse to disclose information on the basis that such information is exempt from disclosure, Northern shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

*III. Definitions*

For purposes of this exemption:

(a) The term "affiliate" of another person means: (1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such person; (2) any officer, director, partner, employee, or relative (as defined in section 3(15) of ERISA) of such other person; and (3) any corporation or partnership of which such other person is an officer, director, partner, or employee;

(b) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual;

(c) The term "Auction Rate Security" or "ARS" means a debt obligation of a corporation, business entity, municipality or other governmental agency with a nominal long-term maturity for which the interest rate is reset through a Dutch Auction typically held every 7, 14, 28, 35 or 49 days, with interest paid at the end of each auction period. The term also means preferred stock issued by a corporation or other business entity for which the dividend is reset and paid through the same process;

(d) The term "Independent Fiduciary" shall mean the fiduciary of the Plan making the decision to engage the Plan in the covered transactions, provided that such fiduciary may not be Northern or an affiliate thereof; and

(e) The term "Plan" means an individual retirement account (an IRA) or similar account described in section 4975(e)(1)(B) through (F) of the Code; or an employee benefit plan as defined in section 3(3) of ERISA.

**EFFECTIVE DATE:** If granted, this proposed exemption will be effective as of October 31, 2008.

**Summary of Facts and Representations**

1. Northern Trust Corporation (hereinafter, either "Northern" or the "applicant") is a financial holding company that is a leading provider of investment management, asset and fund administration, fiduciary, and banking solutions for corporations, institutions, and affluent individuals. Northern conducts business through various U.S. and non-U.S. subsidiaries, including The Northern Trust Company (the "Bank"), an Illinois bank headquartered in Chicago, Illinois.

The Bank is a member of the Federal Reserve System, its deposits are insured by the FDIC, and it is subject to regulation by both of those entities, as well as by the Division of Banking of the Illinois Department of Financial and Professional Regulation. Northern's national bank subsidiaries are members of the Federal Reserve System and are subject to regulation by the Office of the Comptroller of the Currency, with deposits insured by the FDIC to the extent provided by the Federal Deposit Insurance Act. Northern Trust Bank, FSB is a federal savings bank that is not a member of the Federal Reserve System and is subject to regulation by the Office of Thrift Supervision and the FDIC.

Northern also has a number of direct and indirect subsidiary registered investment advisers that are subject to the Investment Advisers Act of 1940, and a subsidiary broker-dealer, Northern Trust Securities, Inc. (NTSI), an SEC registered broker-dealer that is subject to the supervision of various governmental and self-regulatory bodies.

Northern has a network of 79 offices in 18 states and has international offices in 16 locations in North America, Europe, and the Asia-Pacific region. As of December 31, 2009, Northern had consolidated total assets of $74.3 trillion and stockholders' equity of $6.3 trillion. The Bank, founded in 1889, conducts its business through its U.S. operations, its Toronto, London, and Singapore branches, and various U.S. and non-U.S. subsidiaries. As of December 31, 2009, the Bank had assets under management of $627.2 billion and assets under custody of $3.7 trillion.

2. In connection with the liquidity problems in the Auction Rate Securities (ARS) market, Northern offered to purchase certain ARS from certain client accounts, including certain Plan (as defined in Section III(e)) accounts.[3] The ARS typically trade through Dutch Auctions.[4] While many of these

[3] ARS may be issued as either debt or preferred stock. In the case of debt, they generally have a long-term nominal maturity and an interest rate that is reset through a Dutch Auction process. In the case of preferred stock, they generally have no maturity and a dividend that is reset through a Dutch Auction process. A Dutch Auction is a competitive process used to determine rates on each auction date. Bids are submitted to the auction agent by the broker-dealer on behalf of the investors interested in selling their securities. The auction agent matches bids with securities offered by the bondholders and the winning bid is the highest price (lowest interest rate or dividend) at which the auction clears. That means the lowest interest rate at which the total number of securities demanded equals the total number auctioned. If the market does not clear, then there is a failed auction, and the securities may not be sold in their entirety.

[4] In a Dutch Auction, prospective investors may submit a bid that specifies the par amount of the securities they wish to acquire and the minimum interest rate or dividend they are willing to accept. Existing holders may submit (i) a hold order, which means they want to hold their position at whatever rate is set via the auction, (ii) a hold at rate order, which means they want to hold their position but only if the rate is set at or above their specified level, or (iii) a sell order, which means they wish to exit their position, regardless of the rate set via the auction. The auctions generally take place periodically (*i.e.,* daily or 7, 28, 35 or 49 day periods are typical). The securities trade at par and are bought or sold on designated auction dates,

Continued

securities continue to be rated by independent credit rating agencies as investment grade credit, many ARS continue to experience failed auctions.

Because Northern is a party in interest or disqualified person with respect to the ERISA or the Code Plan accounts, Northern requests an administrative exemption granting both retroactive and prospective relief for the sale (the Sale) by a Plan of an ARS to Northern where the auctions for those securities have failed. The applicant opines that, in instances where Northern is not a fiduciary, section 408(b)(17) of ERISA should provide the necessary exemptive relief.[5] In some cases, Northern has discretionary authority with respect to the Plan accounts. In other cases, Northern may have provided advice such that IRA owners or other Plan fiduciaries could claim that Northern is a fiduciary. Where Northern is or could be a fiduciary with respect to a Plan, exemptive relief is necessary to cover Northern's purchases of eligible ARS from specified Plan accounts, including (i) individual retirement accounts or similar accounts (which may be beneficially owned by an employee, officer, director or partner of Northern); and (ii) employee benefit plans.

3. Northern made one or more written offers (an "Offer") to all of its eligible customers to purchase all eligible ARS held by such customers for cash at par value, plus accrued but unpaid interest, pursuant to the relevant Offer, described further in Item 4, below. Each Offer was open for a minimum of 30 days from the date it was first distributed by Northern to its eligible customers, or for such longer period as determined by Northern from time to time.

Acceptance of an Offer would cause Northern to purchase the eligible ARS on the next applicable coupon interest payment date as described in the relevant Offer Document. Purchase dates may vary depending on when an Offer is accepted and when the next coupon interest payment date for such eligible ARS occurs.

Acceptance of the Offer could be withdrawn at any time until three business days prior to the payment date. If an eligible customer has not accepted the Offer and the eligible customer holds an account with respect to which Northern has discretionary control, Northern documents the customer's direction to retain the eligible ARS and clarifies that Northern has no investment responsibility with respect to those securities.

4. The Offer that Northern distributed to its eligible customers was marked, or otherwise prepared in a manner reasonably designed to prominently indicate to the recipient the subject matter, importance, and time-sensitivity of the information provided.

The Offer complies with "plain English" standards and included disclosure of, or a fair and adequate summary of, all material aspects of:

- The terms and conditions of the Offer, including reference to a Web site containing a description of the eligibility criteria used by Northern;
- A list of eligible ARS held in the account (including the amount, identifying information, and CUSIP);
- The background of the Offer;
- The methods and timing by which eligible customers may accept the Offer;
- The manner of determining the purchase dates for eligible ARS pursuant to the Offer;
- The timing of payment for eligible ARS purchased pursuant to the Offer;
- The methods and timing by which a customer may elect to withdraw its acceptance of the Offer;
- The expiration date of the Offer;
- A suggestion that eligible customers consult their tax advisors to determine the tax consequences, if any, of accepting the Offer and to ensure that accounting and financial reporting complies with applicable accounting guidance;
- For advisory clients, disclosure that (a) acceptance of the Offer by an eligible customer will constitute such customer's direction to Northern to purchase the eligible ARS, and (b) rejection of the Offer by an eligible customer will constitute such customer's direction to Northern to retain the eligible ARS in the account; and
- How to obtain additional information concerning the Offer.

All client accounts which accepted the Offer were paid on a date that coincided with the interest payment date so that there would be no accrued but unpaid interest, or were paid accrued interest. No brokerage commissions or other fees were charged.

5. In summary, the applicant represents that the transactions described herein satisfy the statutory criteria of section 408(a) of ERISA because, among other things:

(a) Each covered Sale shall be made pursuant to a written Offer;

(b) Each covered Sale shall be a one-time transaction for no consideration other than cash payment against prompt delivery of the ARS;

(c) The sales price in each covered Sale shall equal the par value of the ARS, plus any accrued but unpaid interest or dividends as applicable, as of the date of the Sale;

(d) Plans would not waive any rights or claims in connection with any covered Sale as a condition for engaging in such transaction;

(e)(1) the decision to accept an Offer or retain the ARS shall be made by an Independent Fiduciary; and (2) neither Northern nor an affiliate thereof shall exercise investment discretion or render investment advice, within the meaning of 29 CFR 2510.3–21(c), in connection with the decision to accept the Offer or retain the ARS;

(f) Plans shall not pay any commissions or transaction costs with respect to any covered Sale;

(g) A covered Sale shall not be part of an arrangement, agreement, or understanding designed to benefit a party in interest or disqualified person to the affected Plan.

**Notice to Interested Persons**

The applicant represents that all the potentially interested persons cannot be identified and that, therefore, the only practicable means of notifying interested persons of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing are due within 45 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Ms. Karin Weng of the Department, telephone (202) 693–8557. (This is not a toll-free number.)

The United Brotherhood of Carpenters Pension Fund (the Plan or the Applicant) Located in Las Vegas, Nevada [Application No. D–11634]

**Proposed Exemption**

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).[6] If the exemption is granted, the restrictions of sections 406(a)(1)(A), (D)

presuming a successful auction. These securities also may be redeemed by issuers (through announced full or partial redemptions). Although they nominally are long term instruments, because of the interest rate and dividend reset features, they historically have been priced and traded as short term instruments due to the auction process. They generally are issued in minimum denominations ranging from $25,000 to $100,000.

[5] The Department expresses no opinion herein as to whether the conditions of section 408(b)(17) of ERISA were or are satisfied by any purchase of ARS from a Plan by Northern.

[6] For purposes of this proposed exemption, references to the provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975(c)(1)(A) and (D) of the Code, shall not apply to the proposed sale (Sale) of a 10.89 acre parcel of real property (the Parcel), which is part of larger parcel of real property (the Nevada Property), from the Plan-owned Bermuda Hidden Well, LLC (Bermuda LLC) to the Southwest Regional Council of Carpenters (the Council), a party in interest with respect to the Plan; provided that the following conditions are satisfied:

(a) The terms and conditions of the Sale are at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party;

(b) The Sale is a one-time transaction for cash;

(c) As consideration, the Plan receives the greater of $5,383,577, or the fair market value of the Parcel as determined by a qualified, independent appraiser (the Appraiser) in an appraisal (the Appraisal) of the Nevada Property, which is updated on the date of Sale (Sale Date);

(d) The Plan pays no commissions, costs or fees with respect to the Sale, except for customary closing costs (the Seller Closing Costs) and 50% of certain rental credits (the Rental Credits) that are paid to unrelated parties; and

(e) The Plan fiduciaries review and approve the methodology used by the Appraiser, ensure that such methodology is properly applied in determining the fair market value of the Parcel, and also determine whether it is prudent to go forward with the proposed transaction.

**Summary of Facts and Representations**

*The Parties*

1. United Brotherhood of Carpenters and Joiners of America (UBC), the Plan sponsor, is an international labor organization with 725 local unions and 37 councils, including the Council. UBC's General President has the authority to appoint members to the Plan's Board of Trustees (the Board), with approval of UBC's General Executive Board. UBC is a fiduciary with respect to the Plan.

2. The Council, which is based in Los Angeles, California, is a contributing employer to the Plan and some of its employees are covered by the Plan. The Council is an intermediate labor organization that is aligned with 35 local unions. In this regard, the Council represents over 65,000 carpenters in Southern California, Nevada, Arizona, Utah, New Mexico and West Texas. It has its own by-laws, elected officers, representatives and employers.

Although the Council is aligned with the UBC, as mentioned above, it is a separate and autonomous entity from UBC. As a contributing employer to the Plan, the Council is a party in interest. However, it is not a fiduciary with respect to the Plan because the Board is not comprised of any Council members or local union members within the jurisdiction of the Council. Further, the Council has no discretion over the management or disposition of the Plan's assets.

3. The Plan is a defined benefit, multiemployer plan, located in Las Vegas, Nevada. As of December 31, 2009, the Plan had 4,615 participants and beneficiaries. Also, as of December 31, 2009, the Plan had total assets of $588,857,770.

The Board consists of eight trustees (the Trustees), who include representatives from UBC, the Chicago Regional Council of Carpenters, the St. Louis Missouri District Council, the Alberta and Northwest Territories Regional Council and Local Union 745 (which is not in the territory of the Council). Of the Trustees, four are general officers of UBC. The four remaining Trustees are officers of councils or local unions that are not aligned with the Council.

The Board has appointed a subcommittee to make decisions regarding the Parcel and the Sale described herein. Michael Draper, the District Vice President of UBC for the Western District of UBC and Frank Libby, the Executive Secretary-Treasurer of the Chicago Regional Council of Carpenters are the sole members of the subcommittee.

*The Nevada Property—History and the Plan's Acquisition*

4. The Nevada Property is located at 6855 Bermuda Road Las Vegas, Nevada, south of the McCarran International Airport. UBC owns a building to the west of the Nevada Property, located at 6801 Placid Street, Las Vegas, Nevada. The Nevada Property is zoned as M–1, Light Industrial district by the City of Las Vegas. The permitted uses for this district include office, light industrial, general commercial and auto related uses.

The Nevada Property can be subdivided into two parcels. The Parcel, itself, a 10.89 acre tract of land, consists solely of asphalt-paved parking areas with curbs, light poles and some chain link fencing around the perimeter. The Parcel represents approximately 36.1% of the Nevada Property. The remaining 19.25 acre tract of land, which is not subject to the proposed Sale, represents 63.9% of the Nevada Property. Situated on the 19.25 acre tract are a car rental facility, which has a passenger terminal, a car wash, a car repair facility with a service bay, steel canopies, and other site improvements, such as covered parking spaces, yard lighting, fencing curbing and several booths.

5. On April 19, 2001, the Plan incorporated Bermuda LLC, a limited liability company, in the State of Delaware, with the Plan serving as both sole member and owner. Bermuda LLC was formed to hold real property on behalf of the Plan and specifically to acquire the Nevada Property.

On June 11, 2001, Bermuda LLC acquired the Nevada Property from LV-Airport Investors, LLC, an unrelated party, for a total cash price of $10,464,126. At the time of the acquisition, the Nevada Property was encumbered by a lease (the Lease) between LV-Airport Investors, LLC, as lessor and Alamo Rent-A-Car, LLC (Alamo), an unrelated party, as lessee. Alamo, which provided car rental services from the Nevada Property, used the Nevada Property as its office and as a car pick-up and return facility.

LV-Airport Investors, LLC had originally entered into the Lease with Alamo on April 12, 2001. The Lease was subject to separate guaranty by ANC Rental Corporation, an unrelated party and an affiliate of Alamo, that would guarantee the rental payments and other obligations under the Lease on behalf of Alamo.

6. Bermuda LLC assumed the Lease in June 2001 and remains the lessor under the Lease. Although the Nevada Property has been continuously leased, the lessee has repeatedly changed from 2001 to the present. In 2003, Vanguard Car Rental USA, Inc. (Vanguard), an unrelated party, assumed the Lease from Alamo pursuant to an assignment during bankruptcy proceedings involving ANC Rental Corporation, Alamo and related entities. In addition, as part of the bankruptcy proceedings, ANC Rental Corporation's guaranty was eliminated. Currently, the Lease payments are no longer subject to a guaranty.

7. In April 2007, McCarran International Airport opened a centralized car return facility. As a result, the Nevada Property would no longer be used for vehicle pick-ups and returns. Instead, the Nevada Property would be used henceforth for car cleaning and maintenance. On April 5, 2007, Vanguard entered into a sublease with the Clark County Aviation Authority (the Authority) for the Parcel and an additional 7.8 acres of the Nevada Property. Thus, the Authority subleased approximately 18.69 acres

from the Plan for $105,883 per month or $.13 per month per square foot. The sublease expired on April 14, 2009 and it was not renewed. Currently, the Parcel is not being subleased.

8. By letter dated June 13, 2007, Vanguard advised Bermuda LLC that all of Vanguard's issued and outstanding stock had been purchased by an affiliate of Enterprise Rent-A-Car (Enterprise). The Applicant represents that this purchase would not result in a change in the Vanguard corporate legal entity, and that Vanguard and/or its subsidiaries would continue to be responsible for all of its respective obligations following the purchase with respect to the Plan.

9. Effective August 1, 2009, in accordance with Alamo's bankruptcy proceedings, Alamo officially assigned the Lease to Enterprise Lease Company—West, LLC (Enterprise Leasing), an unrelated party, who is the current lessee of the Nevada Property. The Lease expires on April 30, 2021. There are two 5 year renewal options at market rent that could possibly extend the Lease until 2031.

10. The Lease is a triple net lease requiring the lessee to pay for real estate taxes, insurance and maintenance costs. Under the Lease, the annual basic rent for the Nevada Property was $908,500 for the first year. Thereafter, the annual rent has been subject to an increase based upon the lesser of (a) the product obtained by multiplying the basic rent for the prior rental period by 2%, or (b) the product obtained by multiplying the basic rent for the prior year by three times the percentage change in the Department's Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers—U.S. City Average (CPI) during such prior rental period. The current rent cannot be reduced below the rent floor set in the prior rental period. For the rental year ending April 30, 2011, the monthly rent for the Nevada Property is $88,704.36 per month or $1,064,452.32 per rental year.

*The Management and Holding of the Nevada Property*

11. Although Bermuda LLC holds the Nevada Property for the Plan, the Plan and any officers, that it may select, make all management decisions for Bermuda LLC. From September 1, 2002 through June 30, 2004, the Plan had retained Strategic Property Advisors (SPA) to serve as the qualified professional asset manager (QPAM) for the Nevada Property. From July 1, 2004 through the present, the Plan has retained Strategic Capital Advisers (SCA) to serve as the Plan's QPAM. SPA has entered into a subadvisory role with SCA and SPA remains a fiduciary with respect to the Plan. Currently, Commerce TNP, Inc. (Commerce TNP) serves as the property manager for the Nevada Property.

12. The Nevada Property has annually generated income in excess of expenses for the Plan since the time of acquisition. For the period between 2001 through 2005, the Plan income and expenses for the Nevada Property are presented as follows in Table 1:

TABLE 1

| | 2001 | 2002 | 2003 | 2004 | 2005 | Totals |
|---|---|---|---|---|---|---|
| Total Rental Income | 454,250 | 920,613 | 939,026 | 957,806 | 976,962 | 4,248,657 |
| **Property Expenses** | | | | | | |
| Property Management Fee | 0 | 0 | 0 | 0 | 0 | |
| Administration Fee | 97 | 0 | 195 | 0 | 0 | |
| Engineering Expense | 0 | 0 | 0 | 0 | 0 | |
| Statement of Business Publication Fee | 25 | 25 | 25 | 25 | 30 | |
| Legal Fee | 1,100 | 0 | 0 | 0 | 0 | |
| Appraisal Fee | 0 | 0 | 0 | 6,498 | 0 | |
| Delaware State Franchise Tax | 0 | 200 | 100 | 305 | 200 | |
| Nevada Annual List of Managers Fee | 0 | 85 | 105 | 155 | 155 | |
| Nevada/Delaware CSC Reg. Agent Fee | 0 | 350 | 448 | 468 | 488 | |
| Asset Management Fee | 0 | 0 | 5,000 | 7,000 | 13,000 | |
| Total Property Expenses | 1,222 | 660 | 5,873 | 14,451 | 13,873 | 36,079 |
| Net Income | 453,028 | 919,953 | 933,153 | 943,355 | 963,089 | 4,212,578 |

It should be noted that the 2001 income reflects the period from April 1, 2001 to December 31, 2001. Additionally, the 2001 and 2002 expenses are estimates.

13. For the period 2006–2010, the Plan income and expenses for the Nevada Property are presented as follows in Table 2:

TABLE 2

| | 2006 | 2007 | 2008 | 2009 | 2010 | Totals |
|---|---|---|---|---|---|---|
| Rental Income | 996,501 | 1,016,431 | 1,036,760 | 1,043,581 | 1,146,200 | 5,239,473 |
| **Property Expenses** | | | | | | |
| Property Management Fee | 0 | 0 | 12,000 | 14,400 | 14,400 | |
| Administration Fee | 0 | 0 | 25 | 0 | 0 | |
| Engineering Expense [7] | 0 | 0 | 0 | 2,500 | 16,974 | |
| Statement of Business Publication Fee | 30 | 30 | 30 | 30 | 30 | |
| Legal Fee | 0 | 0 | 0 | 0 | 480 | |

TABLE 2—Continued

| | 2006 | 2007 | 2008 | 2009 | 2010 | Totals |
|---|---|---|---|---|---|---|
| Appraisal Fee | 0 | 6,000 | 2,900 | 6,000 | 6,000 | |
| Delaware State Franchise Tax | 200 | 200 | 200 | 250 | 250 | |
| Nevada Annual List of Managers Fee | 155 | 155 | 125 | 125 | 125 | |
| Nevada Sec of State-Business License Fee | 0 | 0 | 0 | 0 | 200 | |
| Nevada/Delaware CSC Reg. Agent Fee | 508 | 528 | 552 | 582 | 612 | |
| Asset Management Fee | 13,000 | 13,000 | 13,000 | 13,000 | 13,000 | |
| Total Property Expenses | 13,893 | 19,913 | 28,832 | 36,887 | 52,071 | 151,596 |
| Net Income | 982,608 | 996,518 | 1,007,928 | 1,006,694 | 1,094,369 | 5,088,117 |

14. After combining the expenses in Tables 1 and 2, the Plan has incurred total expenses of $187,675 excluding acquisition costs for the Nevada Property. The acquisition cost to the Plan was $10,464,126 for the Nevada Property. Therefore, the total acquisition and holding costs for the Nevada Property are $10,651,801 (*i.e.,* $10,464,126 acquisition costs + $187,675 in holding costs). After combining the rental income in Tables 1 and 2, the Plan's total rental income for the years 2001–2010 is $9,488,130. After factoring in total rental income, the Plan's net acquisition and holding costs for the Nevada Property are $1,163,671 (*i.e.,* total acquisition and holding costs of $10,651,801—total rental income of $9,488,130).

*Lease Modification and Rental Credit*

15. On April 23, 2010, SPA, a sub-adviser to SCA, the Plan's QPAM, negotiated a modification to the Lease on behalf of the Plan. This modification would permit the potential termination of Enterprise Leasing's leasehold interest in the 10.89 Parcel in return for a termination fee of $100,000 paid to Enterprise Leasing (Lease Modification Fee). The 19.25 acre tract of land would remain subject to the Lease. Additionally, the Lease Modification would result in a pro rata reduction in Enterprise Leasing's rental payments to 63.9% of the original monthly rent since it would no longer be leasing the Parcel from the Plan.

In order to free the Parcel for sale, the Lease Modification requires that Enterprise Leasing agree not to sublease the Parcel until the proposed Sale is finalized. Therefore, SPA negotiated the Rental Credit that went into effect beginning in mid-October 2010 through mid-January 2011. The Applicant represents that the Rental Credit is necessary because Enterprise Leasing is restricted from subleasing the Parcel while the Applicant awaits an administrative exemption from the Department. In accordance with the Lease Modification, the Plan has been required to provide Enterprise Leasing a $15,000 per month rental credit since October 2010. The Rental Credit is to be applied in calendar year 2011. The Rental Credit was renewed in mid-January 2011 through mid-July 2011. To assist the Plan, SPA and the Council later agreed that the Council would pay $7,500 per month or 50% of the total Rental Credit.

*The Appraisal*

16. SPA retained Cushman & Wakefield of Nevada, Inc., located in Las Vegas, the Plan's current appraiser, to appraise a leased fee interest in the Nevada Property (*i.e.,* the 10.89 acre Parcel and the 19.25 acre tract) effective March 1, 2010 in an appraisal report dated June 11, 2010. Associate Director Stephen E. Wilson and Senior Director Kaye A. Cuba, who are employed by the Appraiser, conducted the Appraisal. Mr. Wilson entered the real estate business in 1998. He is a Certified General Appraiser in both Nevada and Arizona and is an associate member of the Appraisal Institute (MAI). Mr. Wilson is experienced in appraising multi-family, office, retail, industrial/warehouse, residential subdivisions and vacant land. He has also completed professional courses and seminars with various appraisal organizations including the MAI.

Ms. Cuba has 25 years of experience in the appraisal field primarily in the banking industry and fee appraisal business. She is an MAI Appraiser and a Certified General Appraiser in Nevada, California and Arizona. Ms. Cuba also serves on the Appraisal Institute's Education Committee and is the 2010 President of its Las Vegas chapter. She has served as a panelist addressing appraisal review issues at local chapter seminars and a regional conference. Furthermore, Ms. Cuba has extensive experience and knowledge in the preparation of appraisals for commercial properties, including retail properties, restaurants, residential properties, light industrial properties, health care facilities, residential subdivisions and vacant land. She joined the Appraiser in February 2007 as Senior Director of Valuation & Advisory Services in the Las Vegas office. Her responsibilities include real estate valuation and consulting services for clients with properties located in Southern Nevada and Northwest Arizona.

The Appraiser represents that the fees it received from the Council and its affiliates in 2009 were less than 1% of the Appraiser's annual gross income within that year. The Appraiser also acknowledges it is aware that the Appraisal is being used for the purposes of obtaining an individual exemption from the Department.

17. According to the Appraisal, the Appraiser determined that the Nevada Property, subject to the Lease had an "As-Is" fair market value of $14,900,000.00 as of March 1, 2010. The Appraiser used the Cost Approach and the Income Capitalization Approach to valuation. The Appraiser explains it did not use the Sales Comparison Approach because the Nevada Property has a specialized land use and public information regarding similar sale transactions was generally insufficient.

Under the Cost Approach, the Appraiser approximated the cost to replace the Nevada Property with an equivalent facility. In order to do so, the Appraiser used sale comparisons to determine that the value of the underlying land was $11,820,000. After considering such factors as the replacement cost of the Nevada Property, indirect costs, entrepreneurial profit, the structures, depreciation and a rent deficit, the Appraiser concluded that, under the Cost Approach, the Nevada Property was worth $15,700,000.00 as of March 1, 2010.

Under the Income Capitalization Approach, the Appraiser approximated

[7] The Plan paid $2,500 in 2009 and $16,974 in 2010 for engineering fees (Engineering Fees). The Engineering Fees included the surveying of the Nevada Property and the creation of a new, separate legal description for the 10.89 acre Parcel.

the anticipated income and expenses (*i.e.,* anticipated economic benefits) to determine the fair market value of the Nevada Property. The Appraiser determined that this approach resulted in a fair market value of $14,900,000 for the Nevada Property as March 1, 2010.

The Appraiser then reconciled the various valuation methods and determined that the fair market value of the leased fee interest in the Nevada Property was $14,900,000 as of March 1, 2010. The Appraiser weighed the Income Capitalization Approach more heavily in the Appraisal because this methodology mirrored the methodology used by purchasers of this type of property. Thus, on the basis of the Appraisal, the fair market value of the Parcel was $5,383,577 as of March 1, 2010 ($14,900,000 × 10.89 acres/30.14 acres).

It should be noted that the Appraiser, also surveyed local real estate brokers for the Appraisal. These brokers indicated that upon the completion of renovations at the adjacent McCarran International Airport, the Nevada Property could increase in value. The Nevada Property appraised valued peaked in 2007 when it was appraised at $21,740,000 by the Appraiser. In an August 4, 2010 letter, the Appraiser represented that at the date of the Appraisal, the Appraiser did not anticipate that the completion of the McCarran Airport renovations would have any significant short-term effect on industrial land values within the subject's submarket. Moreover, the Appraiser represented that it did not anticipate that the Nevada Property would return to its 2007 peak value within the next few years. Instead, any recovery with the industrial market would require a significant improvement in the Las Vegas unemployment rate and an improvement in the local, state and national manufacturing sectors.

The Nevada Property is also located within the vicinity of real property owned by UBC. In a separate December 15, 2010 letter, Mr. Wilson stated that the Appraiser did not believe the Nevada Property had any assemblage value due to its close proximity to UBC's building.

Finally, the Appraiser provided an updated summary appraisal report (the Summary Appraisal), dated March 3, 2011, which valued a leased fee interest of the 10.89 acre Parcel and the 19.25 acre tract of land comprising the Nevada Property (in an "as is" condition) at $11,000,000 as of March 1, 2011. The Summary Appraisal utilized both the Cost Approach and the Income Capitalization Approach to valuation, but gave the most weight to the Income Capitalization Approach because it mirrored the methodology used by purchasers of this property type. Thus, on the basis of the Summary Appraisal, the fair market value of the Parcel was $3,960,000 as of March 1, 2011 ($11,000,000 * 10.89 acres/30.14 acres).

*Terms of the Sale*

18. The Council had been trying to obtain property for the construction of a training facility over the past five years. The Council had made offers on several tracts of land and such offers have either been refused or encountered problems. The Council selected the Parcel because it is suitable for a training facility and is visible to freeways. The Council may lease a future facility to the Southwest Carpenters Training Fund, the Applicant represents that the Council has not voted whether to enter into such future lease.[8]

Although the Plan has not any made efforts to sell the Parcel to unrelated parties nor has it received any unsolicited purchase offers from unrelated parties, the Council's purchase of the Parcel would allow the Plan to receive a profit. In this regard, the proposed Sale price for the Parcel that will be paid by the Council will be (excluding certain Seller Costs and Rental Credits) the higher of $5,383,577 ($14,900,000[9] * 10.89 acres/30.14 acres) or the fair market value of the Parcel on the Sale Date as determined by the Appraiser in an updated Appraisal on the Sale Date. The pro rata purchase price for the Parcel was approximately $3,780,834 ($10,464,126 original purchase price * 10.89 acres/30.14 acres). Therefore, the pro rata gain for the Parcel is $1,602,743 ($5,383,577 purchase price − $3,780,834 original purchase price) or an approximately 42% gain ($1,602,743 gain/$3,780,847 cost basis) for the Parcel, without taking into account certain Seller Closing Costs and Rental Credits.

19. The Plan will pay certain Seller Closing Costs in connection with the Sale. These Seller Closing Costs include owner's title insurance of $4,263.79, escrow fees of $1,265, recording fees of approximately $100 and the Clark County real estate transfer tax which is estimated to be approximately $27,458.40, or total Seller Closing Costs of $33,087.19.[10] The Seller Closing Costs amount to less than 1 percent of the proposed Sale price.

In addition to the Seller Closing Costs, the Plan will pay Enterprise Leasing 50% of all Rental Credits, as described above in Representation 15. These Rental Credits will cost the Plan a total of $67,500. Accordingly, the Plan's aggregate costs are estimated at $100,587.19.

The Applicant represents that a hypothetical sale to an unrelated third party would require the Plan to pay a sales commission. The Applicant states that such commissions typically amount to 4% of the value of the Sale or, in this case, $215,343. In a hypothetical sale to an unrelated third party, the Plan would pay $248,432 (i.e., a $215,343 commission plus $33,087 in Seller Closing Costs). Thus, according to the Applicant, the Plan would pay less in closing and transaction costs in the proposed Sale when compared to a hypothetical sale to an unrelated third party. (The Department notes, however, that it is unlikely that a hypothetical buyer would also pay a Lease Modification Fee and 50% of the Rental Credits like the Council).

*Rationale for the Sale*

20. The Applicant represents that the following reasons support the Sale:

- The Lease is no longer subject to the ANC Rental Corporations's guaranty and is appraised at below market value.
- Enterprise no longer uses the Nevada Property as its car pick-up and return site and the Parcel is vacant.
- Annual rental increases are subject to the lesser of 2% or a CPI-linked formula. Accordingly, annual rental increases may not keep pace with periods of high inflation.
- The Lease is subject to two extensions that could lock the Plan into the Lease until 2031.

[8] The Department wishes to point out that any future leasing of the Parcel by the Council to the Southwest Carpenters Training Fund for training purposes must be compliant with the terms and conditions of PTE 78–6, 43 FR 23024 (May 30, 1978). PTE 78–6 exempts, among other transactions, the leasing of real property other than office space by an apprenticeship plan from a contributing employer, a wholly-owned subsidiary of such employer, or an employee organization any of whose members' work results in contributions being made to the apprenticeship plan. The Department also notes that PTE 78–6 provides exemptive relief from section 406(a)(1)(A), (C) and (D) of the Act, but no relief from the fiduciary self-dealing or conflict of interest provisions under section 406(b)(1) and (2) of the Act.

[9] The Council proposes to base the purchase price for the Parcel on the $14.9 million fair market value of the Nevada Property as determined as of March 1, 2010 in the Appraisal rather than the $11 million fair market value for such property as determined as of March 1, 2011 in the Summary Appraisal.

[10] Susan Borst, director of the Commerce Real Estate Solutions, an alliance member of the Appraiser, and a certified Commercial Investment Member, with over 15 years of real estate industry experience, represented that it is the customary and normal practice in Clark County, Nevada for the seller to pay real estate transfer taxes. Ms. Borst also states that less than 1% of her 2010 annual income was derived from the Council and its affiliates.

• SCA has advised that it would be advantageous to the Plan to enter into the proposed Sale.

• The Council would pay a portion of the costs associated with the Sale. Aside from purchase price, the Council would pay: (a) $16,734 to the Plan for its 2010 Engineering Fees; (b) 50% of all Rental Credits from October 2010 through mid-July 2011 or $67,500; (c) the Lease Modification Fee of $100,000 to Enterprise Leasing; (d) an ALTA title insurance upgrade which is approximately $2,842.53; and (e) escrow charges of approximately $1,265.00. Therefore, the total transaction costs paid by the Council would be $188,341.53 (which is more than the Seller Closing Costs and Rental Credits paid by the Plan).

• The Plan would not have to pay a sales commission in connection with the Sale.

• Because the value of the Nevada Property peaked in 2007 and has declined up to the time of the Summary Appraisal, selling the Parcel would allow the Plan to recognize some profit it has gained since the purchase of the Nevada Property.

• Because the Nevada Property had a 12 month rate of return of negative 13.39%, the Sale would reduce risks to the Plan from holding the Parcel and allow the Plan to receive a profit from a portion of such property.

*Exemptive Relief Requested*

21. According to the Applicant, the Sale represents a sale and transfer of plan assets between the Plan and the Council, a party in interest, that would violate section 406(a)(1)(A) and (D) of the Act. The Applicant also requests exemptive relief from the fiduciary conflict of interest provision of section 406(b)(2) of the Act. The Applicant represents that although none of the Trustees are employees or officers of the Council, it is possible a potential conflict of interest exists since two of the Trustees (Mr. Draper and Mr. Libby), who are members of the Board subcommittee, are UBC officers or officers of other intermediate labor councils aligned with UBC. Because the Council is, itself, aligned with UBC, the Applicant contends that these two Trustees may have interests which are adverse to the interests of the Plan or the interests of the Plan's participants or beneficiaries. Therefore, the Applicant asserts that exemptive relief from section 406(b)(2) of the Act is required.

*Appropriateness of the Sale*

22. The Applicant represents that the proposed Sale by the Plan of the Parcel to the Council would be administratively feasible because the Sale would be a one-time transaction for cash. Furthermore, the Plan would pay no commissions, costs or fees in connection with the Sale, except for 50% of the Rental Credits and the Seller Closing Costs which are customarily paid to unrelated parties. Finally, Mr. Draper and Mr. Libby would review and approve the methodology used by the Appraiser, ensure that such methodology is properly applied in determining the fair market value of the Parcel, and also determine whether it is prudent to go forward with the proposed transaction.

The Applicant states that the proposed Sale would also be in the interests of the Plan and its participants and beneficiaries because the Plan would realize a gain of nearly 42% stemming from its acquisition and holding of the Parcel and further diversify its assets, and become more liquid. Further, the Applicant states that the proposed Sale would be protective of the rights of the Plan's participants and beneficiaries because the Plan would receive the greater of $5,383,577 or the fair market value of the Parcel as determined by the Appraiser in an Appraisal of the Nevada Property, which is updated on the Sale Date. Furthermore, the terms of the Sale would be no less favorable to the Plan than the terms negotiated under similar circumstances at arm's length with unrelated parties. Accordingly, the Applicant requests an exemption from the Department.

*Summary*

23. In summary, the Applicant represents that the Sale will satisfy the statutory requirements for an exemption under section 408(a) of the Act because:

(a) The terms and conditions of the Sale will be at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party;

(b) The Sale will be a one-time transaction for cash;

(c) As consideration, the Plan will receive the greater of $5,383,577, or the fair market value of the Parcel as determined by the Appraiser in an Appraisal of the Nevada Property, which is updated on the Sale Date;

(d) The Plan will pay no commissions, costs or fees, with respect to the Sale, except for the Seller Closing Costs and 50% of the Rental Credits that are paid to unrelated parties; and

(e) The Plan fiduciaries will review and approve the methodology used by the Appraiser, ensure that such methodology will be properly applied in determining the fair market value of the Parcel, and also will determine whether it is prudent to go forward with the proposed transaction.

**Notice to Interested Parties**

Notice of the proposed exemption will be given to interested persons within 20 days of the publication of the notice of proposed exemption in the **Federal Register**. The notice will be given to interested persons by first class mail or personal delivery. Such notice will contain a copy of the notice of proposed exemption, as published in the **Federal Register**, and a supplemental statement, as required pursuant to 29 CFR 2570.43(b)(2). The supplemental statement will inform interested persons of their right to comment on and/or to request a hearing with respect to the pending exemption. Written comments and hearing requests are due within 50 days of the publication of the notice of proposed exemption in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anh-Viet Ly of the Department at (202) 693–8648. (This is not a toll-free number.)

Wolverine Bronze Profit Sharing Plan and Trust (the Plan) and BDR Oil, LLC Located in Roseville, Michigan

Exemption Application Number D–11639

**Proposed Exemption**

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[11]

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) and (D), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), (D) and (E) of the Code, shall not apply, to the cash sale (the Sale) by the Plan of a note receivable (the Note) and royalty interests (ORRIs), collectively known as the Alternative Investments, to BDR Oil, LLC, which is owned by Richard A. Smith, William Smith and Douglas Smith (also know as the Alternative Investment Group or the AIG), provided that the following conditions are met:

(a) The Sale is a one-time transaction for cash;

[11] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer to the corresponding provisions of section 4975 of the Code as well.

(b) The terms and conditions of the Sale are at least as favorable as those obtainable in an arm's length transaction with an unrelated third party;

(c) The Plan will receive no less than the fair market value of the Alternative Investments at the closing of the proposed transaction;

(d) The fair market value of the Alternative Investments will be determined by a qualified independent appraiser;

(e) All valuations will be updated by a qualified independent appraiser on the date that the Sale is consummated;

(f) The Plan pays no commissions, fees or other expenses in connection with the Sale;

(g) The Sale was not part of an arrangement, agreement, or understanding designed to benefit a party in interest to the Plan and is a result of the Plan's conversion from a "traditional" profit sharing plan to a 401(k) plan;

(h) The Plan will reallocate $1,450.17 to the account balances of its participants and beneficiaries, excluding the AIG, to reflect the difference between the value assigned to the Note by the Plan trustee on the date of the Plan conversion, and the value of the Note on that same date as determined by the qualified independent appraiser;

(i) An independent fiduciary, who is not a party to the proposed transaction,

(1) Determines, among other things, whether it is in the best interest of the Plan to proceed with the sale of the Alternative Investments;

(2) Reviews and approves the methodology used in the appraisal that is being relied upon; and

(3) Ensures that such methodology is applied by the qualified independent appraiser in determining the fair market value of the Alternative Investments, as updated, on the day of the Sale; and

(j) The Plan has not waived or released and does not waive or release any claims, demands, and/or causes of action which such Plan may have in connection with the Sale.

**Summary of Facts and Representations**

1. Wolverine Bronze Company (Wolverine), a privately held non-ferrous jobbing foundry, located in Roseville, Michigan, is the sponsor of Wolverine Bronze Profit Sharing Plan and Trust (the Plan). The Shareholders of Wolverine are: Richard A. Smith, Christopher S. Smith, Robert J. Smith, William P. Smith, Jr., and Nicolas L. Smith. The Plan was a "traditional" profit sharing plan maintained by Wolverine before its conversion to a 401(k) plan effective January 1, 2010. Prior to the conversion, the Plan's assets were invested in, among other things, stocks, bonds, and mutual funds which were selected by the discretionary trustees. The discretionary trustees also invested the Plan's assets into a note receivable (the Note) for Robert O. Keller, Jr., an unrelated third party, and royalty interests (ORRIs)[12], collectively known as the Alternative Investments. As of December 31, 2009 the Plan had approximately 104 participants and total assets of approximately $6,282,474.95. The trustees of the Plan are Richard A. Smith and Charles Arent.

The conversion to a 401(k) plan was a result of the Plan sponsor's determination that it would be in the best interest of the participants to make elective deferrals and self direct investments. Participants were given the option to select from a group of mutual funds representing a broad range of investment alternatives, and also were given the opportunity to have all or a portion of their account invested in the Alternative Investments.

2. Following the Plan's conversion to a 401(k) plan, only 3 participants selected to invest in the Alternative Investments, which were offered.[13] The group of individuals who selected these investments are Richard A. Smith (fiduciary and Chief Executive Officer), William Smith (V.P. of Operations, prior to his termination of employment on January 1, 2011) and Douglas Smith (V.P. of Manufacturing, prior to his termination of employment on January 1, 2011)—these 3 individuals are brothers, and are collectively known as the Alternative Investment Group (the AIG). The AIG determined that they were not able to diversify their investments in the Plan so as to minimize risk. The discretionary trustees then concluded that in order for the AIG to fully participate in the new Plan design and minimize fiduciary risk, the Alternative Investments should be liquidated so that the proceeds may be reinvested in the investment offerings provided under the Plan. As a result, the AIG proposes to purchase the Alternative Investments from the Plan.

3. The principal amount of the Note, dated June 1, 2007, was $65,000.00. The Note bears interest on the unpaid principal balance at the fixed rate of 10 percent per annum and is payable in equal monthly installments of $1,381.06 which includes both principal and interest. Payments under the Note commenced on July 1, 2007 and will continue until a final installment equal to the total unpaid principal balance is due on June 1, 2012. To date, all required payments on the Note have been paid as due.

The Note was executed by the Plan and Mr. Robert O. Keller, Jr., an unrelated third party, and secured by a lien interest on a 1980 Diesel Truck owned by Mr. Keller. According to the applicant, the Plan has incurred no costs in connection with the administration of the Note.

4. At the time of the conversion, a fair market value of $36,254.83 was assigned to the Note by the Plan trustee. The Note was recently valued by Andrew Malec with Gordon Advisors, P.C., (Gordon Advisors) located in Troy, Michigan, who has a PhD in economics. Mr. Malec used a different methodology than originally used by the Plan trustees, and determined at that time that a fair market value of $37,950.00 was appropriate. Mr. Malec's calculation, which uses the present value of the expected cash flows from the Note, results in an amount of $1,450.17 more than the opening balances actually credited to the participants and beneficiaries. The applicant represents that the methodology used by Gordon Advisors for purposes of establishing the value of the Note will be used for the proposed transaction. The applicant further represents that the resulting $1,450.17 difference between the value originally assigned to the Note by the trustee, as compared to the value determined by Gordon Advisors, will be reallocated to the participant and beneficiary account balances to reflect the change in calculation for the opening balances.

The applicant represents Mr. Malec to be a qualified independent appraiser with an expertise in valuing privately-held securities, spanning across a broad range of industries. Mr. Malec's experience has involved performing for

[12] According to the valuation completed by Andrew M. Malec, Ph.D. of Gordon Advisors, an ORRI is an investment in which an investor receives cash flow from oil sales resulting from production in the oil well according to the ownership percentage, net of oil well production tax, but does not pay for drilling or monthly operating expenses of the well. In addition, the life of an ORRI investment is perpetual (subject to the terms of the lease), changes in the working interest holder will not affect the standing of the interest holder of the royalties, and the owner of the royalty interest benefits from future oil sales on any additional wells drilled on the lease.

[13] Prior to such conversion, the Department's Cincinnati Regional Office conducted an investigation of the Plan and focused on, among other things, the valuation of the ORRIs. As a result of the investigation, the Plan modified its valuation of the ORRIs that was used for purposes of valuing the individual account balances. The applicant represents that this modification satisfied the Regional Office's requirements, and that the Plan will use the same modified valuation for the proposed transaction as was used for other purposes including the conversion of the Plan from a "traditional" profit sharing plan to a 401(k) plan.

numerous purposes including acquisitions, fairness opinions, financial reporting, gift and estate taxation, litigation, marital dissolution, purchase price allocation, shareholder disputes, other tax and corporate related matters, and shareholder planning. The previously referenced cash flow methodology used by Mr. Malec takes into account that the rate of return on a debt security is composed of a nominal risk-free rate of interest [14] plus several factors that reflect inflation, the risk of the security, and the security's marketability. As a result, Mr. Malec concluded that a 6.98% rate of return should apply to the cash flow stream of the Note as of the valuation date. As of December 22, 2010, the estimated fair market value of the Note is $23,628.00. There were 18 remaining payments on the Note as of December 27, 2010.

5. The ORRIs also were valued by Andrew Malec. Based on the valuation of the ORRIs completed on February 9, 2010, the Plan maintains investments in 23 ORRIs. These ORRIs represent interests in various oil wells located within the state of Texas. The Plan originally acquired the ORRIs on March 12, 1990 from Peter Nunez, an unrelated third party, for the purchase price of $141,205.12. As of December 31, 2009, the estimated fair market value of the ORRIs is $555,000.00.

In determining the required rate of return for the ORRIs, the Dividend Discount Model (DDM), an Income Approach, was used. The DDM is a procedure for valuing the price of a stock by using predicted dividends and discounting them back to present value. It is essentially a method for valuing stocks based on the net present value of the future dividends. Mr. Malec stressed the importance of an appropriate rate of return commensurate with achieving the expected cash flow based on the fact that investors typically place a great deal of weight upon the expected future cash flow earned on the various ORRI investments. Therefore, the appraiser represents that the DDM is an appropriate methodology for valuing the ORRIs because it estimates the annual cash flow to be received by the royalty interest (*i.e.* the "stream of payments" to the investor) by taking into account the rate of return proportionate with realizing this estimated cash flow.

6. The applicant proposes the sale of the Alternative Investments from the Plan to the AIG through BDR Oil, LLC (BDR), a Michigan limited liability company and entity owned by the AIG, at fair market value at the time of the closing of the Sale. The Alternative Investments constitute approximately 9% of the total Plan assets (as of December 31, 2009). The applicant represents that the Sale of the Alternative Investments to BDR is in the best interests of the Plan because the administrative burden of separately accounting for and valuing the Alternative Investments would no longer be necessary, thereby reducing the costs to the Plan. Further, the participants comprising the AIG would be able to diversify their investments in the Plan, which will, in turn, ensure that the Plan will have sufficient liquidity to pay the benefits when due.

7. The applicant represents that the Sale will be a one-time transaction for cash and that the Plan will incur no fees, commissions, or other expenses in connection with the Sale. BDR will bear the costs of the exemption application and of notifying interested persons. The applicant further represents that to-date the valuations performed by Mr. Malec were paid by Wolverine on behalf of the Plan for yearly valuation purposes, but that the update of the valuation for the Sale will be paid by BDR. The applicant also represents that the fees that will be paid to Gordon Advisors by BDR represent less than 1% of the firm's annual income.

8. It is also represented that a Plan fiduciary, Charles Arent, who is neither a party to the proposed subject transaction nor a relation to the AIG members, both has and will continue to review and approve the methodology used by the qualified independent appraiser, thereby ensuring that such methodology is properly applied, and that it is prudent to go forward with the proposed transaction. With respect to the Sale, the applicant represents that Richard A. Smith has recused himself from his fiduciary responsibilities to the Plan.

9. The Plan has not waived or released and does not waive or release any claims, demands, and/or causes of action which such Plan may have against BDR and/or the AIG in connection with the sale of assets to BDR.

10. In summary, the applicant represents that the proposed transaction satisfies the criteria for an exemption under section 408(a) for the following reasons: (a) The Sale is a one-time transaction for cash; (b) the terms and conditions of the Sale are at least as favorable as those obtainable in an arm's length transaction with an unrelated third party; (c) the Plan will receive no less than the fair market value of the Alternative Investments at the closing of the proposed transaction; (d) the fair market value of the Alternative Investments are to be determined by a qualified independent appraiser; (e) all valuations will be updated on the date that the Sale is consummated; (f) the Plan pays no commissions, fees or other expenses in connection with the Sale; (g) the Sale was not part of an arrangement, agreement, or understanding designed to benefit a party in interest to the Plan and is a result of the Plan's conversion from a "traditional" profit sharing plan to a 401(k) plan; (h) the Plan will reallocate $1,450.17 to the account balances of its participants and beneficiaries, excluding the AIG, to reflect the difference between the value assigned to the Note by the Plan trustee on the date of the Plan conversion, and the value of the Note on that same date by the qualified independent appraiser; (i) the Plan fiduciary who is not an interested party to the proposed transaction, Charles Arent, (1) determines, among other things, whether it is in the best interest of the Plan to proceed with the sale of the Alternative Investments; (2) reviews and approves the methodology used in the appraisal that is being relied upon; and (3) ensures that such methodology is applied by the qualified independent appraiser in determining the fair market value of the Alternative Investments, as updated, on the day of the Sale; and (j) the Plan has not waived or released and does not waive or release any claims, demands, and/or causes of action which such Plan may have in connection with the Sale.

**FOR FURTHER INFORMATION CONTACT:** Breyana A. Penn of the Department, telephone (202) 693–8546. (This is not a toll-free number.)

Verizon Communications, Inc. (Verizon) and Cellco Partnership, doing business as Verizon Wireless (Verizon Wireless; collectively, the Applicants)
Located in Basking Ridge, New Jersey
[Application Nos. L–11651 and L–11652]

**Proposed Exemption**

The Department is considering granting an exemption under the authority of section 408(a) of the Act and in accordance with the procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and (b) of the Act shall not apply to the reinsurance of risks and the receipt of premiums therefrom by Exchange Indemnity Company (EIC), a wholly-owned subsidiary of Verizon, in connection with an insurance contract sold by Prudential Life Insurance Company (Prudential) or any successor

[14] Mr. Malec selected this component of the rate of return based on 1-Year U.S. Treasury Notes.

insurance company to Prudential which is unrelated to Verizon, to provide group-term life insurance to certain employees and retirees of Verizon and Verizon Wireless under The Plan for Group Insurance maintained by Verizon and the Verizon Wireless Health and Welfare Benefits Plan maintained by Verizon Wireless (collectively, the Plans), provided the following conditions are met:

(a) EIC—

(1) Is a party in interest with respect to the Plan by reason of a stock or partnership affiliation with Verizon that is described in section 3(14)(E) or (G) of the Act,

(2) Is licensed to sell insurance or conduct reinsurance operations in at least one State as defined in section 3(10) of the Act,

(3) Has obtained a Certificate of Authority from the Insurance Commissioner of its domiciliary state which has neither been revoked nor suspended,

(4)(A) Has undergone and shall continue to undergo an examination by an independent certified public accountant for its last completed taxable year immediately prior to the taxable year of the reinsurance transaction; or

(B) Has undergone a financial examination (within the meaning of the law of its domiciliary State, Vermont) by the Insurance Commissioner of Vermont within 5 years prior to the end of the year preceding the year in which the reinsurance transaction occurred, and

(5) Is licensed to conduct reinsurance transactions by a State whose law requires that an actuarial review of reserves be conducted annually by an independent firm of actuaries and reported to the appropriate regulatory authority;

(b) The Plans pay no more than adequate consideration for the insurance contracts;

(c) In subsequent years, the formula used to calculate premiums by Prudential or any successor insurer will be similar to formulae used by other insurers providing comparable coverage under similar programs. Furthermore, the premium charge calculated in accordance with the formula will be reasonable and will be comparable to the premium charged by the insurer and its competitors with the same or a better rating providing the same coverage under comparable programs;

(d) The Plans only contract with insurers with a rating of A or better from A.M. Best Company. The reinsurance arrangement between the insurer and EIC will be indemnity insurance only, i.e., the insurer will not be relieved of liability to the Plans should EIC be unable or unwilling to cover any liability arising from the reinsurance arrangement;

(e) No commissions, costs or other expenses are paid with respect to the reinsurance of such contracts; and

(f) For each taxable year of EIC, the gross premiums and annuity considerations received in that taxable year by EIC for life and health insurance or annuity contracts for all employee benefit plans (and their employers) with respect to which EIC is a party in interest by reason of a relationship to such employer described in section 3(14)(E) or (G) of the Act does not exceed 50% of the gross premiums and annuity considerations received for all lines of insurance (whether direct insurance or reinsurance) in that taxable year by EIC. For purposes of this condition (f):

(1) The term "gross premiums and annuity considerations received" means as to the numerator the total of premiums and annuity considerations received, both for the subject reinsurance transactions as well as for any direct sale or other reinsurance of life insurance, health insurance or annuity contracts to such plans (and their employers) by EIC. This total is to be reduced (in both the numerator and the denominator of the fraction) by experience refunds paid or credited in that taxable year by EIC.

(2) all premium and annuity considerations written by EIC for plans which it alone maintains are to be excluded from both the numerator and the denominator of the fraction.

**Summary of Facts and Representations**

1. Verizon Communications, Inc. (Verizon) is a world-wide telecommunications company. Verizon maintains The Plan for Group Insurance, a welfare plan within the meaning of section 3(1) of the Act, for the benefit of its employees. The Plan for Group Insurance provides various types of welfare benefits and includes a group-term life insurance component (basic, supplemental and dependent coverage), which is fully insured.

2. (2) Verizon Wireless is a Delaware Partnership and is a worldwide cellular telephone company. Verizon Wireless is a majority owned subsidiary of Verizon. Verizon Wireless maintains the Verizon Wireless Health and Welfare Benefits Plan, a welfare plan within the meaning of section 3(1) of the Act, for the benefit of its employees. The Verizon Wireless Health and Welfare Benefits Plan provides various types of welfare benefits and includes a group-term life insurance component (basic, supplemental and dependent coverage), which is fully insured.

3. EIC is a 100% owned subsidiary of Verizon (EIC is 53% owned by NYNEX and 47% owned by GTE, each of which are wholly owned subsidiaries of Verizon). EIC is domiciled in the State of Vermont. As of September 30, 2010, EIC reported approximately $918 million in 2010 gross annual premiums and $1,713 million in total assets. The Applicants represent that for each taxable year of EIC, the total amount of premiums, both for the subject reinsurance transactions as well as for any direct sale or other reinsurance of life insurance and health insurance for all employee benefit plans for which EIC is a party in interest by reason of a relationship to the sponsoring employer described in section 3(14)(E) or (G) of the Act have not exceeded and will not exceed 50% of the gross premiums received by EIC from all lines of insurance in that taxable year.

4. The group-term life insurance component of The Plan for Group Insurance has approximately 74,774 participants and beneficiaries and the group-term life insurance component of the Verizon Wireless Health and Welfare Benefits Plan has approximately 66,522 participants and beneficiaries. The proposed reinsurance shall only apply with respect to certain participants (the Affected Participants) in the Plans. Affected Participants shall include: (a) Non-union represented employees and their dependents; (b) retirees who were non-union represented employees while employed, and their dependents; and (c) union represented employees and retirees of Verizon Wireless.

5. The life insurance is currently underwritten by Prudential Life Insurance Company (Prudential), an unaffiliated insurance carrier. Verizon and Verizon Wireless have entered into a policy with Prudential for 100% of this coverage. Verizon proposes to use its subsidiary, EIC, to reinsure 100% of the risk through a reinsurance contract between EIC and Prudential in which Prudential would pay 100% of the premiums to EIC. The Applicants represent that there is no additional cost to the Plan as a result of the reinsurance arrangement. From the Affected Participants' perspective, they have a binding contract with Prudential, which is legally responsible for the group-term life insurance risk associated under the Plan. Prudential is liable to provide the promised coverage regardless of the proposed reinsurance arrangement.

6. The Applicants represent that the proposed transaction will not in any way affect the cost to the insureds of the

group-term life insurance contracts, and the Plans will pay no more than adequate consideration for the insurance. Verizon, Verizon Wireless and/or EIC will not profit from the reinsurance arrangement at the expense of the Plans or the Affected Participants. Also, the Affected Participants are afforded insurance protection from Prudential at competitive rates arrived at through arm's-length negotiations. Prudential is rated "A+" by the A. M. Best Company, whose insurance ratings are widely used in financial and regulatory circles. Prudential has assets in excess of $667 billion. Prudential will continue to have the ultimate responsibility in the event of loss to pay insurance benefits to the employee's beneficiary. The Applicants represent that EIC is a sound, viable company which is dependent upon insurance customers that are unrelated to itself and its affiliates for premium revenue.

7. The Applicants represent that the proposed reinsurance transaction will meet all of the conditions of PTE 79–41 covering direct insurance transactions: (a) EIC is a party in interest with respect to the Plans (within the meaning of section 3(14)(G) of the Act) by reason of stock affiliation with Verizon and Verizon Wireless, which maintain the Plans.

(b) EIC is licensed to do business in the State of Vermont.

(c) EIC has undergone an examination by an independent certified public accountant for its fiscal year ending December 31, 2009.

(d) EIC has received a Certificate of Authority from its domiciliary State (as defined in Act section 3(10)), the State of Vermont, which has neither been revoked nor suspended.

(e) The Plans will pay no more than adequate consideration for the insurance. The proposed transaction will not in any way affect the cost to the insureds of the group-term life insurance transaction.

(f) No commissions, costs or other expenses will be paid with respect to the acquisition of reinsurance by Prudential from EIC.

(g) For each taxable year of EIC, the "gross premiums and annuity considerations received" in that taxable year for group life and health insurance (both direct insurance and reinsurance) for all employee benefit plans (and their employers) with respect to which EIC is a party in interest by reason of a relationship to such employer described in section 3(14)(E) or (G) of the Act will not exceed 50% of the "gross premiums and annuity considerations received" by EIC from all lines of insurance in that taxable year. All of the premium income of EIC comes from reinsurance. EIC has received no premiums for the group-term life insurance in the past.

8. In summary, the Applicants represent that the proposed transaction will meet the criteria of section 408(a) of the Act because: (a) Plan participants and beneficiaries are afforded insurance protection by Prudential, an "A+" rated group insurer, at competitive market rates arrived at through arm's-length negotiations; (b) EIC is a sound, viable insurance company which does a substantial amount of public business outside its affiliated group of companies; and (c) each of the protections provided to the Plans and the Affected Participants and their beneficiaries by PTE 79–41 will be met under the proposed reinsurance transaction.

**FOR FURTHER INFORMATION CONTACT:** Gary H. Lefkowitz of the Department, telephone (202) 693–8546. (This is not a toll-free number.)

**General Information**

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 2nd day of May, 2011.

**Ivan Strasfeld,**

*Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.*

[FR Doc. 2011–10999 Filed 5–4–11; 8:45 am]

BILLING CODE 4510–29–P

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Proposed Information Collection for Growing America Through Entrepreneurship (GATE) II Evaluation; Comment Request

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Employment and Training Administration (ETA) is soliciting comments on a new data collection for the GATE II Evaluation. A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

**DATES:** Written comments must be submitted to the office listed in the addressee section below on or before July 5, 2011.

**ADDRESSES:** Richard Muller, Office of Policy Development and Research, U.S. Department of Labor, Room N–5641, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 693–3680 (this is not a toll-free number), fax number (202) 693–2766 or e-mail: *Muller.Richard@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Many individuals have the motivation and skills to develop small businesses but lack business expertise and training. Recognizing this untapped potential, ETA created and evaluated a demonstration program designed to assist individuals interested in self-employment to develop their businesses—Project GATE. In helping individuals develop businesses, Project GATE promoted both workforce and economic development. Project GATE was an experimental design demonstration that investigated the impact of providing entrepreneurship training services to individuals interested in starting or growing a business. The cornerstone of the evaluation was random assignment. A total of 4,198 applicants to GATE were randomly assigned to either a program group or a control group. The project was implemented in both rural and urban locations in Maine, Pennsylvania, and Minnesota from 2002 to 2009.

In Project GATE, treatment group members were offered an assessment of their business needs, classroom training, one-on-one technical assistance, and assistance in applying for business financing. A telephone survey of participants and control group members was conducted to collect three waves of data at approximately six months after random assignment, 18 months after random assignment, and 60 months after random assignment. A process evaluation as well as an impact evaluation of the effectiveness of the GATE model were conducted utilizing site visits, surveys, and administrative data.

The early impacts of Project GATE services were reported to ETA in July 2008 (see Benus, J., McConnell, S., Bellotti, J., Shen, T., Fortson, K., & Kahvecioglu, D. "Growing America Through Entrepreneurship: Findings from the Evaluation of Project GATE" *U. S. Department of Labor, Employment and Training Administration, 2008*). The positive findings in this report led the Department to issue a Solicitation for Grant Applications (SGA) for States to implement the GATE model of entrepreneurship services targeted at older and rural WIA dislocated workers. That is, unlike the first Project GATE demonstration, which was available to all applicants, services under this new demonstration (known as GATE II) were targeted towards dislocated workers.

An evaluation of the GATE II grants is necessary for policymakers and program developers to determine whether the model can be successfully implemented for dislocated workers. A follow-up survey, as envisioned in the GATE II evaluation design, is the only way to collect information on self-employment experiences, receipt of microenterprise services, and household income.

GATE II will be evaluated using an experimental design. Individuals that submitted an application for GATE II in each site and who met minimal eligibility criteria are being randomly assigned to either a program group or a control group. Members of the program group are eligible to receive GATE II services, while members of the control group are not eligible to receive GATE II services, although they will not be prohibited from receiving self-employment services from other sources.

As noted above, unlike the first Project GATE demonstration, which was available to all applicants, services under GATE II are targeted towards WIA dislocated workers. In June 2008 grants were awarded to implement GATE II in four states—Alabama, Minnesota, North Carolina, and Virginia. Two states, Alabama and North Carolina, were selected to target services to dislocated workers in rural areas, while the two other States, Minnesota and Virginia, were selected to target dislocated workers 45 years old and older.

The evaluation will address the following key questions:

(1) What are the impacts of GATE II on participants' labor market and self-employment outcomes?

(2) Does the program increase the use of self-employment services?

(3) Does the program lead to an increase in the completion of business plans and applications and receipt of loans?

(4) Does the program increase the likelihood of self-employment?

(5) Does the program promote employment and other aspects of economic development?

(6) Does the program increase employment, earnings, and satisfaction with employment and reduce the receipt of Unemployment Insurance (UI) and public assistance?

(7) Is GATE II effective in rural areas and for older workers?

(8) Does the effectiveness of the program vary by population subgroup?

Addressing these questions will involve conducting process and impact analyses. The process evaluation is based on information collected during two rounds of site visits to each site, during which detailed information will be collected on the implementation of the program from interviews with program staff, observations of services, and focus groups with program participants. Data will also be collected using a Participant Tracking System developed specifically for the study. The impact evaluation will involve comparing outcomes of members of the program group with outcomes of members of the control group. Data on these outcomes will be collected from UI benefit records and quarterly wage records, and a follow-up survey that will occur approximately 18 months after random assignment.

## II. Review Focus

The Department is particularly interested in comments which:

- 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 submissions of responses.

## III. Current Actions

The follow-up survey, which is the subject of this notice, will be conducted by telephone approximately 18 months following random assignment. The survey will collect data unavailable from administrative records. The survey is designed to collect detailed information about sample members' participation and experiences in receiving self-employment services, their experiences starting a business, their experiences in jobs working for someone else, their receipt of public assistance, and some background data on their socio-economic and demographic characteristics. It is also designed to collect their experiences in self-employment and developing small

businesses, their experiences in jobs working for someone else, and their income and receipt of public assistance.

*Type of Review:* New

*Agency:* Employment and Training Administration

*Title:* Partnership for Self-Sufficiency: Growing America Through Entrepreneurship

*OMB Control No.:* 1205–0NEW

*Affected Public:* Individuals

| | Total respondents | Frequency | Total responses | Average time per respondent | Burden (hours) |
|---|---|---|---|---|---|
| GATE II FOLLOW–UP SURVEY | 1,584 | Once | 1,584 | 30 minutes | 792 |
| Totals | | | 1,584 | | 792 |

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information request; they will also become a matter of public record.

Dated: April 29, 2011.

**Jane Oates,**

*Assistant Secretary for Employment and Training Administration.*

[FR Doc. 2011–10938 Filed 5–4–11; 8:45 am]

BILLING CODE 4510–FN–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2010–0018]**

## Final Regulatory Guide: Issuance, Availability

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of Issuance and Availability of Regulatory Guide 8.18, Revision 2, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions will be As Low As is Reasonably Achievable."

**FOR FURTHER INFORMATION CONTACT:** Hector L. Rodriguez-Luccioni, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *telephone:* 301–251–7685 or e-mail: *Hector.Rodriguez-Lucionni@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a revision to an existing 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.

Revision 2 of Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions will be As Low As is Reasonably Achievable," was issued with a temporary identification as Draft Regulatory Guide, DG–8037.

This guide is directed specifically toward medical licensees and recommends methods that the staff of the NRC considers acceptable to maintain occupational exposures as low as is reasonably achievable (ALARA) in medical institutions. In a medical institution, certain persons other than employees are exposed to radiation from licensed radioactive material. These persons include visitors and patients other than those being treated with radioactive material. This guide addresses the protection of these individuals. The content of this guide is also applicable to veterinary medical institutions, insofar as specific diagnostic or therapeutic procedures are performed. Similar protection practices are applicable for keeping employee and visitor exposures ALARA, whether the patients are animal or human.

### II. Further Information

In January 2010, DG–8037 was published with a public comment period of 60 days from the issuance of the guide. The public comment period closed on March 19, 2010.

You can access publicly available documents related to this notice using the following methods:

*NRC's Public Document Room (PDR):* The public may examine and copy (for a fee) publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

*NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/doc-collections/.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents (*http://www.nrc.gov/reading-rm/adams.html*). If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.* Regulatory Guide 8.18, Revision 2 is available electronically under ADAMS Accession Number ML102350460. The regulatory analysis may be found under ADAMS Accession Number ML102350474 and the staff's responses to the public comments received are located under Accession Number ML102350467.

*Federal Rulemaking Website:* Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2010–0018.

**FOR FURTHER INFORMATION CONTACT:** Hector L. Rodriguez-Luccioni, Project Manager, Regulatory Guide Development Branch, Division of Engineers, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Mail Stop: CSB–02A07M, Washington, DC 20555–0001. *Telephone:* (301) 251–7685; fax number: (301) 251–7422; *e-mail: Hector.Rodriguez-Lucionni@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 28th day of April, 2011.

For the Nuclear Regulatory Commission.

**Harriet Karagiannis,**

*Acting Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2011–10876 Filed 5–4–11; 8:45 am]

BILLING CODE 7590–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. IC–29663]**

## Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

April 29, 2011.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of April 2011. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202)551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 24, 2011, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

*For Further Information Contact:* Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Office of Investment Company Regulation, 100 F Street, NE., Washington, DC 20549–4041.

**Federated American Leaders Fund, Inc. [File No. 811–1704]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On September 18, 2009, applicant transferred its assets to Federated Clover Value Fund, a series of Federated Equity Funds, based on net asset value. Expenses of approximately $577,896 incurred in connection with the reorganization were paid by applicant, Federated Equity Management Company of Pennsylvania, applicant's investment adviser, or its affiliates.

*Filing Dates:* The application was filed on April 12, 2011 and amended on April 26, 2011.

*Applicant's Address:* Federated Investors Funds, 4000 Ericsson Dr., Warrendale, PA 15086–7561.

**Banknorth Funds [File No. 811–10021]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On August 27, 2004, applicant transferred its asset to corresponding series of Federated Equity Funds, Federated Total Return Series, Inc., and Federated Municipal Securities Income Trust, based on net asset value. Expenses of approximately $71,914 incurred in connection with the reorganization were paid by Federated Equity Company of Pennsylvania and Federated Investment Management Company, the investment advisers to the surviving funds, or their affiliates.

*Filing Dates:* The application was filed on February 4, 2011 and two amendments were filed on April 7, 2011.

*Applicant's Address:* Federated Investors Tower, 1001 Liberty Ave., Pittsburgh, PA 15222–3779.

**Tortoise Total Return Fund, LLC [File No. 811–22085]**

*Summary:* Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On January 5, 2011, applicant made a final liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $14,996 incurred in connection with the liquidation were paid by applicant. Applicant has retained approximately $10,188 in cash to pay any remaining outstanding expenses.

*Filing Dates:* The application was filed on February 15, 2011 and amended on April 8, 2011.

*Applicant's Address:* 11550 Ash St., Suite 300, Leawood, KS 66211.

**Neuberger Berman Income Opportunity Fund [File No. 811–21334] Neuberger Berman High Yield Strategies Fund [File No. 811–21342]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 6, 2010, each applicant transferred its assets to Neuberger Berman High Yield Strategies Fund Inc., based on net asset value. Each applicant's preferred stockholders received an equivalent number of shares of preferred stock of the acquiring fund. Expenses of $200,000 were incurred in connection with each reorganization and were paid by the respective applicant.

*Filing Date:* The applications were filed on March 28, 2011.

*Applicants' Address:* 605 Third Ave., 2nd Floor, New York, NY 10158–0180.

**Greenwich Advisors Trust [File No. 811–21996]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On February 25, 2011, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $28,680 incurred in connection with the liquidation were paid by applicant and Greenwich Advisors LLC, applicant's investment adviser.

*Filing Date:* The application was filed on March 31, 2011.

*Applicant's Address:* Greenwich Advisors LLC, 330 Railroad Ave., Greenwich, CT 06830.

**BlackRock Apex Municipal Fund, Inc. [File No. 811–5227]**

*Summary:* Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On February 28, 2011, applicant transferred its assets to BlackRock MuniAssets Fund, Inc., based on net asset value. Expenses of approximately $203,515 incurred in connection with the reorganization were paid by applicant.

*Filing Date:* The application was filed on April 4, 2011.

*Applicant's Address:* 100 Bellevue Parkway, Wilmington, DE 19809.

**Lord Abbett Municipal Income Trust [File No. 811–6418]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On November 19, 2010, applicant transferred its assets to Lord Abbett Municipal Income Fund, Inc., based on net asset value. Expenses of $150,000 incurred in connection with the reorganization were paid by Lord, Abbett & Co. LLC, applicant's investment adviser.

*Filing Date:* The application was filed on March 30, 2011.

*Applicant's Address:* 90 Hudson St., Jersey City, NJ 07302.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Cathy H. Ahn,**

*Deputy Secretary.*

[FR Doc. 2011–10931 Filed 5–4–11; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

## Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange

Commission will hold a roundtable discussion on money market funds and systemic risk on Tuesday, May 10, 2011, in the Multipurpose Room, L–006, beginning at 2 p.m. The roundtable will be webcast on the Commission's Web site at *http://www.sec.gov* and will be archived for later viewing.

The agenda for the roundtable will include a panel discussion on money market funds and systemic risk and will provide a forum for various stakeholders in money market funds to exchange views on the potential effectiveness of certain options in mitigating systemic risks associated with money market funds. These will include, but are not limited to, options raised in the President's Working Group report on possible money market fund reforms that was issued in October 2010 (*http://www.treasury.gov/press-center/press-releases/Documents/10.21%20PWG%20Report%20Final.pdf*).

This Sunshine Act notice is being issued because a majority of the Commission may attend the roundtable.

For further information, please contact the Office of the Secretary at (202) 551–5400.

May 2, 2011.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–11061 Filed 5–3–11; 11:15 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–64370; File No. SR–CHX–2011–07]**

## Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change To Amend Minor Rule Violation Plan

April 29, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 20, 2011, the Chicago Stock Exchange, Inc. ("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the CHX. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CHX proposes to amend its rules that pertain to the Exchange's minor rule violation plan. The text of this proposed rule change is available on the Exchange's Web site at *(http://www.chx.com)* and in the Commission's Public Reference Room, and at *http://www.sec.gov.*

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange's Minor Rule Violation Plan ("Plan") provides an effective and efficient method for the Exchange to encourage its members to fully comply with applicable rules. Under the Plan, the Exchange may impose a monetary fine, instead of instituting a formal disciplinary proceeding, for a rule violation that the Exchange has found to be minor in nature, but which the Exchange believes should still be the subject of a meaningful sanction.[3] Currently, fines imposed under the Plan can be up to $2,500 per violation. Each individual violation is identified to the Minor Rule Violation Panel ("Panel"), which is composed of individuals associated with an Exchange Participant firm. The Panel decides whether to assess fines under the Plan and determines the amount of the fine.

[3] Fines under the Minor Rule Violation Plan provide an appropriate sanction in many situations. For example, where member conduct is not intentional or of such magnitude that it can be considered reckless, a fine under the Minor Rule Violation Plan might be an appropriate response to a first, second or third violation by an Exchange member. The Exchange is mindful, however, that more egregious violations should not be handled through the summary proceedings authorized by the Minor Rule Violation Plan. The mere fact that the Exchange is authorized to impose a sanction pursuant to the Plan does not preclude it from instituting other disciplinary proceedings. Article 12, Rule 8(f).

### Proposed New Rules for the Minor Rule Violation Plan

The Exchange is seeking to revise its list of rules eligible for disposition under the Plan as well as its Recommended Fine Schedule ("Fine Schedule") to include a number of new rules that are currently not eligible for disposition under the Plan. As a general matter, the new rules fall into one of two categories: Reporting and recordkeeping provisions or trading-related rules.

The new reporting and recordkeeping provisions include the following: Failure to notify the Exchange of a request to withdraw capital contribution (Article 3, Rule 6(b)); failure to request Exchange approval of the transfer of equity securities of a participant firm (Article 3, Rule 11), reporting of loans (Article 3, Rule 12), failure to provide the Exchange with information (Article 6, Rules 7); impede or delay an Exchange examination, inquiry or investigation (Article 6, Rule 9); designation of email addresses (Article 3, Rule 13); registration and approval of personnel (Article 6, Rule 2(a)); written supervisory procedures (Article 6, Rule 5(b)); failure to report short positions (Article 7, Rule 9); furnishing of records (Article 11, Rule 1), maintenance of books and records (Article 11, Rule 2) participant communications (Article 11, Rule 4); market maker registration and appointment (Article 16, Rule 1), market maker reporting of position information (Article 16, Rule 10) and institutional broker registration and appointment (Article 17, Rule 1).

The new trading violations which the Exchange proposes to add to the Plan include the reporting of transactions (Article 9, Rule 13); institutional broker obligations for entry of orders into an automated system (Article 17, Rule 3(a)); and institutional broker responsibilities for handling orders within an integrated system (Article 17, Rule 3(b)).

In general, the majority of these rules are similar in nature to the rules already eligible for disposition under the Plan inasmuch as they relate to recordkeeping or reporting obligations of participants to the Exchange or the manner in which trading activity occurs on the Exchange.[4] A number of these additions also relate to registration, recordkeeping or trading responsibilities of Exchange-registered market makers or institutional brokers. Articles 16 and 17 of the Exchange's rules set forth a

[4] A number of these rules had been included in previous iterations of the Plan.

number of specific obligations as to these two categories of participants.

As it applies to market makers, this filing proposes to include market maker registration requirements under Article 16, Rule 1 and reporting of position information under Article 16, Rule 10 to the Plan.

As it applies to institutional brokers, this filing proposes to add to the Plan certain aspects of an institutional broker's obligation in the handling of orders in the Exchange's Brokerplex system. This includes Article 17, Rule 3(a) which requires an institutional broker to enter all orders it receives for execution on the Exchange into the Exchange's Brokerplex system and Article 17, Rule 3(b) which requires an institutional broker to use an electronic system, acceptable to the Exchange, for the handling of orders that integrates the institutional broker's on-Exchange trading activities with its trading activities in other market centers.

These rules under Article 17, Rule 3 which the Exchange proposes to add to the Plan involve an institutional broker's obligation in order handling only to the extent that it pertains to internal handling and entry of such orders. It is not uncommon for an institutional broker to manually handle a customer order (*i.e.,* a phone order, instant message, etc.) on the Exchange. As such, the requirements of Article 17, Rule 3 ensure that both manual and electronic orders are being properly handled, entered and recorded in the Exchange's automated system, *i.e.,* the Exchange's Brokerplex system. For example, under Article 17, Rule 3(a), an institutional broker must enter all orders it receives for execution on the Exchange into an automated system as required by the provisions of Article 11. Specifically, this requirement pertains to the institutional broker's responsibility to record such orders in the Exchange's Brokerplex system (or any other Exchange approved automated system), which is an electronic means for order maintenance and recordation.

The Exchange also proposes to add to the Plan its rules requiring Participants to provide information to the staff of the Exchange upon request.[5] Additionally, the Exchange proposes to add its rule requiring Participants to not impede or delay an Exchange examination, inquiry or investigation by failing to provide information or cooperation.[6] Finally, the Exchange proposes to add the failure of any Participant to establish, maintain and/or enforce written procedures to supervise the types of business in which it engages and to supervise the activities of registered and associated persons.[7] The Exchange believes that these measures will enhance the ability of the staff to sanction Participants for violations of these trading rules, or for the failure to provide requested information or to adequately have supervisory procedures in place which are properly maintained and enforced.

**Elimination of Obsolete Rule References and Clarifying Changes to Others**

The Exchange also seeks to revise its list of Rules eligible for MRVP disposition as well as its Recommended Fine Schedule ("Fine Schedule") to eliminate a number of obsolete rule references and to make certain non-substantive, clarifying changes to other rule references.

The list of Rules eligible for MRVP disposition contained in Rule 8(h) of Article 12 and the Fine Schedule contain certain rules which are either no longer rules of the Exchange or appropriate for disposition under the Plan. For example, the violations cited in the current version of Rule 8(h)(ii)(1) and (2) relate to use of the Intermarket Trading System ("ITS"), which was retired in 2007.[8] The other violation noted in the Plan and Fine Schedule which is no longer a rule of the Exchange relates to officers, directors and principal stockholders (Article 4, Rules 3 and 4). The Exchange believes that the rule addressing dealings in stocks on put, call, straddle or option (Article 9, Rule 22) should be deleted from the Plan and Fine Schedule, since no violations of that rule have been addressed via the Plan for many years.[9] The Exchange also believes that the reference to improper use of the "SOLD" designator should be deleted from the Plan and Fine Schedule, as the Exchange's systems no longer facilitate the use of that designator by Participants on our trading facilities.

Additionally, a number of the rules referenced in the Fine Schedule relate to trading by Exchange specialists, which were eliminated when the Exchange adopted its New Trading Model.[10] These rules include the written reports of transactions (former Article XXX, Rule 5), record of orders (former Article XXX, Rule 11), submission of the Co-Specialists survey (former Article VIII, Rule 11), primary market protection (former Article XX, Rule 7, interpretation and policy .06), "stopped" orders (former Article XX, Rules 28 and 37(a)(6)), trading ahead (former Article XXX, Rule 2), competitive basis rule (former Article XXX, Rule 3), BEST rule (former Article XX, Rule 37(a)(2), (3)) and approval for manual execution mode (former Article XX, Rule 37, interpretations and policies .04). Other obsolete rule references in the Fine Schedule include the now-deleted Market Maker requirements of former Article XXXIV.[11] Additionally, several rules cited in the Fine Schedule pertain to the now-defunct ITS system.[12] Other rules have previously been deleted from the Plan due to changes in Exchange rules associated with the adoption of the New Trading Model, but remained as a

[5] CHX Article 6, Rule 7; Article 11, Rule 1. Other markets have included similar rules in their Minor Rule Plans, including NYSE Archipelago ("NYSE Arca"). *See* NYSE Arca Rule 10.12(h)(1) relating to a firm's failure to submit trade data in a timely manner (NYSE Arca Rule 10.2(e)) and NYSE Arca Rule 10.12(h)(3) relating to a failure to furnish in a timely manner books, records or other requested information or testimony in connection with an examination of financial responsibility and/or operational conditions (NYSE Arca Rule 4.11(c)); Philadelphia Stock Exchange ("PHLX") Rule 970 which includes any violations of a floor procedure advice including violations of Floor Procedure Advice F–8 which relates to a firm's failure to comply with an Exchange inquiry; and National Stock Exchange ("NSX") Rule 8.15 which includes violations of NSX Rules 4.1 and 4.2 relating to the submission of responses to Exchange requests for trading data, as well as financial or regulatory records and information.

[6] CHX Article 6, Rule 9. NYSE Arca has a similar rule in their Minor Rule Plan. *See* NYSE Arca Rule 10.12(h)(6) relating to delaying, impeding or failing to cooperate in an investigation (NYSE Arca Rule 10.2(d)).

[7] CHX Article 6, Rule 5(b). NYSE Arca has a similar rule in their Minor Rule Plan. *See* NYSE Arca Equity Rule 10.12(h)(8)(c) which relates to establishing, maintaining, and enforcing written procedures to supervise the business in which it engages and the activities of its associated persons that are reasonably designed to achieve compliance with applicable federal securities laws and regulations and with the NYSE Arca Equity Rules (NYSE Arca Rule 6.18(c)).

[8] These rules include the failure to issue ITS pre-opening notification or properly issue a pre-opening response (former Article 19, Rule 1) and the failure to comply with trade-through, locked markets and block trade rules (former Article 19, Rule 2). The Exchange also proposes to delete an exclusionary reference to ITS commitments in the firm quote rule citation. Article 12, Rule 8(h)(ii)(11).

[9] Any violations of this provision could be addressed through other disciplinary mechanisms, such as a formal disciplinary proceeding under Article 12, Rule 1 or the Summary Procedure under Article 12, Rule 2.

[10] *See* Securities Exchange Act Release No. 54550 (September 29, 2006), 71 FR 59563 (October 10, 2006) (approving CHX's proposed new trading model).

[11] These rules include the failure to comply with the 50% requirement (former Article XXXIV, Rule 3), and failure to comply with the public outcry rule (former Article XXXIV, Rule 10).

[12] These rules include the failure to issue ITS pre-opening notification or properly issue a pre-opening response (former Article XX, Rule 39) and the failure to comply with trade-through, locked markets and block trade rules (former Article XX, Rule 40) as well as the above-noted reference to ITS commitments in connection with the firm quote rule.

legacy in the Fine Schedule.[13] The citations for the remaining rules have changed since the Fine Schedule was last updated. The proposed rule amendment would conform the rules noted in the Fine Schedule to those rules which are part of the Plan as set forth in Article 12, Rule 8.

Finally, the Exchange proposes to make certain non-substantive, clarifying changes to some of the current rules referenced in the Plan. For example, the filing proposes to clarify that the short sale rule (Article 9, Rule 23) applies to all sell orders and not just those of a proprietary nature.[14] In addition, the filing proposes to make changes to address proper rule cites and/or description of rules. For example the filing proposes to clarify that an Institutional broker's best execution obligations under Article 17, Rule 3 specifically fall under paragraph (d) of such rule and is titled *Obligations in Handling Orders* (as opposed to *failure to meet best execution obligations*).

**Increased Fines**

The Exchange is also proposing to increase the maximum fine pursuant to the Plan from $2,500 to $5,000 and to increase the fines in the Fine Schedule in order to better deter violative activity and more closely adhere to the fine schedules of other self-regulatory organizations. For most reporting and recordkeeping rule violations and certain trading rule violations, the recommended fines were increased from $100/$500/$1,000 for 1st, 2nd and 3rd tier fines, respectively, to $250/$750/$1,500. The Exchange proposes recommended fines of $500/$1,000/$2,500 for other, more serious trading rule violations (*i.e.,* ones which involve the potential for customer harm), as well as violations of the obligation to establish, maintain and enforce written supervisory procedures, and to provide information to the Exchange in connection with regulatory inquiries or other matters. We seek recommended fines of $1,000/$2,500/$5,000 for the most serious violations contained within the Plan (Trading Ahead). Finally, we are expanding the rolling time period in which violations would result in escalation to the next highest tier from 12 to 24 months, which is consistent with the minor rule plans of other exchanges.

**Elimination of Minor Rule Violation Panel**

The Exchange proposes to eliminate the role of the Panel in issuing sanctions pursuant to the Plan and authorize certain members of the Exchange's Market Regulation staff to issue MRVP sanctions. Specifically, MRVP sanctions would be imposed either by the Exchange's Chief Enforcement Counsel or Chief Regulatory Officer. The Exchange notes that allowing members of its staff to issue MRVP fines is consistent with the practice at other exchanges regarding MRV plans and is also similar to the method by which formal disciplinary actions are instituted by the CHX under Article 12, Rule 1.[15] The Exchange believes that the proposed change will help to expedite the process of issuing MRVP sanctions and will eliminate an inherent source of potential conflicts (or appearance thereof) whenever Participants determine disciplinary sanctions.

**Censure**

The Exchange proposes to add a censure authority to the Plan to provide additional flexibility in imposing sanctions in particular cases. Censures could be used in initial findings of a violation where the Exchange wants to put the Respondent on notice that certain conduct violates CHX rules or in other circumstances in which a monetary fine is not appropriate or necessary.

**Pleadings**

The Exchange seeks to clarify the pleading requirements of a Respondent who seeks to challenge a sanction by instituting a formal disciplinary proceeding. The proposed changes require a Respondent which is challenging a MRVP sanction to file an answer which meets the standards for an answer under Article 12, Rule 5(b). The proposal would authorize the Secretary of the Exchange (the person to whom such responses are directed) to deny the answer for a failure to meet these standards. The denial of the answer by the Secretary without leave to amend and refile shall be considered the final action of the Exchange, and the MRVP fine shall become due and payable and/or a censure will be imposed. The Exchange has also added language incorporating the requirement of Exchange Act Rule 19d–1 relating to the reporting of Exchange disciplinary actions to the Commission.[16]

2. Statutory Basis

Approval of the rule changes proposed in this submission is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b). The proposed rule change is consistent with Section 6(b)(5) of the Act because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. The proposed rule change is also consistent with Sections 6(b)(6) and 6(b)(7) of the Act because it would promote the Exchange's ability to appropriately discipline its Participants and provide procedures of fair practice when addressing violations of Exchange rules that are deemed by the Exchange to be minor in nature. Generally, the Exchange believes that the proposed rule change will strengthen its ability to carry out its oversight responsibilities as a self-regulatory organization and reinforce its surveillance and enforcement functions. In addition, the proposed rule change will promote consistency in minor rule violations and respective SRO reporting obligations as set forth pursuant to Regulation 240.19d–1(c)(2) of the Act.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission my designate up to

[13] *See, e.g.,* Limit order display rule provisions (former Article XX, Rule 7, Interpretation and Policies .05).

[14] Currently, the Plan only addresses a Participant's duty to comply with the short sale rule when selling short for their own account (*e.g.,* proprietarily). *See* Article 12, Rule 8(h)(ii)(5).

[15] *See, e.g.,* Chicago Board Options Exchange ("CBOE") Rule 17.50(a), Imposition of Fines for Minor Rule Violations (provides for fines to be issued by "the Exchange"); BATS Exchange ("BATS") Rule 8.15(a), Imposition of Fines for Minor Violation(s) of Rules (provides for fines to be issued by "the Exchange"); International Stock Exchange ("ISE") Rule 1614(a), Imposition of Fines for Minor Rule Violations (provides for fines to be issued by "the Exchange"). Formal disciplinary actions under Article 12, Rule 1 are authorized by the Exchange's Chief Regulatory Officer.

[16] Our proposed language is based upon language in the Minor Rule Violation plan for the CBOE. (CBOE Rule 17.50(a)).

90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Exchange 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 Number SR–CHX–2011–07 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 Number SR–CHX–2011–07. 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 website (*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 website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2011–07 and should be submitted on or before May 26, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

**Cathy H. Ahn,**

*Deputy Secretary.*

[FR Doc. 2011–10928 Filed 5–4–11; 8:45 am]

**BILLING CODE 8011–01–P**

---

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–64371; File No. SR–NASDAQ–2011–056]**

## Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change to Adopt Additional Listing Requirements for Reverse Mergers

April 29, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 18, 2011, The NASDAQ Stock Market LLC ("Nasdaq") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. 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 the Substance of the Proposed Rule Change**

Nasdaq proposes to adopt additional listing requirements for a company that has become public through a reverse merger. Nasdaq will implement the proposed rule for applications received after approval.

The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.[3]

**5110. Change of Control, Bankruptcy and Liquidation, and Reverse Mergers**

(a)–(b) No change

*(c) Reverse Mergers between a Private Operating Company and a Public Shell Company*

*A Company that is formed by a combination between a private operating company and a public shell company shall be eligible to submit an application for initial listing only after the combined entity has: (i) Traded for at least six months in the over-the-counter market, on another national securities exchange, or on a listed foreign market, following the filing with the Commission or Other Regulatory Authority of audited financial statements for the combined entity; and (ii) maintained a Bid Price of $4 per share or higher on at least 30 of the 60 trading days immediately preceding the filing of the initial listing application.*

*In addition, such a company may only be approved for listing if, following the business combination, it has timely filed: (i) In the case of a domestic issuer, at least two required periodic financial reports with the Commission or Other Regulatory Authority; or (ii) in the case of a Foreign Private Issuer, one or more reports including financial statements for a period not less than six months.*

*This Rule 5110(c) shall not apply if the Company lists in connection with a firm commitment, underwritten public offering.*

* * * * *

**5210. Prerequisites for Applying to List on The Nasdaq Stock Market**

(a)–(h) No change

*(i) Reverse Mergers between a Private Operating Company and a Public Shell Company*

*A security issued by a Company formed by a combination between a private operating company and a public shell company shall be eligible for initial listing only if the conditions set forth in Rule 5110(c) are satisfied.*

* * * * *

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, Nasdaq 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. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

---

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at *http://nasdaqomx.cchwallstreet.com.*

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

In recent months there has been an extraordinary level of public attention to listed companies that went public via a reverse merger, where an unlisted operating company becomes a public company by merging with a public shell.[4] The financial press, short sellers and others have raised allegations of widespread fraudulent behavior by these companies, leading to concerns that their financial statements cannot be relied upon. Concerns have also been raised that certain individuals who aggressively promote these transactions have significant regulatory histories or have engaged in transactions that are disproportionately beneficial to them at the expense of public shareholders. The Public Company Accounting Oversight Board ("PCAOB") has also identified issues with the audits of these companies and, in response, has issued Staff Audit Practice Alert No. 6/July 12, 2010 and Staff Research Note #2011–P1/March 2011, cautioning registered accounting firms to follow certain specified auditing practices. The SEC recently took an enforcement action based on a firm's audit of a reverse merger company.[5] In addition, Nasdaq is aware of situations where it appeared that promoters and others intended to manipulate prices higher to satisfy Nasdaq's initial listing bid price requirement and where companies have, for example, gifted stock to artificially satisfy the 300 round lot public holder requirement. Nasdaq does not list companies in instances such as these, where it appears the company has achieved compliance with a requirement in an inappropriate manner.

In response to these concerns, Nasdaq staff has, over the past year, adopted heightened review procedures for reverse merger applicants. However, Nasdaq also believes that additional requirements for listing reverse merger companies are appropriate to discourage inappropriate behavior on the part of companies, promoters and others. Accordingly, Nasdaq proposes to adopt certain "seasoning" requirements for reverse mergers.[6]

Specifically, Nasdaq proposes to prohibit a company going public via a reverse merger from applying to list until six months after the combined entity submits audited financial statements to the SEC.[7] Further, Nasdaq proposes to require that the company maintain a $4 bid price on at least 30 of the 60 trading days immediately prior to submitting the application. Finally, under the proposed rule, Nasdaq would not approve any reverse merger for listing until the company has filed at least two financial reports with the SEC if it is a domestic issuer (this could be two quarterly filings or a quarterly and an annual filing) or one financial report covering at least a six month period if it is a foreign private issuer (this could be an interim report on Form 6–K or an annual report on Form 20–F). While most companies will satisfy this requirement due to the six month delay before they can apply, Nasdaq believes that it is important to assure that this requirement be satisfied in all cases.

Nasdaq believes that this proposal will result in significant investor protection benefits. Specifically, a six month seasoning requirement will allow FINRA more time to view trading patterns and uncover potentially manipulative trading.[8] It will also result in a more bona fide shareholder base and assure that the $4 bid price was not satisfied through a quick manipulative scheme. Requiring additional SEC filings will tend to improve the reliability of the reported financial results, since the auditors will have reviewed several quarters, at least, of the public company's operating results, as will the company's audit committee. To the extent the company had adopted new internal controls at the time of the merger, those too will have been in place and able to exert a corrective influence over any previous flaws in the company's financial reporting process.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[9] in general and with Section 6(b)(5) of the Act,[10] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change is designed to enhance investor protection by imposing additional requirements on a category of companies that have raised regulatory concerns.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

*A. By order approve or disapprove such proposed rule change, or*

*B. institute proceedings to determine whether the proposed rule change should be disapproved.*

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with

[4] *See, e.g.,* Beware This Chinese Expor, Barron's (August 28, 2010), available at *http://online.barrons.com/article/SB50001424052970204304404575449812943183940.html. See also* Speech by SEC Commissioner by Commissioner Luis A. Aguilar: Facilitating Real Capital Formation (April 4, 2011), available at *http://www.sec.gov/news/speech/2011/spch040411laa.htm.* [sic]

[5] *In re* Moore Stephens Wurth Frazer and Torbet, Order Instituting Public Administrative and Cease-and-Desist Proceedings, Securities Act Release No. 9166 (December 20, 2010).

[6] Reverse merger companies that list on Nasdaq in conjunction with a firm commitment underwritten public offering will not be subject to the proposed rule. These transactions are more similar to IPOs, in that the SEC reviews the registration statement and the underwriters and other experts are strictly liable under the federal securities laws for any misstatements.

[7] A company must file a Form 8–K within four days of completing a reverse merger. The Form 8–K must contain audited financial statements and information comparable to the information provided in a Form 10 for the registration of securities. *See* Form 8–K Items 2.01, 5.06, and 9.01(c).

[8] The Commission notes that FINRA has regulatory authority over transactions in the over-the-counter market.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

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 Number SR–NASDAQ–2011–056 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 Number SR–NASDAQ–2011–056. 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 website (*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 website viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2011–056, and should be submitted on or before May 26, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

**Cathy H. Ahn,**

*Deputy Secretary.*

[FR Doc. 2011–10936 Filed 5–4–11; 8:45 am]

**BILLING CODE 8011–01–P**

[11] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–64312; File No. SR–NASDAQ–2011–053]**

### Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt an Order Price Protection Feature

*Correction*

In notice document 2011–9971 appearing on pages 23351–23352 in the issue of Tuesday, April 26, 2011, make the following correction:

On page 23352, in the second column, in the last line "May 16, 2011" should read "May 17, 2011".

[FR Doc. C1–2011–9971 Filed 5–4–11; 8:45 am]

**BILLING CODE 1505–01–D**

## SECURITIES AND EXCHANGE COMMISSION

**[File No. 500–1]**

### Order of Suspension of Trading; In the Matter of Advanced Refractive Technologies, Inc., Bluebook International Holding Co. (The), CBCom, Inc., Gener8xion Entertainment, Inc., Group Long Distance Inc., HiEnergy Technologies, Inc., and Holter Technologies Holding, A.G. (n/k/a International Consortium Corp.)

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Advanced Refractive Technologies, Inc. because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Bluebook International Holding Co. (The) because it has not filed any periodic reports since the period ended December 31, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of CBCom, Inc. because it has not filed any periodic reports since the period ended September 30, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Gener8xion Entertainment, Inc. because it has not filed any periodic reports since the period ended April 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Group Long Distance Inc. because it has not filed any periodic reports since the period ended July 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of HiEnergy Technologies, Inc. because it has not filed any periodic reports since the period ended October 31, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Holter Technologies Holding, A.G. (n/k/a International Consortium Corp.) because it has not filed any periodic reports since the period ended September 30, 2000.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on May 3, 2011, through 11:59 p.m. EDT on May 16, 2011.

By the Commission.

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2011–11090 Filed 5–3–11; 4:15 pm]

**BILLING CODE 8011–01–P**

## SMALL BUSINESS ADMINISTRATION

**[License No. 09/79–0454]**

### Emergence Capital Partners SBIC, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Emergence Capital Partners SBIC, L.P., 160 Bovet Road, Suite 300, San Mateo, CA 94402, a Federal Licensee under the Small Business Investment Act of 1958, as amended ("the Act"), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration ("SBA") Rules and Regulations (13 CFR 107.730). Emergence Capital Partners SBIC, L.P. proposes to provide equity financing to PivotLink, Inc., 15325 SE. 30th Place, Suite 300, Bellevue, WA 98007. The financing is contemplated for working capital and general operating purposes.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Emergence Capital Partners, L.P. and Emergence Capital Associates, L.P., Associates of Emergence Capital Partners SBIC, L.P., own more than ten percent of PivotLink, Inc. Therefore, PivotLink, Inc. is considered an Associate of Emergence Capital Partners SBIC, L.P. and this transaction is considered Financing an Associate, requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction within 15 days of the date of this publication to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

April 21, 2011.

**Sean J. Greene,**

*Associate Administrator for Investment.*

[FR Doc. 2011–10774 Filed 5–4–11; 8:45 am]

BILLING CODE M

## DEPARTMENT OF STATE

**[Public Notice: 7441; OMB 1405–0161]**

### 30-Day Notice of Proposed Information Collection DS 4053, Department of State Mentor-Protégé Program Application

**ACTION:** Notice of request for public comment and submission to OMB of proposed collection of information.

**SUMMARY:** The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Department of State Mentor-Protégé Program Application.
- *OMB Control Number:* OMB 1405–0161.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Administration, Office of Small and Disadvantaged Business Utilization—A/SDBU.
- *Form Number:* DS–4053.
- *Respondents:* Small and large for-profit companies planning to team together in an official mentor-protégé capacity to improve the likelihood of winning DOS contracts.
- *Estimated Number of Respondents:* 14 respondents per year.
- *Estimated Number of Responses:* 14 per year.
- *Average Hours Per Response:* 21 hours.
- *Total Estimated Burden:* 294 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Required to Obtain Benefit.

**DATES:** Submit comments to the Office of Management and Budget (OMB) for up to 30 days from May 5, 2011.

**ADDRESSES:** Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *E-mail: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

**FOR FURTHER INFORMATION CONTACT:** You may obtain copies of the proposed information collection and supporting documents from Patricia Culbreth, A/SDBU, Patricia Culbreth, SA–6, Room L–500, Washington, DC 20522–0602 who may be reached on 703–875–6881 or at: *culbrethpb@state.gov.*

**SUPPLEMENTARY INFORMATION:** We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary to properly perform our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond.

**Abstract of Proposed Collection**

This information collection facilitates continuation of a mentor-protégé program that encourages business agreements between small and large for-profit companies planning to team together in an official mentor-protégé capacity to improve the likelihood of winning DOS contracts. This program assists the State Department OSDBU office in reaching its small business goals.

**Methodology**

Respondents may submit the information by e-mail using DS–4053, or by letter using fax or postal mail.

*Additional Information:* None.

Dated: April 27, 2011.

**Shapleigh C. Drisko,**

*Operations Director, Office of Small and Disadvantaged Business Utilization, Department of State.*

[FR Doc. 2011–11009 Filed 5–4–11; 8:45 am]

BILLING CODE 4710–24–P

## DEPARTMENT OF STATE

**[Public Notice 7444]**

### 60-Day Notice of Proposed Information Collection: DS–7001 and DS–7005, DOS-Sponsored Academic Exchange Program Application, OMB Control Number 1405–0138

**ACTION:** Notice of request for public comments.

**SUMMARY:** The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* DOS-Sponsored Academic Exchange Program Application.
- *OMB Control Number:* 1405–0138.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Educational and Cultural Affairs, ECA/A/E/EUR.
- *Form Number:* DS–7001, DS–7005.
- *Respondents:* Applicants for the Academic Exchange Program.
- *Estimated Number of Respondents:* 7160 (For DS–7001, 3842 estimated; for DS–7005, 3318 estimated).
- *Estimated Number of Responses:* 7160 (For DS–7001, 3842 estimated; for DS–7005, 3318 estimated).
- *Average Hours per Response:* 0.75.
- *Total Estimated Burden:* 5370 hours.
- *Frequency:* Annually.
- *Obligation to Respond:* Voluntary.

**DATES:** The Department will accept comments from the public up to 60 days from May 5, 2011.

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

- *E-mail: iovinems@state.gov.*
- *Mail (paper, disk, or CD–ROM submissions):* Micaela S. Iovine, ECA/A/E/EUR, SA–5, Floor 4, Department of State, 2200 C St., NW, Washington, DC 20522–0504.
- *Hand Delivery or Courier:* Same as mailing address.

You must include the DS form number (if applicable), information

collection title, and OMB control number in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed information collection and supporting documents, to Micaela S. Iovine, U.S. Department of State, Bureau of Educational and Cultural Affairs, Floor 4, 2200 C St., NW., Washington DC 20522–0504, who may be reached on 202–632–3256 or at *iovinems@state.gov.*

**SUPPLEMENTARY INFORMATION:** We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper performance of our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

*Abstract of proposed collection:*

The Department of State collects this information to identity qualified candidates for exchange activities sponsored by the Office of Academic Exchange Programs.

*Methodology:*

Applications are delivered physically to the offices of the grantees organization, submitted electronically, or through the mail.

*Additional Information:* None.

Dated: March 11, 2011.

**Alina L. Romanowski,**

*Deputy Assistant Secretary for Academic Programs, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2011–11006 Filed 5–4–11; 8:45 am]

**BILLING CODE 4710–05–P**

---

## DEPARTMENT OF STATE

**[Public Notice: 7442]**

## Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals: Youth Leadership Program

*Announcement Type:* New Cooperative Agreement.

*Funding Opportunity Number:* ECA/PE/C/PY–11–69.

*Catalog of Federal Domestic Assistance Number:* 19.415.

*Application Deadline:* June 6, 2011.

**Executive Summary**

The Office of Citizen Exchanges, Youth Programs Division, of the Bureau of Educational and Cultural Affairs (ECA) announces an open competition for the Youth Leadership Program. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals to provide youth and adult participants with three or more separate three-week exchanges focused on civic education, community service, and youth leadership development, and to support follow-on projects in their home communities. U.S. Embassies in the participating countries will recruit, screen, and select the participants. The successful applicant will provide flexible programming and work with ECA and U.S. Embassies as they identify the participating countries in response to emerging circumstances requiring U.S. engagement.

**I. Funding Opportunity Description**

*Authority*

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding authority for the program above is provided through legislation.

*Overview*

The Youth Leadership Program provides three-week exchanges in the United States for high school youth and adult educators from countries identified as Department priorities. Exchange activities will focus on civic education, community service, and youth leadership development. Secondary themes on issues of global relevance may be added. Participants will engage in a variety of activities such as workshops on leadership and service, community site visits related to the program themes and subthemes, interactive training and discussion groups, presentations, visits to high schools, local cultural activities, homestays, and other activities designed to achieve the program's stated goals.

Multiple opportunities for participants to interact meaningfully with their American peers must be included. Follow-on activities with the participants are an integral part of the program, as the students apply the knowledge and skills they have acquired by planning service projects in their home communities.

The goals of the program are to:

(1) Promote mutual understanding between the people of the United States and the people of other countries;

(2) Prepare youth leaders to become responsible citizens and contributing members of their communities; and

(3) Foster relationships among youth from different ethnic, religious, and national groups.

The objectives of the program are for participants to:

(1) Demonstrate a better understanding of the elements of a participatory democracy as practiced in the United States;

(2) Demonstrate critical thinking and leadership skills; and

(3) Demonstrate skills in developing project ideas and planning a course of action to bring the projects to fruition.

The primary themes of the program are:

(1) Civic Education (Citizen Participation, Grassroots Democracy and Rule of Law);

(2) Community Service; and

(3) Youth Leadership Development.

For each project, applicant organizations must focus on these primary themes. Secondary themes such as business and entrepreneurship, the environment, public health, or other topics of global relevance will serve to illustrate the more abstract concepts of the primary themes. For example, the secondary theme of the environment can be used to examine how a group of individuals with an idea can start a recycling campaign in their community. These themes may vary in response to Department priorities connected with the countries that participate.

Using these goals, objectives, and themes, applicant organizations should identify their own specific and measurable outputs and outcomes based on the project specifications provided in this solicitation. Proposals should indicate how recipients will achieve the short-term program objectives, and how these objectives will contribute to the achievement of the stated long-term goals.

*Project Outline*

The amount of funding available is approximately $600,000. ECA

anticipates awarding one cooperative agreement for the management of this Youth Leadership Program. With funding of approximately $7,500 per participant, the program will involve hosting a total of about 70 to 90 high school students and educators for three-week exchanges in the United States in 2012. They will travel in several delegations, each delegation ranging from 14 to 24 participants and each delegation representing a different country or region from around the world, to be determined in consultation with Department stakeholders as emerging events dictate.

Applicants are encouraged to be creative and flexible in making arrangements that will help meet our program goals. For instance, the groups may not all be of equal size and may travel at anytime throughout the year. More exchange participants may be included should funding allow. The Bureau reserves the right to reduce, revise, or increase proposal project configurations, budgets, and participant numbers in accordance with the needs of the program and the availability of funds.

*Participants*

U.S. Embassies in the participating countries will recruit, screen, and select the participants; the award recipient will not be involved in participant selection. The youth participants will be high school students aged 15 to 18 years old. The adult participants may be teachers, trainers, school administrators, and/or community leaders who work with youth. They will have the dual role of both exchange participant and chaperone. The ratio of youth to adult participants will be approximately 7:1. Participants will be proficient in the English language.

*Organizational Capacity*

Applicant organizations must demonstrate their capacity for conducting international youth exchanges, providing projects that address the goals, objectives, and themes outlined in this document, and providing age-appropriate programming for youth.

*U.S. Embassy Involvement*

U.S. Embassies in the participating countries will recruit, screen, and select the participants; provide pre-departure briefings; facilitate visas; and collaborate with the U.S. recipient organization in overseeing alumni follow-on projects. Once a cooperative agreement is awarded and the participating countries are identified, which may take place throughout the agreement period, the recipient must consult regularly with the Public Affairs Section at the U.S. Embassies in the partner countries to implement the exchanges.

*Guidelines*

The cooperative agreement will begin on or about September 1, 2011. The award period will be 18 to 24 months in duration, as appropriate for the applicant's program design. Planning and preparation will start in 2011, and the exchanges will take place primarily in calendar year 2012. Applicants should propose the period of the exchanges in their proposals, but the exact timing may be altered through the mutual agreement of the Department of State and the award recipient.

The award recipient will be responsible for the following:

*Orientations:* Provide pre-departure materials and information about the U.S. program to help the U.S. Embassies, participants, and their families in preparation for the exchange. Also, provide orientations for those participating from the host communities, including host families.

*Logistics:* Manage all logistical arrangements, including international and domestic travel, ground transportation, accommodations, group meals, and disbursement of pocket money.

*Exchange Activities:* Design and plan three weeks of exchange activities that provide a creative and substantive program that develops both the youth and the adult participants' knowledge and skill base in civic education, community service, and youth leadership development. The exchange will take place in no more than two or three locations so that the participants have time to familiarize themselves with a community. The exchange will focus primarily on interactive activities, practical experiences, and other hands-on opportunities that provide a substantive experience on the specified program themes. Some activities should be school and/or community-based, and the exchange will involve as much sustained interaction with American peers as possible (for both the youth and adult participants). Cultural, social, and recreational activities will balance the schedule. Applicants may choose to include a visit to Washington, DC.

*Accommodations:* Arrange home stays for the participants in the United States with properly screened and briefed American families for the majority of the exchange period. Criminal background checks must be conducted for members of host families (and others living in the home) who are 18 years of age or older. Please see the POGI for more details on host family screening and placement.

*Monitoring:* Develop and implement a plan to monitor the participants' safety and well-being while on the exchange and to create opportunities for participants to share potential issues and resolve them promptly. The award recipient will be required to provide proper staff supervision and facilitation to ensure that the teenagers have safe and pedagogically rich programs. Staff, along with the adult participants, will assist the youth with cultural adjustments, provide societal context to enhance learning, and counsel students as needed.

*Follow-on Activities:* Plan and implement activities in the participants' home countries, in coordination with the U.S. Embassies, particularly by facilitating continued engagement among the participants, advising and supporting them in the implementation of community service projects, and offering opportunities to reinforce the ideas, values and skills imparted during the exchange. Exchange participants should return home from the exchange prepared to conduct projects that serve a need in their schools or communities. To amplify program impact, proposals should present creative and effective ways to address the project themes, for both program participants and their peers.

*Evaluation:* Design and implement an evaluation plan that assesses the short- and medium-term impact of the project on the participants as well as on host and home communities.

**Please note:** In a cooperative agreement, the Department of State is substantially involved in program activities above and beyond routine grant monitoring. The Department's activities and responsibilities for the Youth Leadership Program are as follows:

(1) Provide advice and assistance in the execution of all program components.

(2) Manage the recruitment and selection of the participants, provide pre-departure briefings, and oversee follow-on activities.

(3) Issue DS–2019 forms and J–1 visas. All foreign participants will travel on a U.S. Government designation for the J Exchange Visitor Program.

(4) Facilitate interaction within the Department of State, to include ECA, the regional bureaus, and overseas posts.

(5) Arrange meetings with Department of State officials in Washington, D.C. and the participating countries.

(6) Approve publicity materials and final calendar of exchange activities.

(7) Monitor and evaluate the program, through regular communication with the award recipient and possibly one or more site visits.

*Additional Information*

Award recipients will retain the name "Youth Leadership Program" to identify their project. All materials, publicity, and correspondence related to the program will acknowledge this as a program of the Bureau of Educational and Cultural Affairs of the U.S. Department of State. The Bureau will retain copyright use of and be allowed to distribute materials related to this program as it sees fit.

The organization must inform the ECA Program Officer and participating U.S. Embassies of their progress at each stage of the project's implementation in a timely fashion, and will be required to obtain approval of any significant program changes in advance of their implementation.

Proposals must demonstrate how the stated objectives will be met. The proposal narrative should provide detailed information on the major project activities, and applicants should explain and justify their programmatic choices. Projects must comply with J–1 visa regulations for the International Visitor and Government Visitor category. Please be sure to refer to the complete Solicitation Package—this RFGP, the Project Objectives, Goals, and Implementation (POGI), and the Proposal Submission Instructions (PSI)—for further information.

## II. Award Information

*Type of Award:* Cooperative Agreement. ECA's level of involvement in this program is listed under Section I above.

*Fiscal Year Funds:* FY–2011.

*Approximate Total Funding:* $600,000.

*Approximate Number of Awards:* One.

*Anticipated Award Date:* September 1, 2011.

*Anticipated Project Completion Date:* 18–24 months after start date, to be specified by applicant based on project plan.

## III. Eligibility Information

*III.1. Eligible applicants:* Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

*III.2. Cost Sharing or Matching Funds:* There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

*III.3. Other Eligibility Requirements*

(a) Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. ECA anticipates making an award in an amount exceeding $60,000 to support program and administrative costs required to implement this exchange program. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

(b) Proposed sub-award recipients are also limited to grant funding of $60,000 or less if they do not have four years of experience in conducting international exchanges.

(c) The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

## IV. Application and Submission Information

**Note:** Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*IV.1. Contact Information to Request an Application Package*

Please contact the Youth Programs Division, ECA/PE/C/PY, SA–5, 3rd Floor, U.S. Department of State, 2200 C Street, NW., Washington, DC 20037, by telephone (202) 632–9261, fax (202) 632–9355, or e-mail *YLP@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/PE/C/PY–11–69 when making your request.

Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation. It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Program Officer Sarah Shields and refer to the Funding Opportunity Number ECA/PE/C/PY–11–69 on all other inquiries and correspondence.

*IV.2. To Download a Solicitation Package Via Internet*

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/grants/open2.html,* or from the Grants.gov Web site at *http://www.grants.gov.* Please read all information before downloading.

*IV.3. Content and Form of Submission:* Applicants must follow all instructions in the Solicitation Package. The application should be submitted per the instructions under IV.3f. "Application Deadline and Methods of Submission" section below.

*IV.3a.* You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

*IV.3b.* All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

*IV.3c.* All Federal award recipients and sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database and have a Dun and Bradstreet Data

Universal Numbering System (DUNS) number. Recipients and sub-recipients must maintain accurate and up-to-date information in the CCR until all program and financial activity and reporting have been completed. All entities must review and update the information at least annually after the initial registration and more frequently if required information changes or another award is granted.

You must have nonprofit status with the IRS at the time of application. *Please note:* Effective January 7, 2009, all applicants for ECA Federal assistance awards must include in their application the names of directors and/or senior executives (current officers, trustees, and key employees, regardless of amount of compensation). In fulfilling this requirement, applicants must submit information in one of the following ways:

(1) Those who file Internal Revenue Service Form 990, "Return of Organization Exempt From Income Tax," must include a copy of relevant portions of this form.

(2) Those who do not file IRS Form 990 must submit information above in the format of their choice.

In addition to final program reporting requirements, award recipients will also be required to submit a one-page document, derived from their program reports, listing and describing their grant activities. For award recipients, the names of directors and/or senior executives (current officers, trustees, and key employees), as well as the one-page description of grant activities, will be transmitted by the State Department to OMB, along with other information required by the Federal Funding Accountability and Transparency Act (FFATA), and will be made available to the public by the Office of Management and Budget on its USASpending.gov Web site as part of ECA's FFATA reporting requirements.

If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

*IV.3d.* Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1. Adherence to All Regulations Governing the J Visa

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the "Responsible Officer" for the program under the terms of 22 CFR part 62, which covers the administration of the Exchange Visitor Program (J visa program). Under the terms of 22 CFR part 62, organizations receiving awards (either a grant or cooperative agreement) under this RFGP will be third parties "cooperating with or assisting the sponsor in the conduct of the sponsor's program." The actions of recipient organizations shall be "imputed to the sponsor in evaluating the sponsor's compliance with" 22 CFR part 62. Therefore, the Bureau expects that any organization receiving an award under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR part 62 *et seq.*

The Bureau of Educational and Cultural Affairs places critically important emphases on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by recipient organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should *explicitly state in writing* that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR part 62. If your organization has experience as a designated Exchange Visitor Program Sponsor, the applicant should discuss their record of compliance with 22 CFR part 62 *et seq.,* including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, recordkeeping, reporting and other requirements.

The Office of Citizen Exchanges of ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from:

Office of Designation, Private Sector Programs Division, U.S. Department of State, ECA/EC/D/PS, SA–5, 5th Floor, 2200 C Street, NW., Washington, DC 20037.

IV.3d.2. Diversity, Freedom and Democracy Guidelines

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. Program Monitoring and Evaluation

Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the recipient organization will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and

how and when you intend to measure these outcomes (performance indicators). The more that outcomes are "smart" (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes. Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. *Participant satisfaction* with the program and exchange experience.
2. *Participant learning,* such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.
3. *Participant behavior,* concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.
4. *Institutional changes,* such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

**Please note:** Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (*i.e.,* surveys, interviews, or focus groups). (Please note that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Recipient organizations will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

*IV.3e.* Please take the following information into consideration when preparing your budget:

*IV.3e.1.* Applicants must submit SF–424A—"Budget Information—Non-Construction Programs" along with a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification. Please refer to the Solicitation Package (POGI and PSI) for complete budget guidelines and formatting instructions.

IV.3f. Application Deadline and Methods of Submission

*Application Deadline Date:* Monday, June 6, 2011.

*Reference Number:* ECA/PE/C/PY–11–69.

Methods of Submission:

Applications may be submitted in one of two ways:

(1) In hard-copy, via a nationally recognized overnight delivery service (*i.e.,* Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, *etc.*), or

(2) Electronically through *http://www.grants.gov.*

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3f.1. Submitting Printed Applications

Applications must be shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will not notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages *may not* be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

**Important note:** When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to "ECA/EX/PM."

The original and six (6) copies of the application should be sent to: Program Management Division, ECA–IIP/EX/PM, Ref.: ECA/PE/C/PY–11–69, SA–5, Floor 4, Department of State, 2200 C Street, NW., Washington, DC 20037.

With the submission of the proposal package, please also e-mail the Executive Summary, Proposal Narrative, and Budget sections of the proposal, as well as any attachments essential to understanding the program, in Microsoft Word, Excel, and/or PDF, to *YLP@state.gov.* The Bureau may provide these files electronically to the Public Affairs Sections at the relevant U.S. Embassies for their review.

IV.3f.2. Submitting Electronic Applications

Applicants have the option of submitting proposals electronically through Grants.gov (*http://www.grants.gov*). Complete solicitation packages are available at Grants.gov in the "Find" portion of the system.

**Please note:** ECA bears no responsibility for applicant timeliness of submission or data errors resulting from transmission or conversion processes for proposals submitted via Grants.gov.

Please follow the instructions available in the 'Get Started' portion of the site (*http://www.grants.gov/GetStarted*).

Several of the steps in the Grants.gov registration process could take several weeks. Therefore, applicants should check with appropriate staff within their organizations immediately after reviewing this RFGP to confirm or determine their registration status with Grants.gov.

Once registered, the amount of time it can take to upload an application will

vary depending on a variety of factors including the size of the application and the speed of your Internet connection. In addition, validation of an electronic submission via Grants.gov can take up to two business days.

*Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.*

The Grants.gov Web site includes extensive information on all phases/aspects of the Grants.gov process, including an extensive section on frequently asked questions, located under the "For Applicants" section of the Web site. ECA strongly recommends that all potential applicants review thoroughly the Grants.gov Web site, well in advance of submitting a proposal through the Grants.gov system. ECA bears no responsibility for data errors resulting from transmission or conversion processes.

Direct all questions regarding Grants.gov registration and submission to:

Grants.gov Customer Support.

*Contact Center Phone:* 800–518–4726.

*Business Hours:* Monday–Friday, 7 a.m.–9 p.m. Eastern Time.

*E-mail: support@grants.gov.*

Applicants have until midnight (12:00 a.m.), Washington, DC time of the closing date to ensure that their entire application has been uploaded to the Grants.gov site. *There are no exceptions to the above deadline. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.*

Please refer to the Grants.gov Web site, for definitions of various "application statuses" and the difference between a submission receipt and a submission validation. Applicants will receive a validation e-mail from grants.gov upon the successful submission of an application. Again, validation of an electronic submission via Grants.gov can take up to two business days. *Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.* ECA will *not* notify you upon receipt of electronic applications.

It is the responsibility of all applicants submitting proposals via the Grants.gov Web portal to ensure that proposals have been received by Grants.gov in their entirety, and ECA bears no responsibility for data errors resulting from transmission or conversion processes.

*IV.3g. Intergovernmental Review of Applications:* Executive Order 12372 does not apply to this program.

## V. Application Review Information

### *V.1. Review Process*

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards (cooperative agreements) resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below.

1. *Quality of the program idea:* Objectives should be reasonable, feasible, and flexible. The proposal should clearly demonstrate how the institution will meet the program's objectives and plan. The proposed program should be creative, age-appropriate, respond to the design outlined in the solicitation, and demonstrate originality. It should be clearly and accurately written, substantive, and with sufficient detail. Proposals should also include a plan to support participants' community activities upon their return home.

2. *Program planning:* A detailed plan should clearly demonstrate how project objectives would be achieved through the program activities, adhering to the program overview and guidelines described above. The substance of workshops, seminars, presentations, school-based activities, and/or site visits should be described in detail.

3. *Support of diversity:* The proposal should demonstrate the recipient's commitment to promoting the awareness and understanding of diversity in participant recruitment and selection and in program content. Applicants should demonstrate readiness to accommodate participants with physical disabilities.

4. *Institutional capacity and track record:* Proposed personnel and institutional resources in both the United States and in the partner countries should be adequate and appropriate to achieve the program goals. The proposal should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau awards as determined by Bureau Grants Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

5. *Program evaluation:* The proposal should include a plan to evaluate the program's success in meeting its goals, both as the activities unfold and after they have been completed. The proposal should include a draft survey questionnaire or other technique, plus a description of a methodology to link outcomes to original project objectives. The award recipient will be expected to submit intermediate reports after each project component is concluded.

6. *Cost-effectiveness and cost sharing:* The applicant should demonstrate efficient use of Bureau funds. The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate. The proposal should maximize cost-sharing through other private sector support as well as institutional direct funding contributions, which demonstrates institutional and community commitment.

## VI. Award Administration Information

### *VI.1. Award Notices*

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive a Federal Assistance Award (FAA) from the Bureau's Grants Office. The FAA and the original proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The FAA will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

*VI.2. Administrative and National Policy Requirements*

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A 122, "Cost Principles for Nonprofit Organizations."

Office of Management and Budget Circular A–21, "Cost Principles for Educational Institutions."

OMB Circular A–87, "Cost Principles for State, Local and Indian Governments".

OMB Circular No. A 110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations.

Please reference the following Web sites for additional information: *http://www.whitehouse.gov/omb/grants, http://fa.statebuy.state.gov.*

*VI.3. Reporting Requirements:* You must provide ECA with a hard copy original plus one copy of the following reports:

(1) A final program and financial report no more than 90 days after the expiration of the award;

(2) A concise, one-page final program report summarizing program outcomes no more than 90 days after the expiration of the award. This one-page report will be transmitted to OMB, and be made available to the public via OMB's USAspending.gov Web site—as part of ECA's Federal Funding Accountability and Transparency Act (FFATA) reporting requirements.

(3) A SF–PPR, "Performance Progress Report" Cover Sheet with all program reports, including the SF–PPR–E and SF–PPR–F.

(4) Quarterly or interim reports, as required in the Bureau cooperative agreement.

Award recipients will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV.3.d.3 Application and Submission Instructions above for Program Monitoring and Evaluation information.)

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

Program reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document. Financial reports must be submitted through the Payment Management System (PMS).

**VII. Agency Contacts**

For questions about this announcement, contact: Sarah Shields, Youth Programs Division, ECA/PE/C/PY, SA–5, 3rd Floor, U.S. Department of State, 2200 C Street, NW., Washington, DC 20522–0503, by telephone (202) 632–9261 or e-mail *ShieldsSD@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the above title and reference number ECA/PE/C/PY–11–69.

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

**VIII. Other Information**

*Notice*

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: April 29, 2011.

**J. Adam Ereli,**

*Principal Deputy Assistant Secretary, Bureau for Educational and Cultural Affairs, U.S. Department of State.*

[FR Doc. 2011–10998 Filed 5–4–11; 8:45 am]

BILLING CODE 4710–05–P

---

## DEPARTMENT OF STATE

**[Public Notice: 7443]**

## Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals: Young Turkey/Young America: A New Relationship for a New Age

*Announcement Type:* New Grant.

*Funding Opportunity Number:* ECA/PE/C/EUR–SCA–11–34.

*Catalog of Federal Domestic Assistance Number:* 19.415.

*Key Dates:*

*Application Deadline:* June 2, 2011.

*Executive Summary:*

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs invites proposal submissions for the FY 2011 Young Turkey/Young America Program: A New Relationship for a New Age. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 USC 501(c)(3) may submit proposals to conduct this professional fellowship program. The Young Turkey/Young America Program was first announced by Secretary of State Hillary Rodham Clinton in Ankara on March 7, 2009, as part of an ongoing commitment to strengthen U.S. Turkish relations. Turkish Young Turkey/Young America provides opportunities for young leaders, ages 24–35, in Turkey and the United States to advance critical dialogue, identify shared concerns, and develop grassroots initiatives that positively impact people's lives resulting in stronger ties between the two nations. Since the start of the initiative in 2009, more than 79 young Turkish and American leaders have engaged in substantive dialogue and collaborative projects addressing economic, environmental, social, and political issues facing both countries.

**I. Funding Opportunity Description**

*Authority*

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding authority for the program above is provided through legislation.

*I.2. Purpose*

The Young Turkey/Young America Program was created to recognize and support "one of the most important bilateral relationships in the world", create opportunities for sustained

partnerships, and identify ways to deepen ties between emerging young leaders in both countries. Young Turkey/Young America seeks to enhance the ability of rising leaders to more effectively engage in public dialogue, and establish projects of mutual concern around economic, environmental, political, and social challenges facing Turkey and the United States in the 21st Century. Through a two-way professional exchange model, complemented by a robust leadership development component, experiential learning opportunities, and collaborative exercises, Young Turkey/Young America provides opportunities for eligible individuals to work together to advance foreign policy dialogue, enhance their leadership skills, develop or strengthen existing partnerships, and advance concrete strategies to better address complex issues facing both countries.

ECA anticipates funding a total of two (2) to three (3) projects, for approximately $325,000 each, under the themes outlined below. Projects should occur over the course of one to two years and target young professionals currently working to improve and enhance the economic, environmental, political, and/or social well-being of their communities with an expressed interest in advancing US-Turkey bi-lateral relations.

The first project theme "Foreign Policy Dialogue Among Emerging Leaders" will link young Turkish and American leaders in substantive foreign policy dialogue on issues of importance to both countries.

The second project theme "Social and Economic Challenges for Future Leaders" will work to expand the capacity of nascent grassroots or not-for-profit organizations working in or with disadvantaged communities to address existing socio-economic issues and challenges.

Additional information on projects and participants is located under I.6 Young Turkey/Young America Fellowship Themes.

As a tool to developing grassroots initiatives that will positively impact people's lives and deepen ties between the future leaders of both countries, Young Turkey/Young America seeks to:

(1) Enhance the participants' ability to address complex economic, environmental, political, and social challenges through a two-way exchange model;

(2) Provide concrete tools for young professionals to advance as future leaders by developing skills for effective public discourse, negotiation, collaboration, coalitation building, and where applicable, community based management;

(3) Cultivate professional ties with U.S. and Turkish counterparts through collaborative follow-on projects;

(4) Create a network of engaged professionals committed to problem solving and engaged dialogue in both countries; and,

(5) Expand and strengthen the relationship between the people of the United States and Turkey to work in partnership to identify solutions to common issues and problems facing their countries and the global community.

In order to enhance the possibility that these projects will strengthen U.S. Turkish relations and colloborative initiatives continue after the conclusion of the exchange program, proposals should support a variety of follow-on projects. Special emphasis should be placed on ways that existing Web or social technologies can enhance follow-on efforts.

*I.3. Participants*

For the purposes of this program, "participants" are defined as citizens of the eligible countries selected through a merit-based, competition to participate in the Young Turkey/Young America Program. Participants must be early to mid-career professionals with demonstrated leadership abilities, working in grassroots or not-for-profit organizations, foreign policy think-tanks, or other institutions related to the two proposed themes with a stated interested in addressing economic, environmental, political, and/or social challenges through engaged partnership with Turkey and the United States. Every effort must be made to recruit program participants that reflect the diversity of the American and Turkish landscapes. Strong consideration should be given to participants who express a willingness to collaborate on a specific project of mutual interest.

Applicants should strive to maximize the number of participants and the length of the U.S. and Turkey-based program at the given funding levels. Therefore, applicants who engage public and private partners for programming support, and employ other creative techniques to increase or stretch funding dollars will be deemed more competitive than those that do not, under the Cost Effectiveness and Cost-Sharing review criterion.

Additional information about program participants is located under I.7 Young Turkey/Young America Fellowship Themes.

*I.4. Partner Organizations*

Applicants must identify the U.S.-based and any foreign-based organizations and individuals with whom they are proposing to collaborate to implement Young Turkey/Young America, and describe any previous cooperative activities. While having a permanent presence in Turkey is not required, applicants that are able to demonstrate institutional capacity in Turkey (whether through their own resources or through partnerships with other organizations or institutions) will be given strong consideration under the Institutional Planning and Track Record criterion.

Applicants should clearly outline and describe the role and responsibilities of all partner organizations in terms of project logistics, management and oversight. Proposals that include letters of commitment from partner organizations, proposed speakers or other possible U.S-based hosting organizations will be deemed more competitive under the Institutional Planning and Track Record criterion.

*I.5. Project Activities*

Proposals should include a description of the project theme to be addressed, how it advances U.S.-Turkish relations, and how it will be integrated into the exchange experience. Strong project designs will ground and augment the exchange experience with leadership development and experiential learning activities that relate to the proposed theme and larger program goals.

U.S.-based programs should be two to three weeks in length and focus on the development of joint projects between the Turkish and U.S. participants. Proposed schedules should also include a one- or two-day debriefing and evaluation session in Washington, DC at the end of the program. The Turkey component should be one to two weeks in duration and build upon key learning objectives and discussion points explored during the U.S.-based program. Schedules should include ample time to allow for continual implementation of joint community-based projects started during the U.S.-based program.

Proposals should clearly outline strategies to encourage regular communication between participants through electronic and digital communications both during and after the exchange program.

*I.6. Young Turkey/Young America Fellowship Themes*

Proposals need to embrace a program design that fully incorporates one of the

two proposed themes under Young Turkey/Young America.

*1. Foreign Policy Dialogue among Emerging Leaders:* This project is designed to support and promote transatlantic dialogue on foreign policy issues. Projects should allow emerging leaders to examine foreign policy issues in a context that encourages substantive dialogue on issues of common concern, including those that contribute to peace and stability in the Middle East, enhance energy security, promote conflict resolution, advance dialogue on border and immigration issues, and continue cooperation on bilateral economic relations. This program will focus on the elements of strategic partnerships, negotiation around shared interests, and engaged dialogue as an alternative to conflict.

Eligible participants include emerging leaders (approximately 15–20 from the U.S. and Turkey) currently involved in international affairs, youth wings of political parties, not-for-profit organizations with a civic society or youth focus, universities, business organizations, government agencies, media, and think tanks.

*2: Social and Economic Challenges for Future Leaders:* This project will work to expand the effectiveness and capacity of grassroots and not-for-profit organizations working with marginalized populations and economically disadvantaged communities to engage with policy makers and government officials, conduct community outreach and media campaigns, develop organizational capacity, including efforts at fundraising and constituent building, provide educational and other community services, and create strategic partnerships and alliances.

Eligible participants include emerging grassroots leaders (approximately 15–20 from the U.S. and Turkey) currently working within local, regional, or national grassroots and/or community non-profit organizations, government offices, media or think tanks working to improve the social, economic, and political standing of marginalized or disadvantaged communities.

*I.7. ECA and Embassy Involvement*

Proposals should include plans to work with ECA's Office of Public Affairs and Strategic Communications in developing a coordinated media and public outreach strategy to strengthen the identity, increase visibility, and raise public awareness of the Young Turkey/Young America Program. All grantees need to incorporate the respective program's brand (when provided by ECA) and give credit to ECA throughout all of its educational and outreach materials including its website with final approval by ECA.

Proposals should also include an articulated strategy as to how the grantee plans to work closely with the Public Affairs Section of the U.S. Embassy in Turkey during project recruitment and selection, implementation, and follow-on programming. Applicants should include concrete plans for PAS involvement in program outreach and activities and state their willingness to invite representatives of the Embassy to participate in interviews, pre-departure orientations, exchange components, and follow-on projects. All plans must be approved by ECA before their execution within Turkey. Applicants are strongly encouraged to consult with Public Affairs Officer Stefanie Altman-Winans, *winanss@state.gov,* at the U.S. Embassy in Ankara as they develop proposals responding to this RFGP.

*I.8. Proposal Content*

*I.8a. Executive Summary.* The Executive Summary should be one page in length and include the project title, proposed theme, nature of activity, requested funding level, project goals, names of partner organizations responsible for project implementation, number of American and Turkish participants, and anticipated outcomes. Executive summaries should also include a description of proposed participants and information about the wider audience benefiting from the program.

*I.8b. Proposal Narrative.* The narrative should include detailed information and outlined strategies for achieving program objectives and should address the following:

a. Vision (statement of need, objectives, goals, benefits)
b. Participating Organizations
c. Program Activities (advertisement, recruitment, pre-departure and U.S. orientations, cultural program, participant monitoring, etc.)
d. Collaborative and Follow-on Program Components
e. Program Evaluation
f. Project Management
g. Alumni Programming
h. Work Plan/Time Frame

Proposal narratives should be limited to 20 double spaced pages. Proposals should also include an acknowledgement to follow guidance in the PSI entitled "Acknowledgement of ECA's Financial Support and Use of the Department Seal". Proposals must affirm grantee organizations' plan to use ECA-developed program logos and the State Department seal on all relevant program materials, applications, websites, and other related materials.

Proposals must acknowledge compliance with "ECA's General Policy Guidance on Alumni Outreach/Follow-on and Engagement" provided in the PSI and describe efforts to support the Young Turkey/Young America alumni community. Special attention should be paid to creative approaches for integrating ECA's alumni and social media sites into the exchange program (*http://www.state.alumni.gov; http://www.exchangesconnect.gov*).

*I.8c. Budget.* Please refer to section IV.3e. Budget Submission in this document and the PSI for guidance on preparing your budget. The budget narrative and corresponding budget notes should be included under Tab E.

*I.8d Attachments*

I.8d.1. Resumes. Resumes of principal staff of all partner organizations involved in the implementation of the project should be included in Tab E. As outlined in the PSI, no resume should exceed two pages in length.

I.8d.2. Letters of commitment and/or letters of support. Letters of commitment or support from partner organizations and institutions that demonstrate a capacity to arrange and conduct U.S. and overseas activities should also be included in Tab E.

I.8e.3. Project Materials. Materials that support project design and implementation should be included in Tab E. These include but are not limited to:

1. Draft agendas of professional workshops, conferences and seminars including online modules, pre-departure orientation, U.S. based orientation and final conference activities
2. Draft application and recruitment materials
3. Draft selection and interview materials
4. Draft participant proposals and reporting guidelines for collaborative projects
5. Outline of alumni programming including sample small grant applications
6. Sample evaluation and survey instruments
7. Timeline for program implementation
8. Project promotional materials
9. Budget Narrative and budget notes
10. Samples or outlines of on-line sessions including innovative use of ECA's alumni websites.

Attachments that do not directly address the proposed project (i.e., organization brochures, pamphlets, unsolicited reports) are strongly discouraged.

## II. Award Information

*Type of Award:* Grant Agreement.
*Fiscal Year Funds:* FY 2011.
*Approximate Total Funding:* $500,000–$1,000,000.
*Approximate Number of Awards:* 2–3.
*Approximate Average Award:* $325,000.
*Anticipated Award Date:* September 1, 2011.
*Anticipated Project Completion Date:* August 30, 2013.

## III. Eligibility Information

*III.1. Eligible applicants:* Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

*III.2. Cost Sharing or Matching Funds:* There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110 (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

*III.3. Other Eligibility Requirements:*

(a.) Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. ECA anticipates making two awards above this $60,000 threshold to support program and administrative costs required to implement this exchange program. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

(b) Technical Eligibility: All proposals must comply with the following or your proposal will be declared technically ineligible and given no further consideration in the review process:

—Eligible applicants may not submit more than one proposal in this competition.
—If more than one proposal is received from the same applicant, all submissions will be declared technically ineligible and will receive no further consideration in the review process. **Please note:** Applicant organizations are defined by their legal name, and EIN number as stated on their completed SF–424 and additional supporting documentation outlined in the Proposal Submission Instructions (PSI) document.
—Eligible applicants may only propose working with the themes and countries listed in this RFGP.
—Please refer to the Proposal Submission Instructions (PSI) document for additional requirements.

## IV. Application and Submission Information

**Note:** Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*IV.1 Contact Information to Request an Application Package:* Please contact David Gustafson in the Office of Citizen Exchanges, ECA/PE/C, U.S. Department of State, SA–5, 3rd Floor, 2200 C St., NW., Washington, DC 20522–0503, ph: (202) 632–6083, *GustafsonDP@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number: **ECA/PE/C/EUR–SCA–11–34** located at the top of this announcement when making your request. Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation.

Please specify Linnéa E. Alison and refer to the Funding Opportunity Number **ECA/PE/C/EUR–SCA–11–34** located at the top of this announcement on all other inquiries and correspondence.

*IV.2. To Download a Solicitation Package Via Internet:* The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/grants/open2.html,* or from the Grants.gov Web site at *http://www.grants.gov.*

Please read all information before downloading.

*IV.3. Content and Form of Submission:* Applicants must follow all instructions in the Solicitation Package. The application should be submitted per the instructions under IV.3f. "Application Deadline and Methods of Submission" section below.

IV.3a. You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

IV.3b. All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document for additional formatting and technical requirements.

IV.3c. All federal award recipients and sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database and have a Dun and Bradstreet Data Universal Numbering System (DUNS) number. Recipients and sub-recipients must maintain accurate and up-to-date information in the CCR until all program and financial activity and reporting have been completed. All entities must review and update the information at least annually after the initial registration and more frequently if required information changes or another award is granted.

You must have nonprofit status with the IRS at the time of application. **Please note:** Effective January 7, 2009, all applicants for ECA federal assistance awards must include in their application the names of directors and/or senior executives (current officers, trustees, and key employees, regardless of amount of compensation). In fulfilling this requirement, applicants must submit information in one of the following ways:

(1) Those who file Internal Revenue Service Form 990, "Return of Organization Exempt From Income Tax," must include a copy of relevant portions of this form.

(2) Those who do not file IRS Form 990 must submit information above in the format of their choice.

In addition to final program reporting requirements, award recipients will also be required to submit a one-page document, derived from their program reports, listing and describing their grant activities. For award recipients, the names of directors and/or senior executives (current officers, trustees, and key employees), as well as the one-page description of grant activities, will be transmitted by the State Department to OMB, along with other information required by the Federal Funding Accountability and Transparency Act (FFATA), and will be made available to the public by the Office of Management and Budget on its *USASpending.gov* Web site as part of ECA's FFATA reporting requirements.

If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

IV.3d. Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1 Adherence To All Regulations Governing The J Visa.

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the "Responsible Officer" for the program under the terms of 22 CFR part 62, which covers the administration of the Exchange Visitor Program (J visa program). Under the terms of 22 CFR part 62, organizations receiving awards (either a grant or cooperative agreement) under this RFGP will be third parties "cooperating with or assisting the sponsor in the conduct of the sponsor's program." The actions of recipient organizations shall be "imputed to the sponsor in evaluating the sponsor's compliance with" 22 CFR part 62. Therefore, the Bureau expects that any organization receiving an award under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR part 62 *et seq.*

The Bureau of Educational and Cultural Affairs places critically important emphases on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by recipient organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should explicitly state in writing that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR part 62. If your organization has experience as a designated Exchange Visitor Program Sponsor, the applicant should discuss their record of compliance with 22 CFR part 62 *et seq.,* including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

The Office of Citizen Exchanges of ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from:

Office of Designation, Private Sector Programs Division, U.S. Department of State, ECA/EC/D/PS, SA–5, 5th Floor, 2200 C Street, NW., Washington, DC 20037.

IV.3d.2 *Diversity, Freedom and Democracy Guidelines.* Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. *Program Monitoring and Evaluation.* Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the recipient organization will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are "smart" (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes. Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

ECA encourages you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. Participant satisfaction with the program and exchange experience.

2. Participant learning, such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both

substantive (subject-specific) learning and mutual understanding.

3. Participant behavior, concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.

4. Institutional changes, such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

**Please note:** Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (i.e., surveys, interviews, or focus groups). (Please note that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Recipient organizations will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

IV.3e. Please take the following information into consideration when preparing your budget:

IV.3e.1. Applicants must submit SF–424A—"Budget Information—Non-Construction Programs" along with a comprehensive budget for the entire program. **Budget requests may not exceed $325,000**. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

IV.3e.2. Allowable costs for the program include the following:

1. International and Domestic Air Fares; Visas; Transit Costs; Ground Transportation Costs and Airline baggage fees. Please note that all air travel must be in compliance with the Fly America Act. There is no charge for J–1 visas for participants in Bureau sponsored programs.

2. Per Diem. For U.S.-based programming, organizations should refer to the published Federal per diem rates for individual U.S. cities. *Domestic per diem rates* may be accessed at: *http://www.gsa.gov/portal/category/21287*.

ECA requests applicants to budget realistic costs that reflect the local economy and do not exceed Federal per diem rates. *Foreign per diem rates* can be accessed at: *http://aoprals.state.gov/content.asp?content_id=184&menu_id=78*.

3. Book and Cultural Allowance. Participants are entitled to a one-time cultural allowance of $150 per person, plus a book allowance of $50. U.S. program staff members are not eligible to receive these benefits.

4. Consultants. Consultants may be used to provide specialized expertise or to make presentations. Daily honoraria may not exceed $250 per day. Subcontracting organizations may also be used, in which case the written agreement between the prospective grantee and subcontractor should be included in the proposal. Subcontracts should be itemized in the budget.

5. Room Rental. Room rental may not exceed $250 per day per conference room.

6. Materials Development. Your proposal may contain costs to purchase, develop and translate materials for participants.

7. Supplies. Proposals may contain costs to purchase equipment for programming such as computers, fax machines. Costs for furniture are not allowed. Supply costs for the purchase of equipment must be kept to a minimum.

8. Working Meal. No more than two working meals may be provided for each program component. At least one working meal should be budgeted for the D.C. final debrief. The cost per person should not exceed $45 for the working meal. No charges may be made against U.S. Government funds for alcoholic beverages. The number of invited guests should not exceed the number of funded program participants by more than a factor of two (i.e., no more than twenty invited guests for a working meal involving ten funded program participants).

9. Return Travel Allowance. A return travel allowance of $70 for each participant may be included in the budget. The allowance may be used for incidental expenses incurred during international travel.

10. Health Insurance. Foreign participants will be covered under the terms of a U.S. Department of State-sponsored health insurance policy. The premium is paid by the U.S. Department of State directly to the insurance company. Applicants are permitted to include costs for travel insurance for participants in the budget.

11. Wire Transfer Fees. When necessary, applicants may include costs to transfer funds to partner organizations overseas. Grantees are urged to research applicable taxes that may be imposed on these transfers by host governments.

12. In-country Travel Costs for Visa Processing Purposes. Given the requirements associated with obtaining J–1 visas for ECA-supported participants, applicants should include costs for any travel associated with visa interviews or DS–2019 pick-up.

13. Administrative Costs. Costs necessary for the effective administration of the program may include salaries for grantee organization employees, benefits, and other direct and indirect costs per detailed instructions in the Application Package. While there is no rigid ratio of administrative to program costs, proposals in which the administrative costs do not exceed 25% of the total requested ECA grant funds will be more competitive under the cost effectiveness and cost sharing criterion, per item V.1 in the RFGP. Proposals should show strong administrative cost sharing contributions from the applicant, the in-country partner and other sources. For organizations located outside of the DC metropolitan area, please also include in the administrative portion of your budget plans to travel to Washington, DC, to meet with your program officer within the first 45 days after the grant has been awarded.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

*IV.3f. Application Deadline and Methods of Submission*

*Application Deadline Date:* June 2, 2011

*Reference Number:* ECA/PE/C/EUR–SCA–11–34

*Methods of Submission:*

Applications may be submitted in one of two ways: (1) In hard-copy, via a nationally recognized overnight delivery service (i.e., Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.), or

(2) Electronically through *http://www.grants.gov.*

Along with the Project Title, all applicants must enter the above

Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3f.1. Submitting Printed Applications

Applications must be shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will not notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages may not be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

**Important note:** When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to "ECA/EX/PM".

The original and eight (8) copies of the application should be sent to: Program Management Division ECA–IIP/EX/PM, Ref.: ECA/PE/C/EUR–SCA–11–34, SA–5, Floor 4, Department of State, 2200 C Street, NW., Washington, DC 20037.

Applicants submitting hard-copy applications must also submit the "Executive Summary" and "Proposal Narrative" sections of the proposal in text (.txt) or Microsoft Word format on CD–ROM. As appropriate, the Bureau will provide these files electronically to Public Affairs Section(s) at the U.S. Embassy(ies) for its(their) review.

IV.3f.2. Submitting Electronic Applications

Applicants have the option of submitting proposals electronically through Grants.gov (*http://www.grants.gov*). Complete solicitation packages are available at Grants.gov in the "Find" portion of the system.

**Please Note:** ECA bears no responsibility for applicant timeliness of submission or data errors resulting from transmission or conversion processes for proposals submitted via Grants.gov.

Please follow the instructions available in the 'Get Started' portion of the site (*http://www.grants.gov/GetStarted*).

Several of the steps in the Grants.gov registration process could take several weeks. Therefore, applicants should check with appropriate staff within their organizations immediately after reviewing this RFGP to confirm or determine their registration status with Grants.gov.

Once registered, the amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your internet connection. In addition, validation of an electronic submission via Grants.gov can take up to two business days.

Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.

The Grants.gov website includes extensive information on all phases/aspects of the Grants.gov process, including an extensive section on frequently asked questions, located under the "For Applicants" section of the website. ECA strongly recommends that all potential applicants review thoroughly the Grants.gov website, well in advance of submitting a proposal through the Grants.gov system. ECA bears no responsibility for data errors resulting from transmission or conversion processes.

Direct all questions regarding Grants.gov registration and submission to:

**Grants.gov Customer Support**

*Contact Center Phone:* 800–518–4726
*Business Hours:* Monday–Friday, 7 a.m.–9 p.m. Eastern Time
*Email: support@grants.gov*

Applicants have until midnight (12 a.m.), Washington, DC time of the closing date to ensure that their entire application has been uploaded to the Grants.gov site. There are no exceptions to the above deadline. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.

Please refer to the Grants.gov website, for definitions of various "application statuses" and the difference between a submission receipt and a submission validation. Applicants will receive a validation e-mail from grants.gov upon the successful submission of an application. Again, validation of an electronic submission via Grants.gov can take up to two business days. *Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.* ECA will *not* notify you upon receipt of electronic applications.

It is the responsibility of all applicants submitting proposals via the Grants.gov web portal to ensure that proposals have been received by Grants.gov in their entirety, and ECA bears no responsibility for data errors resulting from transmission or conversion processes.

IV.3g. Intergovernmental Review of Applications: Executive Order 12372 does not apply to this program.

## V. Application Review Information

*V.1. Review Process*

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for grant agreements resides with the Bureau's Grants Officer.

**Review Criteria**

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

*1. Quality of the Program Idea:* Proposals should exhibit originality, substance, precision, and relevance to the Bureau's mission.

*2. Program Planning and Ability to Achieve Objectives:* Program objectives should be stated clearly and should reflect the applicant's expertise in the subject area and region. Objectives should respond to the topics in this announcement and should relate to the current conditions in the target country/countries. Detailed agendas and relevant work plans should complement the narrative in explaining how objectives will be achieved. Timelines should be comprehensive in nature and include deadlines for completion of major tasks. The substance of workshops, seminars and/or consulting should be described in detail with sample schedules

included for each major workshop, seminar, or conference proposed. Responsibilities of proposed in-country partners should be clearly described. A discussion of how the applicant intends to address language issues should be included, if needed.

*3. Institutional Capacity and Track Record:* Proposals should include (1) the institution's mission and date of establishment; (2) detailed information about proposed in-country partner(s) and the history of the partnership; (3) an outline of prior awards—U.S. government and/or private support received within the scope of RFGP's theme of either U.S. Turkish foreign policy or social and economic development; and (4) descriptions and resumes of experienced staff members who will implement the program. The proposal should reflect the institution's expertise in the subject area and knowledge of the conditions in the target country/countries. Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by Bureau Grants Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants. Proposed personnel and institutional resources should be adequate and appropriate to achieve the program's goals. The Bureau strongly encourages applicants to submit letters of support from proposed in-country partners, part participants, or proposed hosting organizations.

*4. Cost Effectiveness and Cost Sharing:* Overhead and administrative costs in the proposal budget, including salaries, honoraria and subcontracts for services, should be kept to a minimum. Proposals in which the administrative costs do not exceed 25% of the total requested ECA grant funds will be more competitive under this criterion. Applicants are strongly encouraged to cost share a portion of overhead and administrative expenses. Cost-sharing and in-kind contributions, including contributions from the applicant, proposed in-country partner(s), and other sources should be included in the budget request. Proposal budgets that do not reflect cost sharing will be deemed not competitive under this criterion.

*5. Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venue, program evaluation, etc.) and program content (orientation, wrap-up sessions, program meetings, resource materials, follow-up activities, etc.). Applicants should refer to the Bureau's Diversity, Freedom and Democracy Guidelines in the Proposal Submission Instructions (PSI).

*6. Multiplier Effect and Follow-on Activities:* Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term institutional and individual linkages.

*7. Project Evaluation:* Proposals should include a detailed plan to evaluate the program, both as activities unfold and at the end of the program. Program objectives should target clearly defined results in quantitative terms. Competitive evaluation plans will describe how applicant organizations would measure these results, including the evaluative methodology and tools to be utilized and proposals. Proposals should include draft data collection instruments (surveys, questionnaires, etc.) in Tab E and if relevant, samples data sets from similarly conducted programs.

## VI. Award Administration Information

### *VI.1a. Award Notices*

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive a Federal Assistance Award (FAA) from the Bureau's Grants Office. The FAA and the original proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The FAA will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

### *VI.2. Administrative and National Policy Requirements*

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, "Cost Principles for Nonprofit Organizations."

Office of Management and Budget Circular A–21, "Cost Principles for Educational Institutions."

OMB Circular A–87, "Cost Principles for State, Local and Indian Governments".

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations

Please reference the following websites for additional information: *http://www.whitehouse.gov/omb/grants, http://fa.statebuy.state.gov.*

*VI.3. Reporting Requirements:* You must provide ECA with an electronic copy of the following reports at reportseca@state.gov:

**Mandatory**

(1) A final program and financial report no more than 90 days after the expiration of the award;

(2) A concise, one-page final program report summarizing program outcomes no more than 90 days after the expiration of the award. This one-page report will be transmitted to OMB, and be made available to the public via OMB's USAspending.gov website—as part of ECA's Federal Funding Accountability and Transparency Act (FFATA) reporting requirements.

(3) A SF–PPR, "Performance Progress Report" Cover Sheet with all program reports.

(4) Quarterly program and financial reports highlighting all major activities undertaken during the grant period including program analysis and lessons learned.

Award recipients will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV. Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

**Program Data Requirements**

Award recipients will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as required. As a minimum, the data must include the following:

(1) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the agreement or who benefit from the award funding but do not travel.

(2) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA Program Officer at least one month prior to the official opening of the activity.

**VII. Agency Contacts**

For questions about this announcement, please contact: Linnéa E. Allison, U.S. Department of State, Office of Citizen Exchanges, 2200 C Street (SA–5, 3rd Floor), NW., Washington, DC 20522–0503,(202) 632–6060 (tel.) (202) 632–6492 (fax), or *allisonle@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the following title and number Young Turkey/Young America, ECA/PE/C/EUR–SCA–11–34

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

**VIII. Other Information**

*Notice*

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: April 29, 2011.

**J. Adam Ereli,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, U.S. Department of State.*

[FR Doc. 2011–11000 Filed 5–4–11; 8:45 am]

**BILLING CODE 4710–05–P**

## DEPARTMENT OF STATE

**[Public Notice: 7438]**

## Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals; International Visitor Leadership Program Assistance Award

*Announcement Type:* New Cooperative Agreement.

*Funding Opportunity Number:* ECA/PE/V–12–01.

*Catalog of Federal Domestic Assistance Number:* 19.402.

*Key Dates:* October 1, 2011—September 30, 2012.

*Application Deadline:* June 17, 2011.

*Executive Summary:* The Office of International Visitors, Bureau of Educational and Cultural Affairs (ECA/PE/V), United States Department of State (DoS), announces an open competition for up to four assistance awards to administer the International Visitor Leadership Program (IVLP). The IVLP is the U.S. Department of State's premier professional exchange program. Launched in 1940, the IVLP is a professional exchange program that seeks to build mutual understanding between the U.S. and other nations through carefully designed short-term visits to the U.S. for current and emerging foreign leaders. These visits reflect the International Visitors' professional interests and support the foreign policy goals of the United States.

The amount of funding available is approximately $4,700,000, pending the availability of FY 2012 funds. ECA anticipates awarding up to four cooperative agreements for the total funding available. The assistance awards, all together, will support programming for approximately *2,000* International Visitors (IVs). Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals. Applicants may submit only one proposal under this competition. If multiple proposals are received from the same applicant, all submissions will be declared ineligible and receive no further consideration in the review process.

**I. Funding Opportunity Description**

*Authority*

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding authority for the program above is provided through legislation.

*Purpose:* The International Visitor Leadership Program seeks to increase mutual understanding between the U.S. and foreign publics through carefully designed professional programs. IVLP projects support U.S. foreign policy objectives. Participants are current or potential foreign leaders in government, politics, media, education, science, non-government organizations (NGOs), the arts, and other key fields. They are selected by officers of U.S. embassies overseas and are approved by the DoS staff in Washington, DC. Since the program's inception in 1940, there have been nearly 200,000 distinguished participants in the program. More than 320 program alumni subsequently became heads of state or government in their home countries. All IVLP projects maintain a non-partisan character.

The Bureau seeks proposals from nonprofit organizations for development and implementation of professional programs for Bureau-sponsored International Visitors to the U.S. Once the awards are made, separate proposals will be required for each group project [Single Country (SCP), Sub-Regional (SRP), Regional (RP), and Multi-Regional (MRP)] as well as less formal proposals for Individual and Individuals Traveling Together (ITT) and Voluntary Visitors (Volvis) programs. Each program will be focused on a substantive theme. Some typical IVLP projects themes are: (1) U.S. foreign policy; (2) U.S. government and political system; (3) economic development; (4) education; (5) media; (6) interfaith dialogue; (7) freedom of information; (8) NGO management; (9) women's issues; (10) tolerance and diversity; (11) counterterrorism; (12) democracy and human rights; (13) rule of law; (14) international crime; and (15) environmental issues. IVLP projects must conform to all Bureau requirements and guidelines. Please refer to the Program Objectives, Goals, and Implementation (POGI) document for a more detailed description of each type of IVLP program.

*Guidelines:* Goals and objectives for each specific IVLP projects will be

shared with the award recipients at an appropriate time following the announcement of the assistance awards. DoS will provide close coordination and guidance throughout the duration of the awards. Award recipients will consult closely with the responsible ECA/PE/V Program Officer throughout the development, implementation, and evaluation of each IVLP projects. Prospective program agencies should demonstrate the potential to develop the following types of programs.

1. Programs must contain substantive meetings that focus on foreign policy goals and program objectives and are presented by experts. Meetings, site visits, and other program activities should promote dialogue between participants and their U.S. professional counterparts. Programs must be balanced to show different sides of an issue.

2. Most programs will be three weeks long and will begin in Washington, DC, with an orientation and overview of the issues and a central examination of Federal policies regarding these issues. Well-paced program itineraries usually include visits to four or five communities. Program itineraries ideally include urban and rural small communities in diverse geographical and cultural regions of the U.S., as appropriate to the program theme.

3. Programs should provide opportunities for participants to experience the diversity of American society and culture. Participants in RPs or MRPs are divided into smaller sub-groups for simultaneous visits to different communities, with subsequent opportunities to share their experiences with the full group once it is reunited.

4. Programs should provide opportunities for the participants to share a meal or similar experience (home hospitality) in the homes of Americans of diverse occupational, age, gender, and ethnic groups. Some individual and group programs might include an opportunity for an overnight stay (home stay) in an American home.

5. Programs should provide opportunities for participants to address student, civic and professional groups in relaxed and informal settings.

6. Participants should have appropriate opportunities for site visits and hands-on experiences that are relevant to program themes. The award recipients may propose professional "shadowing" experiences with U.S. professional colleagues for some programs (a typical shadowing experience means spending a half- or full-workday with a professional counterpart.)

7. Programs should also allow time for participants to reflect on their experiences and, in group programs, to share observations with program colleagues. Participants should have opportunities to visit cultural and tourist sites.

8. The award recipients must make arrangements for community visits through affiliates of the National Council for International Visitors (NCIV). In cities where there is no such council, the award recipients will arrange for coordination of local programs.

*Qualifications*

1. Proposals must demonstrate a minimum of four years of successful experience in coordinating international exchanges.

2. Proposals must demonstrate the ability to develop and administer IVLP programs.

3. Proposals must demonstrate an applicant's broad knowledge of international relations and U.S. foreign policy issues.

4. Proposals must demonstrate an applicant's broad knowledge of the United States and U.S. domestic issues.

5. Award recipients must have a Washington, DC presence. Applicants who do not currently have a Washington, DC presence must include a detailed plan in their proposal for establishing such a presence by October 1, 2011. The costs related to establishing such a presence must be borne by the award recipient. No such costs may be included in the budget submission in this proposal. The award recipient must have e-mail capability, access to Internet resources, and the ability to exchange data electronically with all partners involved in the International Visitor Leadership Program.

6. Proposals must demonstrate that an applicant has an established resource base of programming contacts and the ability to keep this resource base continuously updated. This resource base should include speakers, thematic specialists, or practitioners in a wide range of professional fields in both the private and public sectors.

7. All proposals must demonstrate sound financial management.

8. All proposals must contain a sound management plan to carry out the volume of work outlined in the Project Objectives, Goals, and Implementation guidelines (POGI). This plan should include an appropriate staffing pattern and a work plan/timeframe.

9. Applicant organizations must include a proposed budget and identify the number of visitors the proposed funding levels will support.

10. Proposals must describe capacity to employ additional staff during particularly busy months of the IVLP cycle and to assume additional projects, if requested. The proposed budget should also include a separate budget spreadsheet for any supplemental program team(s) proposed.

11. Include a separate plan for how your organization can feasibly implement a direct billing payment system with hotels in Washington, DC and across the U.S. for all IVLP projects by FY 2014. This proposal should include a detailed timeline, staffing requirements, and total costs involved over time. The plan should identify any proposed savings to the United States Government anticipated from implementing a direct billing payment system.

12. Applicants must include in their proposal narrative a discussion of "lessons learned" from past exchange coordination experiences, and how these will be applied in implementing the International Visitor Leadership Program.

13. Award recipients must have the capability to utilize the World Wide Web for the electronic retrieval of program data from the Department of State's IVLP Web site. The award recipient's office technology must be capable of exchanging information with all partners involved in the International Visitor Leadership Program. The award recipient must have the capability to electronically communicate through eNPA (Electronic National Program Agency), the software application that allows award recipients to share information and data electronically through the Department of State's Exchange Visitor Database (EVDB-e) and with the Councils for International Visitors (CIVs), as well as to produce a national program book and other supporting documents (*e.g.,* appointment requests and confirmations, participant welcome letters, and mailing labels) generated directly into Microsoft Word.

14. Applicants must include as a separate attachment under TAB G of their proposals the following:

a. Samples of at least two schedules for international exchange or training programs that they have coordinated within the past four years that they are particularly proud of and that they feel demonstrate their organization's competence and abilities to conduct the activities outlined in the RFGP;

b. Samples of orientation and NPA self-evaluation materials used in past international exchange or training programs.

*Requirements for Past Performance References*

In addition to Letters of Endorsement, DoS will also use past performance as an indicator of an applicant's ability to successfully perform the work. TAB E of the proposal must contain any letters of endorsement and between three and five references who may be called upon to discuss recently completed or ongoing work performed for professional exchange programs (which may include the IVLP). The reference must contain the information outlined below. Please note that the requirements for submission of past performance information also apply to all proposed sub-recipients when the total estimated cost of the sub-award is over $100,000.

At a minimum, the applicant must provide the following information for each reference:

- Name of the reference organization.
- Project name.
- Project description.
- Performance period of the contract/grant.
- Amount of the contract/grant.
- Technical contact person and telephone number for referenced organization.
- Administrative contact person and telephone number for referenced organization.

DoS may contact representatives from the organizations cited in the examples to obtain information on the applicant's past performance. DoS also may obtain past performance information from sources other than those identified by the applicant.

*Personnel:* Applicants must include complete and current resumes of the key personnel who will be involved in the program management, design, and implementation of IVLP programs. Each resume is limited to no more than two pages per person.

*Budget Guidelines*

Applicants are required to submit a comprehensive line-item administrative budget in accordance with the instructions in the Solicitation Package (Proposal Submission Instructions). The submission must include a summary budget and a detailed budget showing all administrative costs. Proposed staffing and costs associated with staffing must be appropriate to the requirements outlined in the RFGP and in the Solicitation Package. Cost sharing is encouraged and should be shown in the budget presentation.

The Department of State is seeking proposals from public and private nonprofit organizations that are not already in communication with DoS regarding an FY–2012 assistance award from ECA/PE/V. In a cooperative agreement, ECA is substantially involved in program activities above and beyond routine monitoring. All applicants must have a minimum of four years' experience conducting international exchanges, an ability to closely consult with DoS staff throughout program administration, and proven fiscal management integrity. Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

The Bureau of Educational and Cultural Affairs, as sponsor and manager of the International Visitor Leadership Program, plays a significant role in the planning, implementation, and evaluation of all types of International Visitor Leadership Programs and is responsible for all communication with overseas missions. The Bureau will provide close coordination and guidance throughout the duration of the awards. Award recipients will consult closely with the responsible ECA/PE/V Program Officer throughout the development, implementation, and evaluation of each IVLP projects.

All liaisons shall be with the designated elements of the DoS relative to the following responsibilities incurred by the recipient under this agreement:

A. Program Administration—Bureau of Educational and Cultural Affairs, Office of International Visitors, Community Resources Division, ECA/PE/V/C.

B. Financial—Bureau of Educational and Cultural Affairs, Grants Division, ECA–IIP/EX/G.

## II. Award Information

*Type of Award:* Cooperative Agreement.

ECA's level of involvement in this program is listed under number I above.

*Fiscal Year Funds:* FY 2012.

*Approximate Total Funding:* $4,700,000.

*Approximate Number of Awards:* Up to four.

*Approximate Average Award:* $986,464.

*Floor of Award Range:* $630,000.

*Ceiling of Award Range:* $2,700,000.

*Anticipated Award Date:* Pending availability of funds, October 1, 2011.

*Anticipated Project Completion Date:* September 30, 2012.

*Additional Information*

Pending successful implementation of this program and the availability of funds in subsequent fiscal years, it is ECA's intent to renew this grant or cooperative agreement for five additional fiscal years, before openly competing it again.

## III. Eligibility Information

*III.1. Eligible Applicants*

Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

*III.2.* Cost Sharing or Matching Funds: There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

*III.3. Other Eligibility Requirements*

(a) Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. ECA anticipates awarding up to four cooperative agreements, of which the minimum award will be $630,000. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

(b) Technical Eligibility: All proposals must comply with the technical eligibility requirements specified in the Proposal Submission Instructions (PSI) and the Project Objectives, Goals, and Implementation (POGI) documents. Failure to do so will result in proposals being declared technically ineligible and given no further consideration in the review process.

Eligible applicants may not submit more than one proposal in this competition.

—If more than one proposal is received from the same applicant, all submissions will be declared technically ineligible and will receive no further consideration in the review process. *Please note:* Applicant organizations are defined by their legal name and EIN number as stated on their completed SF–424 and additional supporting documentation outlined in the Proposal Submission Instructions (PSI) document.

**IV. Application and Submission Information:**

**Note:** Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*IV.1 Contact Information to Request an Application Package*

Please contact the Office of International Visitors, ECA/PE/V, SA–5, 3rd Floor, U.S. Department of State, 2200 C Street, NW., Washington, DC 20037, (202)632–3288, or e-mail *JohnsonPA2@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/PE/V–12–01 located at the top of this announcement when making your request.

Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation.

It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Patricia Johnson and refer to the Funding Opportunity Number ECA/PE/V–12–01 located at the top of this announcement on all other inquiries and correspondence.

*IV.2. To Download a Solicitation Package Via Internet*

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/grants/open2.html,* or from the Grants.gov Web site at *http://www.grants.gov.*

Please read all information before downloading.

*IV.3. Content and Form of Submission:* Applicants must follow all instructions in the Solicitation Package. The application should be submitted per the instructions under IV.3f. "Application Deadline and Methods of Submission" section below.

*IV.3a.* You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

*IV.3b.* All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

*IV.3c.* All Federal award recipients and sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database and have a Dun and Bradstreet Data Universal Numbering System (DUNS) number. Recipients and sub-recipients must maintain accurate and up-to-date information in the CCR until all program and financial activity and reporting have been completed. *All entities must review and update the information at least annually after the initial registration and more frequently if required information changes or another award is granted.*

You must have nonprofit status with the IRS at the time of application. *Please note:* Effective January 7, 2009, all applicants for ECA Federal assistance awards must include in their application the names of directors and/or senior executives (current officers, trustees, and key employees, regardless of amount of compensation). In fulfilling this requirement, applicants must submit information in one of the following ways:

(1) Those who file Internal Revenue Service Form 990, "Return of Organization Exempt From Income Tax," must include a copy of relevant portions of this form.

(2) Those who do not file IRS Form 990 must submit information above in the format of their choice.

In addition to final program reporting requirements, award recipients will also be required to submit a one-page document, derived from their program reports, listing and describing their grant activities. For award recipients, the names of directors and/or senior executives (current officers, trustees, and key employees), as well as the one-page description of grant activities, will be transmitted by the State Department to OMB, along with other information required by the Federal Funding Accountability and Transparency Act (FFATA), and will be made available to the public by the Office of Management and Budget on its USASpending.gov Web site as part of ECA's FFATA reporting requirements.

If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

*IV.3d.* Please take into consideration the following information when preparing your proposal narrative:

*IV.3d.1 Adherence to All Regulations Governing the J Visa*

The Bureau of Educational and Cultural Affairs places critically important emphases on the security and proper administration of the Exchange Visitor (J visa) Programs and adherence by award recipients and sponsors to all regulations governing the J visa. Therefore, proposals should demonstrate the applicant's capacity to meet all requirements governing the administration of the Exchange Visitor Programs as set forth in 22 CFR part 62, including the oversight of Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, recordkeeping, reporting and other requirements. The Office of International Visitors (ECA/PE/V) will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: Office of Designation, Private Sector Programs Division, U.S. Department of State, ECA/EC/D/PS, SA–5, 5th Floor, 2200 C Street, NW., Washington, DC 20037.

Please refer to Solicitation Package for further information.

*IV.3d.2 Diversity, Freedom and Democracy Guidelines*

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

*IV.3d.3. Program Monitoring and Evaluation*

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. In support of the Bureau's evaluation goals, the Office of International Visitors will administer a post-program evaluation for International Visitors upon conclusion of Regional and Multi-Regional programs.

In addition, applicants must monitor and evaluate the program's success, both as activities unfold and at the end of each program. (See Project Objectives, Goals and Implementation (POGI) document.) Proposal submissions should include a monitoring and evaluation plan that demonstrates: An understanding of overall IVLP goals, as well as the objectives of assigned projects; the anticipated results and outcomes, including specific changes in International Visitors' behavior, knowledge, skills, and status resulting from the program activities; and the link between the outcomes and the original project objectives.

Proposals should further demonstrate how applicants will obtain an understanding of the goals and objectives of each assigned IVLP program, and how applicants will review and analyze the outcomes and results upon conclusion of each IVLP program. For regional and multi-regional programs, participation at a final oral evaluation session is expected and a final program report is required. (See Project Objectives, Goals and Implementation (POGI) document.) Proposal submissions should demonstrate how award recipients will apply the feedback provided by International Visitors to strengthen the overall goals and objectives of the International Visitor Leadership Program.

*IV.3d.4. Alumni Outreach Follow On Programming*

No alumni outreach follow-on programming is expected or will be funded. However, the Bureau expects that all recipient organization(s) will encourage and assist participants in registering and using the State Alumni Web site (alumni.state.gov) and the Exchanges Connect Web site (connect.state.gov) at multiple points during their exchange experience, at a minimum during program orientations and pre-departure briefings as well as at the end of programs to encourage participants to create groups and/or forums on exchanges connect. Proposals should detail how the Web sites will be promoted to exchange participants and how the recipient organization (s) will facilitate participant registration. The Bureau expects that all recipient organization (s) will place a link to both State Alumni and Exchanges Connect on their own Web sites. IV.3e.1 Please take the following information into consideration when preparing your budget:

*IV.3e.1.* Applicants must submit SF–424A—"Budget Information—Non-Construction Programs" along with a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

*IV.3e.2.* Allowable costs for the program include the following:

(1) Staff Salaries and Benefits;
(2) Office and Program Supplies;
(3) Telephone and Communications;
(4) Staff Travel and Per Diem;
(5) ADP Equipment Maintenance and IT Costs;
(6) Indirect Costs.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

*IV.3f. Application Deadline and Methods of Submission*

*Application Deadline Date:* June 17, 2011.

*Reference Number:* ECA/PE/V–12–01.

Methods of Submission

Applications may be submitted in one of two ways:

(1) In hard-copy, via a nationally recognized overnight delivery service (*i.e.,* Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, *etc.*), or

(2) Electronically through *http://www.grants.gov.*

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

*IV.3f.1 Submitting Printed Applications*

Applications must be shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will *not* notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages *may not* be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

**Important note:** When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to "ECA/EX/PM".

The original and 10 copies of the application should be sent to: Program Management Division, ECA–IIP/EX/PM, Ref.: ECA/PE/V–12–01, SA–5, Floor 4, Department of State, 2200 C Street, NW., Washington, DC 20037.

Applicants submitting hard-copy applications must also submit the "Executive Summary" and "Proposal Narrative" sections of the proposal in text (.txt) or Microsoft Word format on CD–ROM. As appropriate, the Bureau will provide these files electronically to Public Affairs Section(s) at the U.S. embassy(ies) for its(their) review.

*IV.3f.2—Submitting Electronic Applications*

Applicants have the option of submitting proposals electronically through Grants.gov (*http://www.grants.gov*). Complete solicitation packages are available at Grants.gov in the "Find" portion of the system.

**Please Note:** ECA bears no responsibility for applicant timeliness of submission or data errors resulting from transmission or conversion processes for proposals submitted via Grants.gov.

Please follow the instructions available in the 'Get Started' portion of the site (*http://www.grants.gov/GetStarted*).

Several of the steps in the Grants.gov registration process could take several weeks. Therefore, applicants should check with appropriate staff within their organizations immediately after reviewing this RFGP to confirm or determine their registration status with Grants.gov.

Once registered, the amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your Internet connection. In addition, validation of an electronic submission via Grants.gov can take up to two business days.

*Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.*

The Grants.gov Web site includes extensive information on all phases/aspects of the Grants.gov process, including an extensive section on frequently asked questions, located under the "For Applicants" section of the Web site. ECA strongly recommends that all potential applicants review thoroughly the Grants.gov Web site, well in advance of submitting a proposal through the Grants.gov system. ECA bears no responsibility for data errors resulting from transmission or conversion processes.

Direct all questions regarding Grants.gov registration and submission to: Grants.gov Customer Support. *Contact Center Phone:* 800–518–4726. *Business Hours:* Monday–Friday, 7AM–9PM Eastern Time, *E-mail: support@grants.gov.*

Applicants have until midnight (12:00 a.m.), Washington, DC time of the closing date to ensure that their entire application has been uploaded to the Grants.gov site. *There are no exceptions to the above deadline. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.*

Please refer to the Grants.gov Web site, for definitions of various "application statuses" and the difference between a submission receipt and a submission validation. Applicants will receive a validation e-mail from grants.gov upon the successful submission of an application. Again, validation of an electronic submission via Grants.gov can take up to two business days. *Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.* ECA will *not* notify you upon receipt of electronic applications.

It is the responsibility of all applicants submitting proposals via the Grants.gov Web portal to ensure that proposals have been received by Grants.gov in their entirety, and ECA bears no responsibility for data errors resulting from transmission or conversion processes.

*IV.3g. Intergovernmental Review of Applications*

Executive Order 12372 does not apply to this program.

**V. Application Review Information**

*V.1. Review Process*

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards cooperative agreements resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Evidence of Understanding/Program Planning:* The proposal should convey that the applicant has a good understanding of the overall goals and objectives of the IVLP. It should exhibit originality, substance, and precision, and be responsive to the requirements stated in the RFGP and the Solicitation Package. The proposal should contain a detailed and relevant work plan that demonstrates substantive intent and logistical capacity. The agenda and plan should adhere to the program overview and guidelines described in the RFGP and the POGI.

2. *Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of program resources and interlocutors, program venue, *etc.*) and program content (orientation and wrap-up sessions, program meetings, resource materials and follow-up activities).

3. *Institutional Capacity:* The award recipient must have a Washington, DC presence. Applicants who do not currently have a Washington, DC presence must include a detailed plan in their proposal for establishing such a presence by October 1, 2011. The costs related to establishing such a presence must be borne by the award recipient. No such costs may be included in the budget submission in this proposal. The proposal should clearly demonstrate the applicant's capability for performing the type of work required by the IVLP and how the institution will execute its program activities to meet the goals of the IVLP. It should reflect the applicant's ability to design and implement, in a timely and creative manner, professional exchange programs which encompass a variety of project themes. Proposed personnel and institutional resources should be adequate and appropriate to achieve the program goals. The proposal must demonstrate that the applicant has or can recruit adequate and well-trained staff. All recipients must submit their IVLP and national itinerary data electronically to the DoS by utilizing either the eNPA tool provided by the Department or the mandated standard data format submission that has been established as an interface to existing legacy systems.

4. *Institution's Record/Ability:* The proposal should demonstrate an institutional record of a minimum of four years of successful experience in conducting IVLP or other professional exchange programs, which are similar in

nature and magnitude to the scope of work outlined in this solicitation. The applicant must demonstrate the potential for programming IVLP participants from multiple regions of the world. Applicants should demonstrate that their organizations would consult with DoS Program Officers on a regular basis to ensure that the assigned visitor projects would consistently meet program objectives. Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau cooperative agreements as determined by Bureau Grants Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

5. *Project Evaluation:* While program agencies do not have sole responsibility for program evaluation, proposals should describe how the program agency will evaluate the activity's success, both as the activities unfold and through required reporting at the conclusion of a group program, and address how lessons learned will be incorporated in future program planning. A description of the methodology to be used to link outcomes to original project objectives is recommended.

6. *Cost-effectiveness:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. This includes acquiring and retaining capable staff. All other costs, such as building maintenance, should be necessary and appropriate.

7. *Cost-sharing:* Proposals should maximize cost-sharing through other private sector support as well as institutional direct funding contributions.

## VI. Award Administration Information

### *VI.1a. Award Notices*

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive a Federal Assistance Award (FAA) from the Bureau's Grants Office. The FAA and the original proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The FAA will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

*VI.1b* The following additional requirements apply to this project:

For assistance awards involving Iran:

A critical component of current U.S. government Iran policy is the support for indigenous Iranian voices. The State Department has made the awarding of grants for this purpose a key component of its Iran policy. As a condition of licensing these activities, the Office of Foreign Assets Control (OFAC) has requested the Department of State to follow certain procedures to effectuate the goals of Sections 481(b), 531(a), 571, 582, and 635(b) of the Foreign Assistance Act of 1961 (as amended); 18 U.S.C. 2339A and 2339B; Executive Order 13224; and Homeland Security Presidential Directive 6. These licensing conditions mandate that the Department conduct a vetting of potential Iran grantees and sub-grantees for counter-terrorism purposes. To conduct this vetting the Department will collect information from grantees and sub-grantees regarding the identity and background of their key employees and Boards of Directors.

**Note:** To assure that planning for the inclusion of Iran complies with requirements, please contact Patricia Johnson, Office of International Visitors, by e-mail *JohnsonPA2@state.gov* for additional information.

Prohibition on the use of Federal Funds to Promote, Support, or advocate for the legalization or practice of Prostitution.

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote, support, or advocate the legalization or practice of prostitution. Nothing in the preceding sentence shall be construed to preclude assistance designed to ameliorate the suffering of, or health risks to, victims while they are being trafficked or after they are out of the situation that resulted from such victims being trafficked.

The recipient shall insert the foregoing provision in all sub-agreements under this award.

This provision includes express terms and conditions of the agreement and any violation of it shall be grounds for unilateral termination of the agreement by the Department of State prior to the end of its term.

For assistance awards involving the Palestinian Authority, West Bank, and Gaza:

All awards made under this competition must be executed according to all relevant U.S. laws and policies regarding assistance to the Palestinian Authority, and to the West Bank and Gaza. Organizations must consult with relevant Public Affairs Offices before entering into any formal arrangements or agreements with Palestinian organizations or institutions.

**Note:** To assure that planning for the inclusion of the Palestinian Authority complies with requirements, please contact Patricia Johnson, Office of International Visitors, by e-mail *JohnsonPA2@state.gov* for additional information.

### *VI.2. Administrative and National Policy Requirements*

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, "Cost Principles for Nonprofit Organizations."

Office of Management and Budget Circular A–21, "Cost Principles for Educational Institutions."

OMB Circular A–87, "Cost Principles for State, Local and Indian Governments."

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations.

Please reference the following Web sites for additional information: *http://www.whitehouse.gov/omb/grants. http://fa.statebuy.state.gov.*

*VI.3. Reporting Requirements:* You must provide ECA with a hard copy original plus one copy of the following reports:

(1) A final program and financial report no more than 90 days after the expiration of the award;

(2) A concise, one-page final program report summarizing program outcomes no more than 90 days after the expiration of the award. This one-page report will be transmitted to OMB, and be made available to the public via OMB's USAspending.gov Web site—as part of ECA's Federal Funding Accountability and Transparency Act (FFATA) reporting requirements.

(3) A SF–PPR, "Performance Progress Report" Cover Sheet with all program reports.

(4) Quarterly financial reports within thirty (30) days following the end of the calendar year quarter. These reports should itemize separately International Visitor costs, Voluntary Visitor costs, English Language Officer/Interpreter costs for International Visitors, English Language Officer/Interpreter costs for Voluntary Visitors, special project costs by projects, and administrative costs for the previous quarter on a cash basis. These reports should also list separately the number of English Language Officers/Interpreters accompanying International Visitors, and the number of English Language Officers/Interpreters accompanying Voluntary Visitors for whom funds are expended. Quarterly financial reports must be certified by the award recipient's chief financial officer or an officer of comparable rank. For further information, please refer to the Project Objectives, Goals, and Implementation (POGI) document.

Award recipients will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. [Please refer to IV. Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.]

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

**VII. Agency Contacts**

For questions about this announcement, contact: Patricia Johnson, U.S. Department of State, Office of International Visitors, ECA/PE/V, SA–5, 3rd Floor, ECA/PE/V–12–01, 2200 C Street, NW., Washington, DC 20037, telephone (202) 632–3288 and fax (202) 632–9393, or e-mail *JohnsonPA2@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/PE/V–12–01.

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

**VIII. Other Information**

*Notice*

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: April 26, 2011.

**J. Adam Ereli,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, U.S. Department of State.*

[FR Doc. 2011–10770 Filed 5–4–11; 8:45 am]

BILLING CODE 4710–05–P

---

## DEPARTMENT OF STATE

**[Public Notice: 7437]**

## Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals; The Future Leaders Exchange (FLEX) Program; Organizational Component

*Announcement Type:* New Grant.

*Funding Opportunity Number:* ECA/PE/C/PY–11–17.

*Catalog of Federal Domestic Assistance Number:* 19.415.

**DATES:** *Key Dates:*

*Application Deadline:* June 07, 2011.

*Executive Summary:* The Future Leaders Exchange (FLEX) program seeks to promote mutual understanding between the United States and the countries of Eurasia by providing secondary school students from the region the opportunity to live in American society for an academic year. In turn, these students will expose U.S. citizens to the culture, traditions, and lifestyles of people in Eurasia. Organizations are invited to submit proposals to recruit and select participants; prepare and process documents for approximately 1,134 participants (1,044 academic year students and 90 short-term participants); organize and run pre-departure orientations in each country; produce program publications; organize staff and student travel; manage information for overseas and domestic support; communicate with the students' natural families while on program; provide advice and counseling for students and placement organizations; and plan and implement follow-up activities with alumni.

**I. Funding Opportunity Description**

*Authority*

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries* * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations* * *and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding authority for the program above is provided through legislation.

*Purpose:* The FLEX Program seeks to provide approximately 1,134 high school students from Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan with an opportunity to live in the United States for the purpose of promoting mutual understanding between our countries. Participants will reside with American host families and attend high school during the 2012–13 academic year or participate in a summer 2013 program.

**II. Award Information**

*Type of Award:* Grant Agreement.

*Fiscal Year Funds:* 2011.

*Approximate Total Funding:* $11,000,000.

*Approximate Number of Awards:* One.

*Anticipated Award Date:* August 2011.

*Anticipated Project Completion Date:* December 2012.

*Additional Information:* Pending successful implementation of this program and the availability of funds in subsequent fiscal years, it is ECA's intent to renew this grant for two additional fiscal years before openly competing it again.

**III. Eligibility Information**

*III.1. Eligible applicants*

Applications may be submitted by public and private non-profit organizations meeting the provisions

described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

*III.2.* Cost Sharing or Matching Funds: There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the Federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

*III.3. Other Eligibility Requirements*

Bureau grant guidelines require that organizations with fewer than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. Since an award to support administrative and program costs for this grant will exceed $60,000, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

## IV. Application and Submission Information

**Note:** Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*IV.1* Contact Information to Request an Application Package: Please contact the Office of Citizen Exchanges, ECA/PE/C/PY/F, SA–5, 3rd Floor, U.S. Department of State, 2200 C Street, NW., Washington, DC 20037 or *wardca@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/PE/C/PY–11–17 located at the top of this announcement when making your request. Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms and standard guidelines for proposal preparation. It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Callie Ward and refer to the Funding Opportunity Number ECA/PE/C/PY–11–17 located at the top of this announcement on all other inquiries and correspondence.

*IV.2.* To Download a Solicitation Package Via Internet: The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/grants/open2.html,* or from the Grants.gov Web site at http://www.grants.gov.

Please read all information before downloading.

*IV.3.* Content and Form of Submission: Applicants must follow all instructions in the Solicitation Package. The application should be submitted per the instructions under IV.3f. "Application Deadline and Methods of Submission" section below.

*IV.3a.* You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

*IV.3b.* All proposals must contain an executive summary, proposal narrative and budget.

Please Refer to the Solicitation Package. It contains the mandatory PSI and POGI documents for additional formatting and technical requirements.

*IV.3c.* All federal award recipients and sub-recipients must maintain current registrations in the Central Contractor Registration (CCR) database and have a Dun and Bradstreet Data Universal Numbering System (DUNS) number. Recipients and sub-recipients must maintain accurate and up-to-date information in the CCR until all program and financial activity and reporting have been completed. All entities must review and update the information at least annually after the initial registration and more frequently if required information changes or another award is granted.

You must have nonprofit status with the IRS at the time of application. **Please note:** Effective January 7, 2009, all applicants for ECA federal assistance awards must include in their application the names of directors and/or senior executives (current officers, trustees, and key employees, regardless of amount of compensation). In fulfilling this requirement, applicants must submit information in one of the following ways:

(1) Those who file Internal Revenue Service Form 990, "Return of Organization Exempt from Income Tax," must include a copy of relevant portions of this form.

(2) Those who do not file IRS Form 990 must submit information above in the format of their choice.

In addition to final program reporting requirements, award recipients will also be required to submit a one-page document, derived from their program reports, listing and describing their grant activities. For award recipients, the names of directors and/or senior executives (current officers, trustees, and key employees), as well as the one-page description of grant activities, will be transmitted by the State Department to OMB, along with other information required by the Federal Funding Accountability and Transparency Act (FFATA), and will be made available to the public by the Office of Management and Budget on its USASpending.gov Web site as part of ECA's FFATA reporting requirements.

If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

*IV.3d.* Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1 Adherence to All Regulations Governing the J Visa

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the "Responsible Officer" for the program under the terms of 22 CFR part 62, which covers the administration of the Exchange Visitor Program (J visa

program). Under the terms of 22 CFR part 62, organizations receiving awards (either a grant or cooperative agreement) under this RFGP will be third parties "cooperating with or assisting the sponsor in the conduct of the sponsor's program." The actions of recipient organizations shall be "imputed to the sponsor in evaluating the sponsor's compliance with" 22 CFR part 62. Therefore, the Bureau expects that any organization receiving an award under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR part 62 *et seq.*

The Bureau of Educational and Cultural Affairs places critically important emphases on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by recipient organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should *explicitly state in writing* that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR part 62. If your organization has experience as a designated Exchange Visitor Program Sponsor, you should discuss your record of compliance with 22 CFR part 62 *et seq.,* including the oversight of the organization's Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: Office of Designation, Private Sector Programs Division, U.S. Department of State, ECA/EC/D/PS, SA–5, 5th Floor, 2200 C Street, NW., Washington, DC 20037.

IV.3d.2 Diversity, Freedom and Democracy Guidelines

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and should encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the fullest extent deemed feasible.

IV.3d.3. Program Monitoring and Evaluation

Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the recipient organization will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are "smart" (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes. Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on both outputs and outcomes should be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. *Participant satisfaction* with the program and exchange experience.
2. *Participant learning,* such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.
3. *Participant behavior,* including concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; and continued contacts between participants, community members, and others.
4. *Institutional changes,* such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

**Please note:** Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) Specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (*i.e.,* surveys, interviews, or focus groups). (Please note that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Recipient organizations will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three

years and provided to the Bureau upon request.

*IV.3e.* Please take the following information into consideration when preparing your budget:

*IV.3e.1.* Applicants must submit SF–424A—"Budget Information—Non-Construction Programs" along with a comprehensive budget for the entire program. Budget requests may not exceed $11,000,000. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

*IV.3e.2.* Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

*IV.3f.* Application Deadline and Methods of Submission:

*Application Deadline Date:* June 07, 2011.

*Reference Number:* ECA/PE/C/PY–11–17.

*Methods of Submission:* Applications may be submitted in one of two ways:

(1.) In hard-copy, via a nationally recognized overnight delivery service (*i.e.,* Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.), or

(2.) electronically through *http://www.grants.gov.*

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3f.1 Submitting Printed Applications

Applications must be shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will *not* notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages *may not* be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

Important note: When preparing your submission, please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to "ECA/EX/PM".

The original and 5 copies of the application should be sent to: Program Management Division, ECA–IIP/EX/PM, Ref.: ECA/PE/C/PY–11–17, SA–5, Floor 4, Department of State, 2200 C Street, NW., Washington, DC 20037.

Applicants submitting hard-copy applications must also submit the "Executive Summary" and "Proposal Narrative" sections of the proposal in text (.txt) or Microsoft Word format, and the "Budget" section in spreadsheet (Microsoft Excel) format on CD–ROM. As appropriate, the Bureau will provide these files electronically to Public Affairs Section(s) at the U.S. embassy(ies) for its (their) review.

IV.3f.2 Submitting Electronic Applications

Applicants have the option of submitting proposals electronically through Grants.gov (*http://www.grants.gov*). Complete solicitation packages are available at Grants.gov in the "Find Grant Opportunities" page.

**Please Note:** ECA bears no responsibility for applicant timeliness of submission or data errors resulting from transmission or conversion processes for proposals submitted via Grants.gov.

Please follow the instructions available in the 'Get Started' portion of the site (*http://www.grants.gov/GetStarted*).

Several of the steps in the Grants.gov registration process could take several weeks. Therefore, applicants should check with appropriate staff within their organizations immediately after reviewing this RFGP to confirm or determine their registration status with Grants.gov.

Once registered, the amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your internet connection. In addition, validation of an electronic submission via Grants.gov can take up to two business days.

Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov.

The Grants.gov Web site includes extensive information on all phases/aspects of the Grants.gov process, including an extensive section on frequently asked questions, located under the "For Applicants" section of the Web site. ECA strongly recommends that all potential applicants review thoroughly the Grants.gov Web site, well in advance of submitting a proposal through the Grants.gov system. ECA bears no responsibility for data errors resulting from transmission or conversion processes.

Direct all questions regarding Grants.gov registration and submission to: Grants.gov Customer Support, Contact Center Phone: 800–518–4726, Business Hours: Monday–Friday, 7 a.m.–9 p.m. Eastern Time, E-mail: *support@grants.gov.*

Applicants have until midnight (12 a.m.), Washington, DC time of the closing date to ensure that their entire application has been uploaded to the Grants.gov site. There are no exceptions to the above deadline. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.

Please refer to the Grants.gov Web site, for definitions of various "application statuses" and the difference between a submission receipt and a submission validation. Applicants will receive a validation e-mail from grants.gov upon the successful submission of an application. Again, validation of an electronic submission via Grants.gov can take up to two business days. Therefore, we strongly recommend that you not wait until the application deadline to begin the submission process through Grants.gov. ECA will not notify you upon receipt of electronic applications.

It is the responsibility of all applicants submitting proposals via the Grants.gov web portal to ensure that proposals have been received by Grants.gov in their entirety, and ECA bears no responsibility for data errors resulting from transmission or conversion processes.

## V. Application Review Information

*V.1. Review Process*

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. In addition, ECA will review the record of compliance with 22 CFR part 62 *et seq.* of applicant organizations designated as Exchange Visitor Program Sponsors by ECA's Office of Private Sector Exchange. If it is determined that an applicant organization submitting a proposal has a record of not being in compliance, their proposal will be deemed technically ineligible and receive no

further consideration in the review process. If in compliance, the applicant organization's record of compliance will be used as one factor in evaluating the record/ability of organizations to carry out successful exchange programs.

All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals also may be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for grant agreements resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Program Planning and Ability to Achieve Program Objectives:* Your proposal should exhibit originality, substance, precision, and relevance to the Bureau's mission and design.

2. *Detailed agenda* and relevant work plan should demonstrate organizational competency and logistical capacity. Agenda and plan should adhere to the program overview, timetable and guidelines described in the POGI. Your proposal should clearly demonstrate an understanding of the program's objectives and how you will achieve them.

3. *Productivity and Innovation:* Your proposal should specify and verify improved productivity as well as proposed program innovations in implementing the activity and lessons learned from conducting similar programs.

4. *Support of Diversity:* Your proposal should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (*e.g.,* staffing, program venue) and program content (especially selection of participants and orientation).

5. *Organization's Institutional Capacity and Record:* Your proposal must demonstrate a well-established infrastructure throughout Eurasia and procedures for dealing with situations where this is a challenge (*e.g.,* Uzbekistan or Belarus). The proposal should reflect the needs of the hosting community (including the American host schools and the placement organizations) and a thorough understanding of how to work effectively with Eurasian authorities, including proposed scenarios for dealing with difficulties that might arise as a result of challenging governments in any of these countries. Your proposal also should demonstrate an institutional record of successful activities that are relevant to this program, as well as responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by the Bureau's Grants Division. Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals. Reviewers will assess the applicant and its partners to determine if they offer adequate resources, expertise, and experience to fulfill program objectives. Partner activities should be clearly defined. Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting and J–1 Visa requirements for past Bureau grants as determined by Bureau Grant Staff. In addition, organizations designated as Exchange Visitor Program Sponsors must include a discussion of their record of compliance with 22 CFR part 62 *et seq.,* including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, recordkeeping, reporting and other requirements. Proposals that fail to include the above information in their narrative will be deemed less or not competitive under this review criterion. ECA will review the record of compliance with 22 CFR part 62 *et seq.* of organizations designated as Exchange Visitor Program Sponsors as one factor in evaluating the record/ability of organizations to carry out successful exchange programs.

6. *Project Evaluation:* Your proposal should include a plan to evaluate the success of the organization in achieving the stated objectives.

7. *Cost-Effectiveness:* The overhead and administrative components of your proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate. Your proposal should maximize cost-sharing through other private sector support as well as institutional direct funding and in-kind contributions.

8. *Value to U.S.-Partner Country Relations:* Your activities in conducting similar activities under current and/or previous grants should receive positive assessments by overseas officers in the Public Affairs Sections (PAS) of the American embassies in partner countries.

## VI. Award Administration Information

*VI.1a. Award Notices*

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive a Federal Assistance Award (FAA) from the Bureau's Grants Office. The FAA and the original proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The FAA will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

*VI.2 Administrative and National Policy Requirements:* Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, "Cost Principles for Nonprofit Organizations."

Office of Management and Budget Circular A–21, "Cost Principles for Educational Institutions."

OMB Circular A–87, "Cost Principles for State, Local and Indian Governments."

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations.

Please reference the following Web sites for additional information: *http://www.whitehouse.gov/omb/grants. http://fa.statebuy.state.gov.*

*VI.3. Reporting Requirements:* You must provide ECA with a hard copy original plus *one* copy of the following reports:

1. A final program and financial report no more than 90 days after the expiration of the award.

2. A concise, one-page final program report summarizing program outcomes no more than 90 days after the expiration of the award. This one-page report will be transmitted to OMB, and be made available to the public via OMB's USAspending.gov Web site—as part of ECA's Federal Funding Accountability and Transparency Act (FFATA) reporting requirements.

3. A SF–PPR, "Performance Progress Report" Cover Sheet with all program reports, including the SF–PPR–E and SF–PPR–F.

4. Quarterly program and financial reports.

Award recipients will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV. Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.)

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

*VI.4. Optional Program Data Requirements:* Award recipients will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as required. As a minimum, the data must include the following:

(1) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the agreement or who benefit from the award funding but do not travel.

(2) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA Program Officer at least three work days prior to the official opening of the activity.

## VII. Agency Contacts

For questions about this announcement, contact: Callie Ward, U.S. Department of State, Youth Programs Division, ECA/PE/C/PY SA–5, 3rd Floor, H–15, ECA/PE/C/PY–11–17, 2200 C Street, NW., Washington, DC 20037; 202–632–6431; *wardca@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/PE/C/PY–11–17.

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

## VIII. Other Information

*Notice*

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: April 26, 2011.

**J. Adam Ereli,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, U.S. Department of State.*

[FR Doc. 2011–10769 Filed 5–4–11; 8:45 am]

**BILLING CODE 4710–05–P**

# DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## Waiver of Aeronautical Land-Use Assurance Marion Municipal Airport; Marion, IN

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of intent of waiver with respect to land.

**SUMMARY:** The Federal Aviation Administration (FAA) is considering a proposal to authorize the release of 0.683 acres of airport property at the Marion Municipal Airport, Marion, Indiana. The State of Indiana notified the Airport of their intent to rebuild a vehicle bridge on State Highway 9 which adjoins the Airport property. The total amount of property which is sought to be purchased by the State of Indiana consists of approximately .683 acres. The FAA issued a categorical exclusion on April 18, 2011.

The acreage being released is not needed for aeronautical use as currently identified on the Airport Layout Plan.

The acreage comprising this parcel was originally acquired with a combination of local and federal funds -ADAP. The Airport will receive the appraised fair market value of $33,630.00

The legal description of the property is: A part of the Northeast Quarter of Section 36, Township 24 North, Range 7 East, Grant County, Indiana, and being that part of the grantor's land lying within the right of way lines described as follows: Beginning at the southeast corner of said quarter section, which is North 0 degrees 07 minutes 13 seconds West 2,618.30 feet from the southeast corner of said section, said southeast corner being designated as point "80" on said plat; thence South 89 degrees 19 minutes 47 seconds West 12.00 feet along the south line of said quarter section to the west boundary of S.R.9; thence continuing South 89 degrees 19 minute 47 seconds West 71.12 feet along said south line; thence North 0 degrees 26 minutes 29 seconds East 317.51 feet to point "901" designated on said plat; thence North 31 degrees 29 minutes 14 seconds East 76.32 feet to point "902" designated on said plat; thence North 89 degrees 52 minutes 47 seconds East 28.00 feet to the west boundary of said S.R. 9; thence continuing North 89 degrees 52 minutes 47 seconds East 12.00 feet to the east line of said section; thence South 0 degrees 07 minute 13 seconds East 381.70 feet along said east line to the point of beginning and containing 0.683 acres, more or less, inclusive of the presently existing right-of-way which contains 0.105 acres, more or less.

**DATES:** Comments must be received on or before June 6, 2011.

**ADDRESSES:** Documents reflecting this FAA action may be reviewed at Chicago Airports District Office, 2300 E. Devon Suite 320, Des Plaines, IL 60018.

**FOR FURTHER INFORMATION CONTACT:** Jim Keefer, Manager, Chicago Airports District Office, Federal Aviation Administration, Airports Division. Telephone Number 847–294–7336/Fax Number 847–294–7046.

**SUPPLEMENTARY INFORMATION:**

Issued in Des Plaines, Illinois on April 27, 2011.

**Jack Delaney,**

*Acting Manager, Chicago Airports District Office, FAA, Great Lakes Region.*

[FR Doc. 2011–10925 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[FMCSA Docket No. FMCSA–2006–25756]**

### Commercial Driver's License (CDL) Standards; Volvo Trucks North America, Renewal of Exemption

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of renewal of exemptions; request for comments.

**SUMMARY:** FMCSA renews an exemption from the requirement to hold a commercial driver's license (CDL) sought by Volvo Trucks North America (Volvo) on behalf of five employees. Volvo requested renewal of the CDL exemption for five Swedish engineers employed by the company to enable these individuals to continue test-driving commercial motor vehicles (CMVs) in the United States. All hold valid Swedish CDLs. FMCSA believes that the training program and knowledge and skills testing that drivers must undergo to obtain a Swedish CDL ensure a level of safety equivalent to, or greater than, the level of safety that would be obtained by complying with the U.S. requirement for a CDL.

**DATES:** Comments must be received on or before June 6, 2011. Effective date of the exemption is April 23, 2011 to April 23, 2013.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System Number FMCSA–2006–25756 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* In the ENTER KEYWORD OR ID box enter FMCSA–2006–25756 and click on the tab labeled SEARCH. On the ensuing page, click on any tab labeled SUBMIT A COMMENT on the extreme right of the page and a page should open that is titled "Submit a Comment." You may identify yourself under section 1, ENTER INFORMATION, or you may skip section 1 and remain anonymous. You enter your comments in section 2, TYPE COMMENT & UPLOAD FILE. When you are ready to submit your comments, click on the tab labeled SUBMIT. Your comment is then submitted to the docket; and you will receive a tracking number.
- *Fax:* 1–202–493–2251.
- *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:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

*Instructions:* All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the Public Participation heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

*Docket:* For access to the docket to read background documents or comments received, go to www.regulations.gov at any time, and in the ENTER KEYWORD OR ID box enter FMCSA–2006–25756 and click on the tab labeled SEARCH.

*Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476) or you may visit www.regulations.gov.

*Public Participation:* The www.regulations.gov Web site is generally available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the "help" section of the www.regulations.gov Web site and also at the DOT's *http://docketsinfo.dot.gov* Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine Hydock, FMCSA Driver and Carrier Operations Division, Office of Bus and Truck Standards and Operations, *Telephone:* 202–366–4325. *E-mail: MCPSD@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the CDL requirements of 49 CFR 383.23 for a maximum 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 procedures for requesting an exemption (including renewals) are prescribed in 49 CFR part 381.

### Volvo Application for Exemption Renewal

Volvo applied for a 2-year renewal of an exemption from 49 CFR 383.23, the CDL requirement for drivers operating CMVs, for Johnny Adolfsson, Goran Alsen, Freddy Blixt, Peter Hofsten, and Lars Svensson. A copy of the request for renewal, dated November 10, 2010, is in the docket identified at the beginning of this notice.

FMCSA initially granted an exemption to seven Swedish engineers and technicians employed by Volvo on May 5, 2009 (74 FR 20778). Detailed information about the qualifications and experience of each of the seven drivers, including the five affected by this notice, was provided by Volvo in its original application, a copy of which is in the docket referenced above. Volvo is seeking a renewal of this exemption because the five drivers are citizens and residents of Sweden, and cannot easily obtain a non-resident CDL, given the small number of States willing to issue such a license. Renewal of the exemption will enable them to operate CMVs in the U.S. and continue to support Volvo's field tests to meet future clean air standards, to test drive prototype vehicles at its test site, and to deliver the vehicles, if necessary. It is estimated that they will drive a combined total of approximately 20,800 miles per year on U.S. roads. The applicants are experienced CMV operators holding valid Swedish-issued CDLs. They have received extensive CMV training, and have satisfied strict regulations in Sweden in order to obtain a CDL. Volvo explained in detail in earlier exemption requests the rigorous training program and knowledge and skills tests that applicants for a Swedish CDL must undergo. Volvo also argued that the Swedish knowledge and skills tests and training program ensure that its drivers operating under the exemption will achieve a level of safety that is equivalent to, or greater than, the level of safety obtained by complying with the U.S. requirement for a CDL.

### Method To Ensure an Equivalent or Greater Level of Safety

FMCSA has previously determined that the process for obtaining a Swedish CDL is comparable to, or as effective as, the requirements of Part 383, and adequately assesses the driver's ability to operate CMVs in the U.S. In recent years FMCSA has granted similar Volvo exemption requests, most recently on August 9, 2010 (75 FR 45198).

**Granting of Exemption Renewal**

FMCSA has evaluated Volvo's application for exemption renewals for Johnny Adolfsson, Goran Alsen, Freddy Blixt, Peter Hofsten, and Lars Svensson and decided to grant them for an additional 2-year extension, i.e. from April 23, 2011 to April 23, 2013. These exemptions are renewed subject to the following terms and conditions: (1) This exemption is valid only when the drivers are acting within the scope of their employment by Volvo; (2) the drivers and Volvo must adhere to drug and alcohol regulations, including testing, as provided by in 49 CFR part 382; (3) the drivers and Volvo must adhere to driver disqualification rules under 49 CFR parts 383 and 391 that apply to all CMV drivers in the United States; (4) the drivers are subject to all other provisions of the Federal Motor Carrier Safety Regulations (FMCSRs) (49 CFR parts 390–397) unless specifically exempted herein; (5) the drivers must keep a copy of the exemption on the vehicle at all times for presentation to a duly authorized Federal, State, or local enforcement official; (6) Volvo must notify FMCSA in writing of any accident, as defined in 49 CFR 390.5, involving an exempted driver; and (7) Volvo must notify FMCSA in writing if an exempted driver is convicted of a disqualifying offense described in sections 383.51 or 391.15 of the FMCSRs.

These exemptions will be valid for 2 years unless revoked earlier by FMCSA. The exemptions will be revoked if: (1) The drivers fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

**Request for Comments**

In accordance with 49 U.S.C. 31315(b)(4), FMCSA requests public comment on the renewal of the exemption from the requirements of 49 CFR 383.23 for Johnny Adolfsson, Goran Alsen, Freddy Blixt, Peter Hofsten, and Lars Svensson. The Agency requests that interested parties with specific data concerning these individuals' safety records submit comments by June 6, 2011. FMCSA will review all comments received by this date and determine whether renewal of the exemption is consistent with the requirements of 49 U.S.C. 31136(e) and 31315. As indicated above, the Agency has previously determined that providing an exemption for these Volvo drivers does not compromise the level of safety that would exist if the exemption were not granted. Interested parties or organizations possessing information that would show that any of these individuals are not currently achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse information submitted and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA will take immediate steps to revoke the exemption.

Issued on: April 26, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy and Program Development.*

[FR Doc. 2011–11026 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–EX–P**

---

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2000–7165; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–12294; FMCSA–2002–13411; FMCSA–2003–14223; FMCSA–2004–17984; FMCSA–2005–20027; FMCSA–2005–20560; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2007–27333; FMCSA–2008–0398; FMCSA–2009–0054]**

### 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 exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 25 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 31, 2011. Comments must be received on or before June 6, 2011.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) numbers: FMCSA–2000–7165; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–12294; FMCSA–2002–13411; FMCSA–2003–14223; FMCSA–2004–17984; FMCSA–2005–20027; FMCSA–2005–20560; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2007–27333; FMCSA–2008–0398; FMCSA–2009–0054, *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.

*Instructions:* 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 Federal Docket Management System (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 DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

**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 25 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 25 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. *They are:*

| | |
|---|---|
| Todd J. Berglund, Sr. | Eric E. Myers |
| Robert A. Casson | Kenneth L. Nau |
| Charles C. Chapman | David W. Peterson |
| Jeffery W. Cotner | Randel G. Pierce |
| Everett A. Doty | Timmy J. Pottenbaum |
| John K. Fank | Manuel H. Sanchez |
| Bobby G. Fletcher | George D. Schell |
| Heather M.B. Gordon | David M. Stout |
| Raymond G. Hayden | Kenneth E. Suter, Jr. |
| Robert E. Hendrick | Thaddeus E. Temoney |
| Gene A. Lesher, Jr. | Daniel R. Viscaya |
| Wallace F. Mahan, Sr. | Harold R. Wallace |
| Anthony R. Miles | |

The 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 provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains 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 25 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (65 FR 33406; 65 FR 57234; 65 FR 66286; 65 FR 78256; 66 FR 13825; 66 FR 16311; 67 FR 46016; 67 FR 57267; 67 FR 76439; 68 FR 10298; 68 FR 10300; 68 FR 10301; 68 FR 13360; 68 FR 19596; 69 FR 33997; 69 FR 61292; 69 FR 62741; 70 FR 2701; 70 FR 7545; 70 FR 12265; 70 FR 14747; 70 FR 17504; 70 FR 30997; 70 FR 16886; 70 FR 16887; 71 FR 62147; 71 FR 63379; 72 FR 180; 72 FR 1050; 72 FR 7812; 72 FR 9397; 72 FR 11426; 72 FR 12665; 72 FR 12666; 72 FR 27624; 72 FR 25831; 73 FR 78422; 74 FR 6211; 74 FR 7097: 74 FR 9329; 74 FR 11988; 74 FR 15584; 74 FR 15586; 74 FR 19270; 74 FR 21427). Each of these 25 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 June 6, 2011.

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 25 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 made on the merits of each case and made 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 22, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–11007 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–EX–P

---

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of denials.

**SUMMARY:** FMCSA announces its denial of 106 applications from individuals who requested an exemption from the Federal vision standard applicable to interstate truck and bus drivers and the reasons for the denials. 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 does not 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, U.S. Department of Transportation, FMCSA, 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 grant an exemption from the Federal vision standard for a renewable 2-year period if it finds "such an exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such an exemption." The procedures for requesting an exemption are set forth in 49 CFR part 381.

Accordingly, FMCSA evaluated 106 individual exemption requests on their merit and made a determination that these applicants do not satisfy the criteria eligibility or meet the terms and conditions of the Federal exemption program. Each applicant has, prior to this notice, received a letter of final disposition on the exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published in this notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

The following 4 applicants lacked sufficient driving experience during the 3-year period prior to the date of their applications:

Jerry Swedberg, James Marrone, Clinton H. Ezell, Wanda Rivera.

The following 17 applicants had no experience operating a CMV:

Howard Karrick, Alexander Tsvetkov, Jamie Donald Daniels, Robert S. Lewton, Michael A. Carson, Todd J. Stubb, James Garvin, James McGlown, Larry McKnight, Jr., Tommy Nguyen, Fatos Syla, Bryan Baker, Ivan Castillo Leon, Jared Matthew Bauer, Shaun Adam Cahoon, John David Beebee, Donald Cyrus Zwanzig.

The following 9 applicants did not have 3 years of experience driving a CMV on public highways with the vision deficiency:

Christopher Kahl, Althea Renita Dowell, Steven DuBois, Steve Campbell, Kenneth Trouth, Robert Hendricks, Sam Antinora, Juan Curiel, Keith Reed.

The following 12 applicants did not have 3 years of recent experience driving a CMV with the vision deficiency:

Gary Aliff, Pedro Pulido, Oliver Murphy, Jerome Smalls, Alan Jenkins, Ryan Forsythe, Terry L. Randoll, Edward Joseph Simanek III, Sven R. Aragon, Joe Alfred Root, Gary L. Smith, Arthur B. Wolf.

The following 7 applicants did not have sufficient driving experience during the past 3 years under normal highway operating conditions:

Robert Salazar, Evan Anderson, John Lunsford, Jerome Sheets, Robert Seals, James Lucas, Gregory T. Grierson.

The following 2 applicants do not have sufficient peripheral vision in the better eye to qualify for an exemption.

Thomas L. Newingham, Joseph Barlow.

The following 2 applicants do not have sufficient visual acuity in the better eye to qualify for an exemption.

Earl L. Wilson, Richard Stewart.

The following 2 applicants had a commercial driver's license suspension during the 3-year review period for moving violations. Applicants do not qualify for an exemption with a suspension during the 3-year period.

Royce Thomas, Randy Fielder.

The following 4 applicants were denied for miscellaneous/multiple reasons:

Ramon Green, Larry Hattery, Joey Heuser, Travis Tucker.

The following 2 applicants never submitted the required documents:

Floyd Butler, John Jacobson.

The following 13 applicants met the current federal vision standards. Exemptions are not required for applicants who meet the current regulations for vision:

David Everts, John Flanders, John Harmon, Jeffery Willemarck, Rick Smith, Luther Smith, Frank Piscitello, Jr., Cortez Burnett, Lee Rains, Yewnet Lakew, Marci Casteel, Ronald Boggs, Robert Shanks.

Finally, the following 32 applicants will not be driving interstate, interstate commerce, or not required to carry a DOT medical card:

Jose Becerra, Merle Burger, Kenneth Dean, Tyrane Harper, Robert Jones, Alfonzo Hawthorne, Nathaniel Guy Edwards, John C. Yoder, Fred Jeffrey, Albert Parker, James Plemmons, Roy Priest, Robert Shepherd, Thomas Guckert, Barry L. Ream, Roger Freeman, Timothy Curran, Jonathan Black Elk, Ward Howard, Alberto Mireles, Jr., Jeremy Pruemer, Larry Keith Abbott, Alan G. Paci, John Savage, Edward Lee Clark, Robert Haynes, Richard A. Whispell, Terry Dennis Helm, Randy Lee Stevens, Rodney D. Neujahr, Dennis R. Bergstrom, Thomas E. Elliott.

Issued on: April 22, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–11019 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–EX–P**

---

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0079]**

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 14 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision standard.

**DATES:** Comments must be received on or before June 6, 2011.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0079 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: 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.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note

that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

*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 DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

**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 grant an exemption from the Federal Motor Carrier Safety Regulations 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." FMCSA can renew exemptions at the end of each 2-year period. The 14 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

## Qualifications of Applicants

*Jan M. Bernath*

Mr. Bernath, age 53, has no light perception in his right eye due to brain and ocular trauma that occurred in 1996. The best corrected visual acuity in his right eye is no light perception and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "My medical opinion is that this patient has sufficient vision function to perform the driving tasks required to operate a commerical vehicle." Mr. Bernath reported that he has driven straight trucks for 30 years, accumulating 180,000 miles and tractor-trailer combinations for 25 years, accumulating 125,000 miles. He holds a Class A Commercial Driver's License (CDL) from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Jason M. Birrenkott*

Mr. Birrenkot, 38, has had ectopia lentis with cataract in his left eye since birth. The best corrected visual acuity in his right eye is 20/20 and in his left eye, count-finger vision. Following an examination in 2010, his optometrist noted, "I certify, in my medical opinion, that Mr. Birrenkott has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Birrenkott reported that he has driven straight trucks for 9 years, accumulating 162,000 miles. He holds a Class D operator's license from North Dakota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*John E. Edler, lll*

Mr. Edler, 50, has had a retinal scar in his right eye since 1979. The best corrected visual acuity in his right eye is 20/400 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "It is my understanding that Mr. Edler has maintained a safe driving record for many years and has always driven with the visual disability of the right eye. Since it has always been present, he has functioned well, and his peripheral visual acuity is excellent. There is no reason to believe that he cannot continue to operate commercial vehicles." Mr. Edler reported that he has driven straight trucks for 31 years, accumulating 77,500 miles and tractor-trailer combinations for 29 years, accumulating 232,000 miles. He holds a Class A CDL from Delaware. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Saul E. Fierro*

Mr. Fierro, 37, has a macular scar in his left eye due to a traumatic injury sustained as a child. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2010, his optometrist noted, "In my opinion, I believe that Saul has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Fierro reported that he has driven straight trucks for 4 years, accumulating 57,600 miles. He holds a Class D operator's license from Arizona. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Mark T. Gileau*

Mr. Gileau, 44, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is count-finger vision and in his left eye, 20/15. Following an examination in 2010, his ophthalmologist noted, "Mr. Gileau has been driving commercial vehicles for a number of years with his present level of vision without incident and because of this I feel he has sufficient vision to perform driving tasks required to operate a commercial vehicle." Mr. Gileau reported that he has driven tractor-trailer combinations for 20 years, accumulating 240,000 miles. He holds a Class A CDL from Connecticut. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Peter D. Gouge*

Mr. Gouge, 60, has a macular scar in his left eye due to a traumatic injury that occurred in 1976. The best corrected visual acuity in his right eye is 20/20 and in his left eye, count-finger vision. Following an examination in 2010, his optometrist noted, "I, Karen Anderson certify in my medical opinion is that Mr. Peter Gouge has sufficient vision function to perform the driving tasks required to operate a commercial vehicle." Mr. Gouge reported that he has driven straight trucks for 27 years, accumulating 21,600 miles and tractor-trailer combinations for 27 years, accumulating 1.2 million miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes but one conviction for speeding in a CMV. He exceeded the speed limit by 10 Miles Per Hour (MPH).

*Thomas M. Harris*

Mr. Harris, 59, has had amblyopia in his left eye since birth. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/100. Following an examination in 2010, his optometrist noted, "Tom unquestionably has the acuity, field, and perceptual skills to perform commercial driving tasks as he has been conducting for many years." Mr. Harris reported that he has driven straight trucks for 13 years, accumulating 507,000 miles. He holds a Class B CDL from Michigan. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Paul M. Hinkson*

Mr. Hinkson, 43, has complete loss of vision in his right eye since childhood. The best corrected visual acuity in his left eye is 20/20. Following an examination in 2010, his optometrist noted, "Mr. Hinkson is fully capable of performing all vision tasks required to operate a commercial motor vehicle in interstate commerce." Mr. Hinkson reported that he has driven straight trucks for 16 years, accumulating 320,000 miles. He holds a Class A CDL from Tennessee. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Lyle H. Lightner*

Mr. Lightner, 60, has loss of vision in his left eye due to a traumatic injury sustained at age 3. The best corrected visual acuity in his right eye is 20/20 and in his left eye, no light perception. Following an examination in 2011, his optometrist noted, "In summary, Mr. Lightner's visual condition is stable and is sufficient to perform required commerical driving tasks." Mr. Lightner reported that he has driven straight trucks for 40 years, accumulating 1.6 million miles. He holds a Class C Chauffeur's license from Michigan. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Ellie L. Murphree*

Mr. Murphree, 69, has had central retinal atrophy in his right eye since 2007. The best corrected visual acuity in his right eye is 20/400 and in his left eye, 20/20. Following an examination in 2010, his optometrist noted, "Therefore, in my medical opinion, Mr. Murphree has sufficient vision to perform driving tasks required to operate a commercial vehicle as he has done successfully since at least 2007 and prior." Mr. Murphree reported that he has driven tractor-trailer combinations for 50 years, accumulating 5.3 millon miles. He holds a Class D operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Claude S. Overstreet*

Mr. Overstreet, 58, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/80. Following an examination in 2010, his optometrist noted, "In my medical opinion, Claude Overstreet has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Overstreet reported that he has driven straight trucks for 26 years, accumulating 910,000 miles. He holds a Class D operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*James F. Partin*

Mr. Partin, 67, has no light perception in his left eye due to a traumatic injury since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, no light perception. Following an examination in 2010, his optometrist noted, "Mr. Partin has sufficient vision in his right eye to operate a commercial vehicle with no restrictions." Mr. Partin reported that he has driven straight trucks for 46 years, accumulating 920,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Kevin W. Van Arsdol*

Mr. Van Arsdol, 48, has congenital glaucoma in his right eye. The best corrected visual acuity in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "Since this condition has been present and unchanged since birth, and considering Kevin has safely mantained a commercial license for more than 20 years, I believe he has sufficient vision to perform the driving tasks required to operate a commercial vehicle". Mr. Van Arsdol reported that he has driven straight trucks for 1 year accumulating 140,000 miles and tractor-trailer combinations for 26 years accumulating 2 million miles. He holds a Class A CDL from Colorado. His driving record for the last 3 years shows no crashes but three convictions for speeding in a CMV. In the first incident, he exceeded the speed limit by 9 MPH, in the second incident, he exceeded the speed limit by 12 MPH and in the third incident, he exceeded the speed limit by 5 MPH.

*Harlon C. VanBlaricom*

Mr. VanBlaricom, 51, has only light perception out of his left eye due to a traumatic injury sustained at age 5. The best corrected visual acuity in his right eye is 20/20 and in his left eye, light perception only. Following an examination in 2010, his optometrist noted, "It is my opinion that Harlon has sufficient vision needed to operate a commercial vehicle." Mr. VanBlaricom reported that he has driven tractor-trailer combinations for 30 years, accumulating 1.5 million miles. He holds a Class A CDL from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business June 6, 2011. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: April 22, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–11016 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–EX–P**

---

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0092]**

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 19 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions

would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision standard.

**DATES:** Comments must be received on or before June 6, 2011.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0092 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:* 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.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

*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 DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

**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 grant an exemption from the Federal Motor Carrier Safety Regulations 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." FMCSA can renew exemptions at the end of each 2-year period. The 19 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

## Qualifications of Applicants

### *Keith E. Allstot*

Mr. Allstot, age 51, has loss of vision in his left eye due to a traumatic injury that occurred in 2002. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/400. Following an examination in 2010, his optometrist noted, "Using both eyes, Keith's vision is sufficient for commercial driving licensing and tasks." Mr. Allstot reported that he has driven straight trucks for 15 years, accumulating 999,990 miles and tractor-trailer combinations for 31 years, accumulating 3 million miles. He holds a Class A Commercial Driver's License (CDL) from Washington. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### *Christopher L. Bagby*

Mr. Bagby, 45, has a misplaced pupil and a mild cataract in his right eye due to an injury sustained as a child. The visual acuity in his right eye is 20/1200 and in his left eye, 20/20. Following an examination in 2010, his optometrist noted, "In my medical opinion, Mr. Bagby has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Bagby reported that he has driven straight trucks for 14 years, accumulating 350,000 miles and tractor-trailer combinations for 6 years, accumulating 150,000 miles. He holds a Class A CDL from Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### *Joseph L. Butler*

Mr. Butler, 47, has a prosthetic left eye due to a chorodial melanoma that occurred in 2003. The best corrected visual acuity in his right eye is 20/20. Following an examination in 2011, his optometrist noted, "It is my medical opinion that Mr. Butler has sufficient vision to perform the driving tasks necessary to operate the commercial vehicles required to maintain his business." Mr. Butler reported that he has driven straight trucks for 30 years, accumulating 600,000 miles and tractor-trailer combinations for 30 years, accumulating 150,000 miles. He holds a Class C operator's license from Indiana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### *Shawn M. Carroll*

Mr. Carroll, 44, has had amblyopia in his left eye since birth. The best corrected visual acuity in his right eye is 20/15 and in his left eye, 20/200. Following an examination in 2010, his optometrist noted, "I have found and determined Shawn Carroll to have sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Carroll reported that he has driven straight trucks for 25 years, accumulating 1.3 million miles and tractor-trailer combinations for 4 years, accumulating 100,000 miles. He holds a Class C operator's license from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### *Erik R. Davis*

Mr. Davis, 30, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/80 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "In my medical opinion I feel that Mr. Davis has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Davis reported that he has driven straight trucks for 8½ years, accumulating 1.3 million miles. He holds a Class A CDL from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Walter C. Dean, Sr.*

Mr. Dean, 67, has complete loss of vision in his right eye due to a traumatic injury sustained as a child. The best corrected visual acuity in his right eye is no light perception and in his left eye, 20/20. Following an examination in 2011, his ophthalmologist noted, "I feel that he has sufficient vision to perform the driving tasks that are required to operate a commercial vehicle." Mr. Dean reported that he has driven straight trucks for 40 years, accumulating 3.1 million miles. He holds a Class D operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*John C. DiMassa*

Mr. DiMassa, 53, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/100 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "In my professional opinion, John has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. DiMassa reported that he has driven straight trucks for 30 years, accumulating 150,000 miles and tractor-trailer combinations for 30 years, accumulating 150,000 miles. He holds a Class A CDL from Washington. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Jerry O. Ekes*

Mr. Ekes, 38, has had a refractive amblyopia in his left eye since birth. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2011, his optometrist noted, "It is my professional opinion that Mr. Ekes has sufficient vision to perform the driving tasks required to operate a commercial vehicle". Mr. Ekes reported that he has driven straight trucks for 15 years, accumulating 180,000 miles. He holds a Class D operator's license from Mississipi. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Robert A. Goerl, Jr.*

Mr. Goerl, 33, has traumatic cataract and macular hole in his left eye since 2000. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/60. Following an examination in 2011, his optometrist noted, "It is my opinion that Mr. Goerl does have sufficient visual function to perform the driving tasks required to operate a commercial vehicle". Mr. Goerl reported that he has driven straight trucks for 12 years, accumulating 60,000 miles. He holds a Class C operator's license from Pennslyvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Eric M. Grayson*

Mr. Grayson, 38, has had amblyopia and exophoria in his left eye since birth. The visual acuity in his right eye is 20/15 and in his left eye, 20/400. Following an examination in 2011, his optometrist noted, "His vision and side vision is sufficient enough for him to drive commercially." Mr. Grayson reported that he has driven straight trucks for 9 years, accumulating 112,500 miles and tractor-trailer combinations for 10 years, accumulating 900,000 miles. He holds a Class A CDL from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Alan D. Harberts*

Mr. Harberts, 56, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/400 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "In my opinion, he has excellent visual skills, and is competent to perform driving tasks associated with commercial vehicle driving." Mr. Harberts reported that he has driven straight trucks for 37 years, accumulating 462,500 miles and tractor-trailer combinations for 25 years, accumulating 187,500 miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Smith Harry, Jr.*

Mr. Harry, 41, has a prosthetic right eye due to a traumatic injury sustained during childhood. The best corrected visual acuity in his left eye is 20/20. Following an examination in 2011, his optometrist noted, "In my professional opinion, Mr. Smith has sufficient vision and central and peripheral visual fields OS to perform the driving tasks required to operate a commercial vehicle." Mr. Harry reported that he has driven straight trucks for 6 years, accumulating 480,000 miles and tractor-trailer combinations for 6 years, accumulating 480,000 miles. He holds a Class A CDL from North Carolina. His driving record for the last 3 years shows no crashes but one conviction for speeding in a CMV. He exceeded the speed limit by 13 Miles Per Hour (MPH).

*Vincent A.R. Neal*

Mr. Neal, 50, has optic atrophy in his left eye due to trauma that occurred 15 to 20 years ago. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/100. Following an examination in 2010, his ophthalmologist noted, "In addition, he should be able to perform his driving task without a problem." Mr. Neal reported that he has driven tractor-trailer combinations for 3 years, accumulating 270,000 miles. He holds a Class A CDL from Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Michael P. Passmore*

Mr. Passmore, 62, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/400. Following an examination in 2010, his optometrist noted, "As the examining doctor, it is my professional opinion that Mr. Passmore has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Passmore reported that he has driven straight trucks for 3½ years, accumulating 175,000 miles and tractor-trailer combinations for 3½ years, accumulating 35,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Timothy L. Porsley*

Mr. Porsley, 54, has complete loss of vision in his left eye due to a traumatic injury sustained in 1971. The best corrected visual acuity in his right eye is 20/20. Following an examination in 2010, his optometrist noted, "In my opinion, nothing has changed visually over the past thirty plus years. If he was visually safe to drive a commercial vehicle in the past, he still is today." Mr. Porsley reported that he has driven straight trucks for 30 years, accumulating 540,000 miles. He holds a Class D operator's license from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*James B. Prunty*

Mr. Prunty, 40, has had refractive amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "In my medical opinion, Mr. Prunty's visual deficiency in the right eye does not make him unsafe for commercial vehicle

operation. I do believe that he is able to operate a commercial vehicle safely without glasses, for his uncorrected vision is 20/25 when using both eyes. Mr. Prunty reported that he has driven straight trucks for 4 years, accumulating 96,000 miles. He holds a Class D operator's license from West Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Wendell S. Sehen*

Mr. Sehen, 46, has a prosthetic right eye due to trauma that occurred at the age of 4. The best corrected visual acuity in his left eye is 20/20. Following an examination in 2011, his optometrist noted, "In my medical opinion, Wendell Sehen has sufficient vision to perform the driving tasks to operate a commercial vehicle." Mr. Sehen reported that he has driven tractor-trailer combinations for 16 years, accumulating 560,000 miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Gary E. Valentine*

Mr. Valentine, 60, has a prosthetic left eye due to an eye injury that occurred in 2007. The visual acuity in his right eye is 20/20 and in his left eye, no light perception. Following an examination in 2011, his optometrist noted, "From these results, I believe Mr. Valentine does have sufficient visual acuity, visual field, and color discrimination to safely operate a commercial vehicle." Mr. Valentine reported that he has driven straight trucks for 40 years, accumulating 3.7 million miles and tractor-trailer combinations for 34 years, accumulating 3.5 million miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Charles Van Dyke*

Mr. Van Dyke, 64, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/100 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, "It is my medical opinion that Charles has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Van Dyke reported that he has driven straight trucks for 42 years, accumulating 2 million miles and tractor-trailer combinations for 2 years, accumulating 160,000 miles. He holds a Class A CDL from Wisconsin. His driving record for the last 3 years shows no crashes but one conviction for speeding in a CMV. He exceeded the speed limit by 13 mph.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business June 6, 2011. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: April 22, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–11014 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–EX–P**

---

## DEPARTMENT OF TRANSPORTATION

## Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0103]**

## Qualification of Drivers; Exemption Applications; Diabetes Mellitus

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA).

**ACTION:** Notice of applications for exemption from the diabetes mellitus standard; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 24 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

**DATES:** Comments must be received on or before June 6, 2011.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0103 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:* 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.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

*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 Federal Docket Management System (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 DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

**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 grant an exemption from the Federal Motor Carrier Safety

Regulations 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 24 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

**Qualifications of Applicants**

*Alfonso L. Abeyta*

Mr. Abeyta, age 57, has had ITDM since 2006. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Abeyta understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Abeyta meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A Commercial Driver's License (CDL) from Texas.

*Perfecto Aquino*

Mr. Aquino, 50, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Aquino understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Aquino meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Illinois.

*James C. Ayotte*

Mr. Ayotte, 50, has had ITDM since 1977. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ayotte understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ayotte meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from South Carolina.

*John C. Beason*

Mr. Beason, 62, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Beason understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Beason meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Tennessee.

*Charles A. Best*

Mr. Best, 27, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Best understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Best meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

*Gregory E. Bichsel, II*

Mr. Bichsel, 42, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bichsel understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bichsel meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Montana.

*Raymond D. Dubose*

Mr. Dubose, 53, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dubose understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dubose meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Georgia.

*Adam Errickson*

Mr. Errickson, 21, has had ITDM since 1998. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Errickson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Errickson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that

he does not have diabetic retinopathy. He holds a Class D operator's license from New Jersey.

*Jon M. Greiner*

Mr. Greiner, 58, has had ITDM since 2003. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Greiner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Greiner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Minnesota.

*Gregory M. Hoyt*

Mr. Hoyt, 38, has had ITDM since 2003. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hoyt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hoyt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Vermont.

*Robert E. Jackson*

Mr. Jackson, 44, has had ITDM since 2002. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jackson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jackson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from North Carolina.

*Kimm D. Jacobson*

Mr. Jacobson, 56, has had ITDM since 2006. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jacobson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jacobson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Daryl D. Jibben*

Mr. Jibben, 54, has had ITDM since 2000. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jibben understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jibben meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Jimmy G. Lee, Jr.*

Mr. Lee, 29, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lee understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lee meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Carolina.

*Daniel S. May*

Mr. May, 22, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. May understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. May meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

*Gerald D. McElya*

Mr. McElya, 51, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McElya understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McElya meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Texas.

*Michael L. Moore*

Mr. Moore, 45, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Moore understands

diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Moore meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

*Stacey W. Nelson*

Mr. Nelson, 34, has had ITDM since 2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Nelson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Nelson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable proliferative and nonproliferative diabetic retinopathy in both eyes. He holds a Class A CDL from Nebraska.

*Ervin W. Ponto*

Mr. Ponto, 61, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ponto understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ponto meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Donald B. Ramaley*

Mr. Ramaley, 69, has had ITDM since 2009. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ramaley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ramaley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

*Bart H. Rideout*

Mr. Rideout, 51, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rideout understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rideout meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Connecticut.

*Floyd M. Tyler*

Mr. Tyler, 72, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tyler understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tyler meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

*Richard G. Wunderlich*

Mr. Wunderlich, 61, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wunderlich understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wunderlich meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Mathew E. Yeates*

Mr. Yeates, 32, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Yeates understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Yeates meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Utah.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice.

We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441)[1]. The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section

[1] Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 USC. 31136 (e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Issued on: April 21, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–11012 Filed 5–4–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

### Notice of Limitation on Claims Against Proposed Public Transportation Project

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notice of Limitation on Claims.

**SUMMARY:** This notice announces final environmental actions taken by the Federal Transit Administration (FTA) for the following project: Central Corridor Light Rail Transit Project, Metropolitan Council, Minneapolis, MN. The purpose of this notice is to announce publicly the environmental decisions by FTA on the subject project and to activate the limitation on any claims that may challenge these final environmental actions.

**DATES:** By this notice, FTA is advising the public of final agency actions subject to Section 139(l) of Title 23, United States Code (U.S.C.). A claim seeking judicial review of the FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before November 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** Katie Grasty, Environmental Protection Specialist, Office of Planning and Environment, 202–366–9139, or Christopher Van Wyk, Attorney-Advisor, Office of Chief Counsel, 202–366–1733. FTA is located at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 9 a.m. to 5:30 p.m., EST, Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that FTA has taken final agency actions by issuing certain approvals for the public transportation project listed below. The actions on this project, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA administrative record for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information on the project. Contact information for FTA's Regional Offices may be found at *http://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303], Section 106 of the National Historic Preservation Act [16 U.S.C. 470f], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period of 180 days for challenges of project decisions subject to previous notices published in the **Federal Register.** The project and actions that are the subject of this notice are:

*Project name and location:* Central Corridor Light Rail Transit Project, City of Minneapolis, MN (Hennepin County) and City of St. Paul, MN (Ramsey County). *Project sponsor:* Metropolitan Council. *Project description:* The Central Corridor Light Rail Transit (LRT) Project (Project) is 10.9 miles long (9.7 miles of new alignment, 1.2 miles on shared alignment) and consists of 23 Central Corridor LRT stations—18 new stations and five shared with the Hiawatha LRT. The Central Corridor Light Rail Transit Project Final Environmental Impact Statement (FEIS) and Section 4(f) Evaluation was published in June 2009. A Record of Decision (ROD) was issued by the Federal Transit Administration (FTA) in August 2009.

Following the June 2009 FEIS and the August 2009 ROD, a lawsuit was filed against the U.S Department of Transportation (USDOT), the FTA and the Metropolitan Council by a coalition of local businesses, residents and non-profit organizations. One of the four claims made in the lawsuit was that the environmental review of the Project violated NEPA by failing to adequately analyze potential loss of business revenues caused during construction of the Project. The Court held that the FEIS prepared in June 2009, had failed to evaluate potential impacts on the loss of business revenue during construction and that it should have been evaluated during the NEPA process. The Court ordered the FTA and Metropolitan Council to supplement the FEIS on this issue and to consider any loss of business revenues as an adverse impact of the construction of the Central Corridor LRT. The results of this analysis, as required by the January 26, 2011, Court order, are documented in the Construction-Related Potential Impacts on Business Revenues Supplemental Environmental Assessment (EA) issued April 20, 2011. This notice applies to only the Finding of No Significant Impact issued on April 20, 2011. This notice does not alter or extend the prior Limitation on Claims notice issued for the Record of Decision issued for the Project in August 2009. *Final agency actions:* Finding of No Significant Impact issued April 20, 2011.

*Supporting documentation:* Final Environmental Impact Statement dated June 2009 and ROD dated August 18, 2009.

Issued on: April 29, 2011.

**Elizabeth S. Riklin,**

*Deputy Associate Administrator for Planning and Environment.*

[FR Doc. 2011–10911 Filed 5–4–11; 8:45 am]

**BILLING CODE P**

## 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 39th session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCOE TDG) to be held June 20–24, 2011, 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**

*Date:* Wednesday, June 8, 2011; 9:30 a.m.–12:30 p.m.

*Address:* The meeting will be held at the DOT Headquarters, West Building, Oklahoma City Conference Room, 1200 New Jersey Avenue, SE., Washington, DC 20590.

*Registration:* Pre-registration for this meeting is not required. Participants are encouraged to arrive early to allow time for security checks necessary to obtain access to the building.

*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/hazmat/regs/international.*

**FOR FURTHER INFORMATION CONTACT:** Mr. Shane Kelley, Senior 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 39th session of the UNSCOE TDG. The 39th session of the UNSCOE TDG is the first of four meetings scheduled for the 2011–2012 biennium. The UNSCOE will consider proposals for the 18th Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations which will be implemented within relevant domestic, regional, and international regulations from January 1, 2015. Copies of proposals 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/c32011.html.*

General topics on the agenda for the UNSCOE TDG meeting include:

- Explosives and related matters.
- Listing, classification and packing.
- Electric storage systems.
- Electronic data interchange (EDI) for documentation purposes.
- Cooperation with the International Atomic Energy Agency (IAEA).
- Global harmonization of transport of dangerous goods regulations.
- Guiding principles for the Model Regulations.
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

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.*

Following the 39th 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 Web site at *http://www.phmsa.dot.gov/hazmat/regs/international.*

PHMSA's site at *http://www.phmsa.dot.gov/hazmat/regs/international* provides additional information regarding the UNSCOE TDG and related matters such as summaries of decisions taken at previous sessions of the UNSCOE TDG.

Issued in Washington, DC, on May 2, 2011.

**Magdy El-Sibaie,**

*Associate Administrator for Hazardous Materials Safety.*

[FR Doc. 2011–10996 Filed 5–4–11; 8:45 am]

BILLING CODE 4910–60–P

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

**ACTION:** Notice; correction.

**SUMMARY:** The Department of the Treasury published a document in the **Federal Register** on April 12, 2011, inviting comments on collections of information submitted to the Office of Management and Budget (OMB) for review. This document contained incorrect references.

**Correction**

In the **Federal Register** of April 12, 2011, in FR Doc. 2011–8675, make the following corrections:

- Page 20449, in the second column, under *OMB Number:* 1545–1800, *Type of Review:* replace "Extension without change" with "Revision".
- Page 20449, in the second column, under *OMB Number:* 1545–1800, *Estimated Total Burden Hours:* replace "9,112" with "913,698".
- Page 20449, in the second column, under *OMB Number:* 1545–2098, *Type of Review:* replace "Extension without change" with "Revision".
- Page 20449, in the second column, under *OMB Number:* 1545–2098, *Estimated Total Burden Hours:* replace "4" with "1,000".

Dated: May 2, 2011.

**Dawn D. Wolfgang,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2011–10948 Filed 5–4–11; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Determination of Foreign Exchange Swaps and Foreign Exchange Forwards Under the Commodity Exchange Act

**AGENCY:** Department of the Treasury, Departmental Offices.

**ACTION:** Notice of proposed determination.

**SUMMARY:** The Commodity Exchange Act ("CEA"), as amended by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"), authorizes the Secretary of the Treasury ("Secretary") to issue a written determination exempting foreign exchange swaps, foreign exchange forwards, or both, from the definition of a "swap" under the CEA. The Secretary proposes to issue a determination that would exempt both foreign exchange swaps and foreign exchange forwards from the definition of "swap," in accordance with the relevant provisions of the CEA and invites comment on the proposed determination, as well as the factors supporting such a determination.

**DATES:** Written comments must be received on or before June 6, 2011, to be assured of consideration.

**ADDRESSES:** *Submission of Comments by mail:* You may submit comments to: Office of Financial Markets, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

*Submission of Comments via regulations.gov:* You are encouraged to submit comments electronically through the Federal eRulemaking Portal—"Regulations.gov." Go to *http://www.regulations.gov* to submit or view public comments. The Regulations.gov home page provides information on using Regulations.gov, including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket.

Please include your name, affiliation, address, e-mail address and telephone number(s) in your comment. In general, comments received will be posted on regulations.gov without change, including any business or personal information provided. Treasury will also make such comments available for public inspection and copying in Treasury's Library, Room 1428, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 622–0990. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

**FOR FURTHER INFORMATION CONTACT:** Office of Financial Markets, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, (202) 622–2730, *fxproposal@treasury.gov;* Thomas E. Scanlon, Office of the General Counsel, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, (202) 622–8170.

**SUPPLEMENTARY INFORMATION:** Title VII of the Dodd-Frank Act [1] amends the CEA, as well as Federal securities laws, to provide a comprehensive regulatory regime for swaps. Section 721 of the Dodd-Frank Act amends section 1a of the CEA, which, in relevant part, defines the term "swap" under the CEA and includes foreign exchange swaps and foreign exchange forwards in the definition.[2] Section 1a(47)(E) of the CEA authorizes the Secretary to make a written determination that "foreign exchange swaps" [3] or "foreign exchange forwards," [4] or both— (I) should not be regulated as swaps under the CEA; and (II) are not structured to evade the Dodd-Frank Act in violation of any rule promulgated by the Commodity Futures Trading Commission ("CFTC") pursuant to section 721(c) of the Dodd-Frank Act.[5]

On October 28, 2010, the Department of the Treasury ("Treasury") published in the **Federal Register** a Notice and Request for Comments ("October 2010 Notice") to solicit public comment on a wide range of issues relating to whether foreign exchange swaps and foreign exchange forwards should be exempt from the definition of the term "swap" under the CEA.[6] In addition, Treasury staff has engaged in a broad outreach to representatives from multiple market segments, as well as market regulators and the Federal regulatory agencies. After assessing the comments in response to the October 2010 Notice, consulting with Federal regulators, and preliminarily considering the factors set forth in section 1b(a) of the CEA, as discussed below, the Secretary believes that proposing a determination to exempt all "foreign exchange swaps" and "foreign exchange forwards" from the definition of the term "swap" under the CEA is appropriate.

In making a determination pursuant to sections 1a(47)(E) and 1b of the CEA, the Secretary must consider the following factors:

(1) Whether the required trading and clearing of foreign exchange swaps and foreign exchange forwards would create systemic risk, lower transparency, or threaten the financial stability of the United States;

(2) Whether foreign exchange swaps and foreign exchange forwards are already subject to a regulatory scheme that is materially comparable to that established by the CEA for other classes of swaps;

(3) The extent to which bank regulators of participants in the foreign exchange market provide adequate supervision, including capital and margin requirements;

(4) The extent of adequate payment and settlement systems; and

(5) The use of a potential exemption of foreign exchange swaps and foreign exchange forwards to evade otherwise applicable regulatory requirements.[7]

Treasury is soliciting comment on this proposed determination,[8] as set forth below, which would exempt any foreign exchange swap and foreign exchange forward from the definition of the term "swap" under the CEA, as permitted by section 1a(47)(E) of the CEA.

## I. Summary of Proposed Determination

The CEA, as amended by the Dodd-Frank Act, provides a comprehensive regulatory regime for swaps and derivatives, including a wide range of foreign exchange derivatives, such as foreign exchange options, currency swaps, or non-deliverable forwards ("NDFs"). Among other measures, this regulatory regime provides for clearing and exchange-trading requirements that are designed to mitigate risks, promote price transparency, and facilitate more stable, liquid markets for derivative instruments. In general, the payment obligations on currency swaps, interest rate swaps, credit default swaps, commodity swaps and other derivatives fluctuate in response to changes in the value of the underlying variables on which those derivative contracts are based. As a result, for most types of swaps and derivatives, the counterparties do not know their payment obligations and the full extent of their exposure throughout the life of the contract. Moreover, as the length of a swap or derivative contract increases, a party generally is exposed to greater counterparty credit risk. Settlement of most types of swaps and derivatives involves only payments of net amounts (not gross amounts) that are based on the change in value of the underlying variables. Given the features of most derivatives, including some types of foreign exchange derivatives, the clearing and exchange-trading requirements under the CEA would mitigate the relevant risks, notably counterparty credit risks.

Foreign exchange swaps and forwards generally are subject to the requirements of the CEA. For these instruments, the most significant requirements under the regulatory regime enacted by the Dodd-Frank Act would be the potential for mandatory central clearing and exchange trading,[9] unless the Secretary

[1] Pub. L. 111–203, title VII.

[2] 7 U.S.C. 1a(47).

[3] 7 U.S.C. 1a(25).

[4] 7 U.S.C. 1a(24).

[5] 7 U.S.C. 1(a)(47)(E)(i).

[6] 75 FR 66,426 (Oct. 28, 2010). Thirty comments were submitted in response to the October 2010 Notice.

[7] 7 U.S.C. 1b(a). In addition, section 1b(b) of the CEA provides that, "[i]f the Secretary makes a determination to exempt foreign exchange swaps and foreign exchange forwards from the definition of the term 'swap'," the Secretary must submit a separate "determination" to the appropriate committees of Congress, which contains (1) an explanation why foreign exchange swaps and foreign exchange forwards are "qualitatively different from other classes of swaps" such that foreign exchange swaps and foreign exchange forwards are "ill-suited for regulation as swaps" and (2) an "identification of the objective differences of foreign exchange swaps and foreign exchange forwards with respect to standard swaps that warrant an exempted status" (i.e., as a result of the underlying "determination").

[8] 5 U.S.C. 553(b).

[9] 7 U.S.C. 2(h)(1)–(2). In general, this section provides that the CFTC must act for each swap, or a category of swaps, to be required to be cleared. In addition, the CEA provides several exceptions to

Continued

makes a determination that foreign exchange swaps and forwards "(I) should not be regulated as swaps under [the CEA]; and (II) are not structured to evade [the Dodd-Frank Act] in violation of any rules promulgated by the [CFTC] pursuant to section 721(c) of the [Dodd-Frank Act]." [10]

The Secretary proposes to issue a determination to exempt foreign exchange swaps and forwards because of the distinctive characteristics of these instruments. As discussed below, unlike most other derivatives, foreign exchange swaps and forwards have fixed payment obligations, are physically settled, and are predominantly short-term instruments. This results in a risk profile that is different from other derivatives, as it is centered on settlement risk, rather than counterparty credit risk. Settlement risk in foreign exchange swaps and forwards already has been addressed through the extensive use of payment-versus-payment ("PVP") settlement arrangements. Even though central clearing could reduce counterparty credit risk, that risk is relatively small in the foreign exchange swaps and forwards market. Imposing central clearing and trading requirements under the CEA on foreign exchange swaps and forwards would introduce risks and operational challenges to the current settlement arrangements that significantly outweigh the marginal benefits.

*A. Foreign Exchange Swaps and Forwards Differ in Significant Ways From Other Swaps and Derivatives*

Under the CEA, a "foreign exchange swap" is narrowly defined as "a transaction that solely involves—(A) an exchange of 2 different currencies on a specific date at a fixed rate that is agreed upon on the inception of the contract covering the exchange" and "(B) a reverse exchange of [those two currencies] at a later date and at a fixed rate that is agreed upon on the inception of the contract covering the exchange." [11] Likewise, the CEA narrowly defines a foreign exchange forward as "a transaction that solely involves the exchange of 2 different currencies on a specific future date at a fixed rate agreed upon on the inception of the contract covering the exchange." [12]

The Secretary's authority to issue a determination is limited to foreign exchange swaps and forwards and does not extend to other foreign exchange derivatives. Foreign exchange options, currency swaps, and NDFs may not be exempted from the CEA's definition of "swap" because they do not satisfy the statutory definitions of a foreign exchange swap or forward.

The payment obligations on foreign exchange swaps and forwards are fixed and predetermined. While the mark-to-market value of a position in a foreign exchange swap or forward may vary based on changes in the exchange rate, the actual settlement amounts do not. These features make foreign exchange swaps and forwards more similar to funding instruments, such as repurchase agreements, which are not covered under the CEA. Businesses that sell goods in international trade, or that make investments in foreign countries, frequently ask their banks to arrange foreign exchange swaps and forwards to control the risk that their own country's currency will rise or fall against the other country's currency while the sale or investment is pending.

Foreign exchange swap and forward participants know their own and their counterparties' payment obligations and the full extent of their exposure throughout the life of the contract, whereas the counterparties to other derivatives contracts do not. Moreover, foreign exchange swap and forward contracts have a very short average length and, therefore, relative to other swaps and derivatives, create significantly lower levels of counterparty credit risk.

Settlement of foreign exchange swap and forward transactions requires the exchange of the full principal amount of the contract in two different currencies, whereas the payment obligations of most other derivatives are based on the incremental profit or loss on a transaction. The physical settlement requirement distinguishes foreign exchange swaps and forwards from other derivatives and contributes to a risk profile that is largely concentrated on settlement risk.

*B. Settlement Risk Is the Main Risk and Already Is Effectively Mitigated*

Settlement of foreign exchange swap and forward transactions requires the exchange of the full principal amount of the contract in two different currencies.[13] Settlement risk is the risk that one party to a foreign exchange swap or forward transaction will deliver the currency it owes its counterparty, but not receive the other currency from its counterparty. In contrast to other derivatives, including the other foreign exchange derivatives discussed above, parties' ultimate payment obligations on a foreign exchange swap or forward are known and fixed from the beginning of the contract and involve the actual exchange of a predetermined amount of principal at settlement. The physical settlement requirement distinguishes foreign exchange swaps and forwards from other derivatives and contributes to a risk profile that is largely concentrated on settlement risk.

The foreign exchange swap and forward market relies on the extensive use of PVP settlement arrangements, which permit the final transfer of one currency to take place only if the final transfer of the other currency also takes place. These settlement arrangements do not guarantee the contract but prevent payment flows from occurring if either party defaults. CLS Bank International ("CLS"), the predominant PVP settlement system, currently provides settlement services for 17 currencies that represent 94 percent of the total daily value of foreign exchange swaps and forwards traded globally.

Currently, roughly 75 percent of the entire foreign exchange market is estimated to settle without settlement risk to either party. This figure includes trades settled by PVP arrangements, as well as trades that are settled without settlement risk. (Transactions that are internally settled between corporate affiliates, cash settled, or settled across a single-bank's books for its clients are not subject to settlement risk.) In the foreign exchange swaps and forwards market in particular, CLS estimates that it settles more than 50 percent of foreign exchange swap and forward transactions that are subject to settlement risk. The use of CLS has also been growing steadily since its introduction in 2002, and CLS has announced plans to further expand its settlement services to include additional currencies, increase volume capacity and add additional settlement times.

*C. Foreign Exchange Swaps and Forwards Are Subject to Less Counterparty Credit Risk Than Other Derivatives*

Counterparty credit risk is the risk of economic loss if either party defaults on a contract. Counterparty credit risk increases with the length of a contract because that increases the length of time during which a counterparty could suffer from adverse developments. Foreign exchange swap and forward contracts have a very short average

the clearing and trading requirements and authorizes the CFTC to impose conditions or limitations on these exceptions.

[10] 7 U.S.C. 1a(47)(E)(i).

[11] 7 U.S.C. 1a(25).

[12] 7 U.S.C. 1a(24).

[13] By contrast, the payment obligations of most other derivatives are based on the incremental profit or loss on a transaction and either party's payment may be made with a common currency.

length. Sixty-eight percent of foreign exchange swap and forward contracts mature in less than a week, and 98 percent mature in less than a year. Other derivatives, such as interest rate swaps, generally have much longer maturity terms (*e.g.,* between two and thirty years) than foreign exchange swaps and forwards, and thus pose significantly more counterparty credit risk than foreign exchange swaps and forwards.

Central clearing could provide foreign exchange swap and forward participants with further protection against the risk of default by their counterparties (*i.e.,* the replacement cost of a transaction if a counterparty fails to perform). However, imposing a central clearing requirement on the foreign exchange swaps and forwards market raises two concerns. First, requiring central clearing may lead to combining clearing and settlement in one facility, which would create large currency and capital needs for that entity due to: (i) The sheer size and volume of the foreign exchange swaps and forwards market; and (ii) the fact that the central clearing facility would be effectively guaranteeing both settlement and market exposure to replacement cost. We believe that it is unlikely a central counterparty ("CCP") would be able to provide the settlement services required by this market, either directly or in conjunction with another service provider, such as CLS.

In addition, providing central clearing separately from settlement presents the second concern, namely: required clearing would disrupt the existing settlement process by introducing additional steps between trade execution and settlement that pose significant operational challenges. The existing settlement process for this market functions well and has been critical to mitigating this market's main source of risk. The operational challenges and potentially disruptive effects on the foreign exchange swaps and forwards market associated with adding a central clearing requirement for these instruments thus significantly outweigh the marginal benefits that central clearing would provide.

*D. Key Players Within the Foreign Exchange Market Already Are Subject to Oversight*

Unlike the derivatives markets, banks are the key players in the foreign exchange swaps and forwards market. Roughly 95 percent of foreign exchange swaps and forwards transactions occur between banks acting either on their own behalf or on behalf of their clients. Banks are subject to consolidated supervision, and supervisors regularly monitor their foreign exchange related exposures, internal controls, risk management systems, and settlement practices.

The foreign exchange market itself also has long been subject to comprehensive and coordinated oversight, reflecting its unique characteristics and functioning. Since the introduction of floating exchange rates in the early 1970s, G10 central banks and regulators have undertaken strong and coordinated oversight measures for the foreign exchange market, given its critical role in monetary policy and the global payments system. This global strategy, which was launched in 1996 by the Bank for International Settlements ("BIS"), resulted in the design and implementation of CLS and other PVP settlement arrangements. The Federal Reserve regularly conducts reviews of the risk management and operational processes of major foreign exchange market participants. These reviews inform Basel Committee on Banking Supervision ("BCBS") and Committee on Payment and Settlement Systems ("CPSS") updates to bank supervisory guidelines on managing foreign exchange settlement risk.

*E. The Foreign Exchange Swaps and Forwards Market Already Is Highly Transparent and Traded Over Electronic Trading Platforms*

Foreign exchange swaps and forwards already trade in a highly transparent market. Market participants have access to readily available pricing information through multiple sources. Approximately 41 percent and 72 percent of foreign exchange swaps and forwards, respectively, already trade across a range of electronic platforms and the use of such platforms has been steadily increasing in recent years.[14] The use of electronic trading platforms provides a high level of pre- and post-trade transparency within the foreign exchange swaps and forwards market. Thus, mandatory exchange trading requirements would not significantly improve price transparency or reduce trading costs within this market.

*F. Foreign Exchange Swaps and Forwards Will Be Subject to Additional Oversight Under the CEA*

Even if the Secretary determines that foreign exchange swaps and forwards should not be regulated as "swaps" under the CEA, that determination would not affect the application of other provisions of the CEA that will prevent evasion by market participants and improve market transparency. Commenters who oppose an exemption argue that it would create a large regulatory loophole that exacerbates systemic risk. However, all foreign exchange transactions would remain subject to the CFTC's new trade-reporting requirements, enhanced anti-evasion authority, and strengthened business-conduct standards. Notably, the creation of a global foreign exchange trade repository, plans for which are already underway, will dramatically expand reporting to regulators and the market more broadly.

**II. Background and Statutory Considerations**

*A. Overview*

(i) Foreign Exchange Swaps and Forwards Distinguished From Other Swaps

Foreign exchange swaps and forwards that would be exempt from the CEA's definition of "swap" under the determination are narrowly defined transactions that are qualitatively different from other derivatives. First, foreign exchange swaps and forwards involve the actual exchange of the principal amounts of the two currencies exchanged and are settled on a physical basis. Unlike many other derivative instruments (*e.g.,* interest rate swaps) whose payment obligations fluctuate daily in response to changes in the values of underlying variables, such as interest rates, the payment obligations of foreign exchange swaps and foreign exchange forwards, as defined by the CEA, are fixed at the onset of the agreement and involve the actual exchange of full principal for settlement.

Second, in stark contrast to other derivatives, over 98 percent of foreign exchange swaps and forwards mature in less than one year, and 68 percent mature in less than one week. For example, interest rate swaps and credit default swaps generally have maturity terms between two and thirty years and five to ten years, respectively. Since counterparty credit risk increases as the length of a contract increases, foreign exchange swaps and forwards carry significantly lower counterparty credit risk.

Third, the use of foreign exchange swaps and forwards is distinct from other derivatives. Because of their unique structure and duration, as outlined above, foreign exchange swaps and forwards are predominantly used as short-term funding instruments similar to repurchase agreements and other money market instruments and for

[14] BIS, Greenwich Associates, Oliver Wyman analysis.

hedging foreign currency risks. Other derivatives, such as interest rate and currency swaps, are used for a broader range of purposes.

Fourth, foreign exchange swaps and forwards already trade in a highly transparent and liquid market. Market participants have access to readily available pricing information through multiple sources.[15] Approximately 41and 72 percent of foreign exchange swaps and forwards, respectively, already trade across a range of electronic platforms.[16] As a result, mandatory exchange trading requirements under the CEA would be unlikely to improve price transparency significantly.

These distinguishing characteristics of foreign exchange swaps and forwards result in a risk profile that is largely concentrated on settlement risk, rather than counterparty credit risk. Settlement risk is effectively addressed in the market for foreign exchange swaps and forwards by the extensive use of CLS and other PVP settlement arrangements. PVP is a foreign exchange settlement mechanism that ensures that a final transfer of one currency occurs only if a final transfer of the other currency (or currencies) takes place, thereby virtually eliminating settlement risk. CLS is a specialized settlement system that operates a multilateral PVP settlement system to reduce foreign exchange settlement risk (but not credit risk, which is mitigated by other measures). CLS, which began operations in September 2002, is now the predominant global PVP settlement system. It currently provides settlement services for 17 currencies, which represent 94 percent of the total daily value of currencies traded globally. CLS estimates that it settles 58 percent of global foreign exchange trading, through 60 settlement member banks and approximately 9,000 third-party users. According to a September 2010 Foreign Exchange Committee ("FXC") [17] survey, roughly 75 percent of foreign exchange transactions are settled without settlement risk to either party. This figure includes trades settled by CLS, settled between affiliates of the same corporation, and settled across a single bank's books for its clients.

(ii) Implications of a Determination to Exempt Foreign Exchange Swaps and Forwards From the Term "Swap" Under the CEA

If the Secretary issues a written determination to exempt foreign exchange swaps or forwards, or both, from the definition of a "swap" under the CEA, these transactions, as well as certain parties that engage in these transactions, would not be subject to some requirements under the CEA, notably the clearing and exchange-trading requirements.

However, even if the Secretary issues such a determination, foreign exchange swaps and forwards and the parties to such transactions would still be subject to trade reporting requirements, business conduct standards (including the anti-fraud provision) in section 4s(h) of the CEA and the rules promulgated thereunder by the CFTC, and anti-evasion requirements promulgated by the CFTC. In this regard, section (c) of the proposed determination—which reflects the language of section 1a(47)(E)(iii)–(iv), 1b(c) of the CEA—would provide that, notwithstanding this determination, certain requirements under the CEA would apply to any foreign exchange swap or foreign exchange forward, or to any party engaged in such a transaction, to the extent provided by such requirements.

In addition, Treasury notes that section 1a(47)(F) of the CEA contains two other provisions applicable to foreign exchange swaps and foreign exchange forwards. First, subparagraph (47)(F)(i) provides that "[a]ny foreign exchange swap and any foreign exchange forward that is listed and traded on or subject to the rules of a designated contract market or a swap execution facility, or that is cleared by a derivatives clearing organization, shall not be exempt from any provision of [CEA], or the amendments under [Title VII of the Dodd-Frank Act] prohibiting fraud or manipulation." [18] Second, "[n]othing in subparagraph (E) [which authorizes the Secretary to issue such a determination] shall affect, or be construed to affect, the applicability of [the CEA] or the jurisdiction of the [CFTC] with respect to agreements, contracts, or transactions in foreign currency pursuant to section 2(c)(2) [of the CEA]." [19]

(iii) Summary of Comments in Response to October 2010 Notice

Commenters who support issuing an exemption generally argue that foreign exchange swaps and forwards are functionally different from other over-the-counter ("OTC") derivatives because foreign exchange swaps and forwards, as defined by the CEA, involve an actual exchange of principal, are predominantly very short in duration and have high turnover rates. These commenters note that this market functions predominantly as a global payments market and is used significantly by end-users for hedging purposes.[20] Many corporate participants expressed concern that the additional costs associated with clearing foreign exchange swaps and forwards would adversely impact their business activities and discourage hedging activity. These commenters also cautioned that imposing mandatory clearing and exchange trading requirements on the foreign exchange market would increase systemic risk by concentrating risk in one or more clearinghouses. They also noted that central clearing could negatively affect U.S. dollar liquidity and threaten the role of the dollar as the world's reserve currency, citing the potential that such requirements could push foreign exchange transactions further offshore and challenge the Federal Reserve's ability to conduct monetary policy.

Settlement risk, they argue, is the primary risk associated with foreign exchange swaps and forwards, and they state that the settlement of trades through CLS has largely addressed these concerns.[21]

Given the short duration of foreign exchange swaps and forwards, most commenters emphasized that counterparty credit risk is not as significant a risk for these transactions (relative to other derivative transactions) and that the use of credit support annexes ("CSAs") and standard ISDA documentation mitigates this risk.

Moreover, commenters who favor an exemption maintain that foreign exchange swaps and forwards generally trade in a heavily liquid, efficient, and transparent inter-bank market, where bank regulators have substantial visibility and exercise strong regulatory oversight over the major market participants, which generally consist of either depository institutions or affiliates of depository institutions. A number of these commenters also stressed that the Federal Reserve has

[15] *See, e.g.,* comment by Global FX Division of the Securities Industry and Financial Markets Assoc., Assoc. for Financial Markets in Europe, and the Asia Securities Industry and Financial Markets Assoc. ("Global FX Division"), at 11.

[16] BIS, Greenwich Associates, Oliver Wyman analysis.

[17] Formed in 1978 under the sponsorship of the Federal Reserve Bank of New York, the FXC is an industry group that produces best practice recommendations for the foreign exchange industry, addressing topics such as management of risk in operations and trading.

[18] 7 U.S.C. 1a(47)(F)(i).

[19] 7 U.S.C. 1a(47)(F)(ii) (referring, in turn, to 7 U.S.C. 2(c)(2)).

[20] *See* comment by 3M, Cargill Inc. *et al.,* at 2.

[21] *See, e.g.,* comment by Global FX Division, at 12–14.

ample authority to craft appropriate regulations governing systemically important financial market utilities and payment, clearing, and settlement activities under Title VIII of Dodd-Frank Act. These commenters also cite the effective functioning of the foreign exchange market during the financial crisis of 2008.

In contrast to these views, commenters who oppose an exemption for foreign exchange swaps and forwards are primarily concerned that the exemption would create a large regulatory loophole, citing the large size of this market, as well as the lack of a fundamental economic difference, in their view, between foreign exchange swaps and forwards and other derivative products.[22] In light of the recent financial crisis, these commenters argue that such loopholes can play a significant role in undermining financial stability by preserving an opaque, unregulated and under-capitalized market. Opponents also express concerns that an exemption could be used to mask complex transactions in an effort to avoid subjecting them to clearing and trading requirements.

*B. Statutory Factors*

As discussed above, in considering whether to exempt foreign exchange swaps and forwards from the definition of the term "swap," the Secretary must consider five factors. Treasury is continuing to consider each of these statutory factors and invites comment on the analysis of each of these factors, as follows.

(i) Systemic Risk, Transparency, Financial Stability

Treasury has considered several factors to assess whether the required trading and clearing of foreign exchange swaps and foreign exchange forwards would create systemic risk, lower transparency, or threaten the financial stability of the United States. Treasury believes that, given the reduced counterparty credit risk profile of this market, the challenges of implementing central clearing within this market significantly outweigh the marginal benefits that central clearing and exchange trading would provide.

Regulating foreign exchange swaps and forwards under the CEA would require insertion of a CCP into an already well-functioning and highly interconnected settlement process, which could result in unnecessary operational and settlement challenges. Other derivative transactions, such as interest rate swaps and credit default swaps, create settlement obligations that equal only the change in the market price of the notional value of the underlying instrument—not the full principal amounts—and, thus, result in much smaller daily payment obligations for those markets. While the existing CLS and other PVP settlement systems protect against the risk of principal loss in the foreign exchange swaps and forwards market, central clearing would further protect participants against the economic loss of profit on a transaction. However, combining these two functions in a market that involves settlement of the full principal amounts of the contracts would require massive capital backing in a very large number of currencies, representing a much greater commitment for a potential CCP than for any other derivatives market.

To date, no CCP has developed a practical solution to guarantee the extraordinarily large volumes of transactions in foreign exchange swaps and forwards, including provision of or coordination with the settlement services that are essential to the foreign exchange swaps and forwards market. Introducing a central clearing facility without settlement capabilities would not improve market functioning; instead, requiring central clearing would raise unnecessary operational challenges by introducing additional steps between trade execution and settlement. Given that any risks created through the increased complexity would be magnified by the number of currencies involved, among other factors, Treasury believes that requiring the use of a CCP for clearing foreign exchange swaps and forwards is not warranted, particularly because existing settlement arrangements currently function well and address the main source of risk, settlement risk.

In response to the October 2010 Notice, end-users of foreign exchange swaps and forwards have expressed significant concern that requiring centralized clearing would substantially increase the costs of hedging foreign exchange risks. Commenters argue that additional costs associated with collateral, margin, and capital requirements required by the CCP would potentially reduce their incentives to manage foreign exchange risks.[23] Such additional costs borne by non-financial end-users could lead to lower cash flows or earnings, which would divert financial resources from investment and discourage international trade, thereby limiting the growth of U.S. businesses.[24] Several commenters also suggest that requiring centralized clearing of foreign exchange swaps and forwards could lead non-financial end-users to move production facilities overseas in order to establish "natural hedges" through the consistent use of local currencies and force them to reconsider the use of CLS in light of the additional costs associated with central clearing.[25]

As noted above, the market for foreign exchange transactions is one of the most transparent and liquid global trading markets. Pricing is readily available through multiple sources and a large portion of foreign exchange trades currently are executed through electronic trading platforms.[26]

In light of these and similar factors raised by the commenters, Treasury believes that mandating centralized clearing and exchange trading under the CEA for foreign exchange swaps and foreign exchange forwards actually would introduce significant operational challenges and potentially disruptive effects in this market which would outweigh any marginal benefits for transparent trading or reducing risk in these instruments.

(ii) Regulatory Scheme Comparable to That of the CEA

Treasury has considered several factors to assess whether foreign exchange swaps and foreign exchange forwards are already subject to a regulatory scheme that is materially comparable to that established by the CEA for other classes of swaps.

Since the introduction of floating exchange rates in the early 1970s, central banks and regulators have undertaken strong and coordinated oversight measures for the foreign

[22] *See, e.g.,* comment by Council for Institutional Investors, at 1–2.

[23] *See, e.g.,* comment by National Assoc. of Manufacturers, at 4.

[24] *See, e.g.,* comment by 3M, Cargill Inc. *et al.,* at 6.

[25] *See, e.g.,* comment by Coalition for Derivatives End-Users, at 16–17.

[26] Furthermore, Treasury understands that plans are being made for the creation of at least one global foreign exchange trading repository pursuant to section 21 of the CEA (7 U.S.C. 24a, as added by section 728 of the Dodd-Frank Act), which will dramatically expand reporting coverage for swaps, including foreign exchange swaps and forwards, regardless of whether the Secretary issues a determination that these transactions should not be regulated as "swaps" under the CEA. 75 FR 76,574 (Dec. 8, 2010). (In its proposed rule regarding swap data recordkeeping and reporting requirements, the CFTC explains that, for the purposes of reporting requirements, foreign exchange swaps and forwards would be included within the category of "currency swap." *Id.* at 76,586. The CFTC also has proposed rules relating to the registration and regulation of swap data repositories that would adopt new part 49 of the CFTC's regulations, 17 CFR Part 49. *See* CFTC, Notice of Proposed Rulemaking: Swap Data Repositories, 75 FR 80898 (Dec. 23, 2010)).

exchange market because of the critical role this market plays in the conduct of countries' monetary policy. More specifically, in 1996, the Bank for International Settlements ("BIS") launched a globally coordinated strategy on behalf of the G10 central banks, calling for specific actions by individual banks, industry groups and central banks to address and reduce risk in the foreign exchange market. This strategy has resulted in specific actions undertaken to address settlement risk, mitigate counterparty credit risk and develop global supervisory guidelines on managing foreign exchange risk. Largely as a result of these measures, many market observers note that the foreign exchange market was one of the few parts of the financial market that functioned effectively throughout the financial crisis.[27]

One of the key goals of this work was to expand the use of PVP settlement systems. Such systems largely eliminate settlement risk, which is the predominant risk in a foreign exchange swap or forward. As noted, PVP settlement ensures that the final transfer of one currency occurs only if a final transfer of the other currency or currencies takes place, thereby virtually eliminating settlement risk. In order to support such PVP arrangements, central banks undertook significant actions by extending operating hours, providing cross-border access to central bank accounts and enhancing the legal certainty around such settlement arrangements.

The creation of CLS was the most successful outcome of this work. As noted earlier, CLS is the predominant PVP settlement system, settling the majority of all global foreign exchange transactions in 17 currencies, through 60 settlement member banks and approximately 9,000 third party users.[28]

A comparable regulatory scheme applies to the settlement system conducted through CLS. While the Federal Reserve is the primary regulator for CLS, a CLS Oversight Committee[29] consisting of 22 central banks was established to provide coordinated oversight of CLS by all central banks whose currencies are settled through its system. As a result of this group's efforts, each participating central bank now maintains accounts for CLS and has created a window period during which real-time gross settlement systems are open to accommodate the funding necessary for the settlement of payment instructions. This group has also developed a set of risk management tests that CLS must apply to each instruction it submits for settlement to mitigate the associated credit, market and liquidity risks.

In addition, Treasury notes that the established regulatory scheme also actively encourages the use of CSAs and master netting agreements to reduce counterparty credit exposures. Similar to changes made to enable the use of PVP settlement arrangements, central banks and governments worked to strengthen the legal foundations of bilateral and multilateral netting. Master netting agreements mitigate credit risk by enabling closeout netting in the event of a default or bankruptcy. CSAs can also be negotiated as a supplement to master agreements to further reduce and mitigate exposures to counterparties by collateralizing transactions.

(iii) Adequacy of Supervision

Treasury also has assessed the extent to which bank regulators supervise participants in the foreign exchange market, including by imposing capital and margin requirements.

The predominant participants in the foreign exchange swaps and forwards market are banks which have long been subject to prudential supervision. In fact, nearly all trading within the foreign exchange market involves bank counterparties. Roughly 95 percent of foreign exchange trading occurs between banks acting in the capacity of either principal or agent. Compared to non-bank entities, banks have distinct advantages to provide the liquidity and funding necessary to conduct foreign exchange swaps and forwards, which involve the exchange of principal, rather than variable cash flows. In conjunction with providing the liquidity and funding needs to conduct these transactions, banks are uniquely qualified to have access to CLS to settle transactions on a real-time basis, and thereby meet the payment and short-term funding needs of the end users. Prudential supervisors regularly monitor the activities, exposures, internal controls and risk management systems of these banks.[30] In order to meet safety-and-soundness requirements, banks have implemented monitoring systems, limits, internal controls, hedging techniques, and similar risk-management measures. Counterparty credit risk management is a fundamental issue for banking supervisors and is extensively addressed in bank supervisory guidelines as well as under the Basel Accords. In addition, CLS itself is subject to comprehensive oversight by 22 central banks whose currencies are settled through its system.

As an example of the continuing supervisory efforts in this market, the Federal Reserve will conduct an assessment of current risk management practices, in conjunction with other jurisdictions, in order to better inform the development of supervisory guidance covering the use of CLS, CSAs, and other systems and controls. Treasury understands that this process might ultimately highlight the need for any additional supervisory or regulatory action, including potential actions under Title VIII of the Dodd-Frank Act. This review will inform BCBS and CPSS updates to bank supervisory guidelines on managing foreign exchange settlement risk.

In addition to the supervisory measures discussed above, the OTC Derivatives Supervisors Group, which includes market and banking regulators from the U.S., France, Germany, Japan, Switzerland and the U.K., has been securing commitments from market participants since 2005 to strengthen market infrastructure, risk management practices, and transparency in the OTC derivatives market. This group is currently engaged with foreign exchange industry groups and market participants, such as the FXC, to secure and monitor new commitments that advance risk management in this market.

(iv) Adequacy of Payment and Settlement Systems

Treasury also has assessed the extent of adequate payment and settlement systems for foreign exchange swaps and forwards. With respect to this factor, as noted, the G10 strategy successfully resulted in the establishment of PVP settlement systems to virtually eliminate the settlement risk associated with foreign exchange swaps and forwards, with CLS being the primary example of this work. Central banks undertook significant actions to support these robust PVP settlement arrangements. As a result, roughly 75 percent of notional foreign exchange is either settled through CLS or otherwise settled without risk, including trades that are settled between affiliates of the same corporation or across a single bank's

[27] *See, e.g.,* comment by Global FX Division, at 11–12.

[28] *See, e.g., http://www.cls-group.com.*

[29] Federal Reserve Board, "Protocol for Cooperative Oversight Arrangement for CLS," Nov. 25, 2008, *available at http://www.federalreserve.gov/paymentsystems/cls_protocol.html.*

[30] *See, e.g.,* supervisory and examination standards for wholesale payments systems developed by the Federal Financial Institutions Examination Council, available at *http://ithandbook.ffiec.gov/it-booklets/ wholesale-payment-systems/ wholesale-payment-systems-risk-management .aspx.*

books for its clients. In the foreign exchange swaps and forwards market in particular, CLS estimates that it settles more than 50 percent of foreign exchange swap and forward transactions that are subject to settlement risk. Furthermore, CLS has announced a multi-year strategic objective to expand settlement services to include additional currencies, increase volume capacity, and add additional settlement times. Treasury understands that the Federal Reserve and the CLS Oversight Committee are currently reviewing these plans, as well as encouraging the expansion of other PVP settlement services.

(v) Possible Use of Exemption to Evade Requirements

Treasury has considered several factors to assess whether the use of an exemption for foreign exchange swaps and foreign exchange forwards could be used to evade otherwise applicable regulatory requirements. Treasury believes that the unique characteristics of foreign exchange swaps and foreign exchange forwards, as defined by the CEA, make it difficult for these products to be structured to replicate currency or interest rate swaps to evade regulatory requirements under the CEA.

Unlike other types of swaps, foreign exchange swaps and forwards are distinct because, as defined by the CEA, these transactions must (1) involve the exchange of the principal amounts of the two currencies exchanged, as opposed to an additional set of cash flows based upon some floating reference rate (e.g. LIBOR), and (2) be settled on a physical basis.[31]

A "swap" regulated under the CEA, such as a currency swap, interest rate swap, or other derivative, generally involves a periodic exchange of a floating amount of cash flows between the counterparties based on some notional amount, whereas a foreign exchange swap (which would be exempt from the definition of "swap" under this determination) involves a simple exchange of principal at one point in time and a reversal of that exchange at some later date. For example, a user of a currency swap could seek funding advantages by obtaining financing in a foreign currency and swapping those cash flows back to the user's locally denominated currency. This would then entail paying or receiving a series of floating interest rate payments (*i.e.,* based on prevailing interest rates) over the life of the transaction. This ability to receive periodic payments during the term of a transaction is a significant feature of "swaps" that will be regulated under the CEA, which is absent from a foreign exchange swap or foreign exchange forward.

While there is a possibility that foreign exchange swaps could be used by some market participants to speculate on the short term path of interest rates, Treasury believes that the operational challenges and transaction costs associated with transforming these instruments to replicate currency or interest rate swaps significantly reduce the likelihood that market participants would actually do so in order to evade regulatory requirements under the CEA.

To begin with, the transactions costs associated with replicating currency swaps through the use of foreign exchange swaps would likely be significant because a market participant would need to regularly roll over its foreign exchange swap position as it seeks to replicate a currency swap. For example, a participant would need to consider the costs associated with the series of separate bid-ask spreads accompanying each of the foreign exchange swap transactions, as well as the costs of monitoring those positions. Moreover, whether a participant would structure foreign exchange swap transactions in order to replicate other, non-exempt swaps that are subject to central clearing requirements would be highly dependent on the costs associated the operational or systems arrangements necessary to execute the foreign exchange swap transactions, relative to the costs imposed by CCPs to clear the other, non-exempt swap transactions (such as margin costs), which could vary among market participants.

Importantly, a determination to exempt foreign exchange swaps and forwards from regulation as "swaps" under the CEA would not affect the application of other provisions that will prevent evasion by market participants and improve market transparency. Opponents of an exemption argue that such a determination would create a large regulatory loophole that exacerbates systemic risk. However, all foreign exchange swaps and forwards would remain subject to the CFTC's new trade-reporting requirements, enhanced anti-evasion authority, and strengthened business-conduct standards for swaps dealers and major swap participants.[32] Notably, the creation of global foreign exchange trade repositories, plans for one of which already are underway, will dramatically expand reporting to regulators and the market more broadly. This additional reporting will also provide regulators with information that can be used to detect attempts by market participants to use foreign exchange swaps or forwards to replicate other derivatives in order to evade regulatory requirements. Lastly, the Dodd-Frank Act amends the CEA and other laws to provide other measures to enhance oversight of key players in the swaps market, which will further reduce the risk that foreign exchange swaps and forwards could be used to evade regulatory requirements.

## III. Procedural Analysis

### *A. Executive Order 12866 and Executive Order 13563*

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

### *B. Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires agencies to prepare a regulatory flexibility analysis unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. It is hereby certified that this determination would not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that entities that engage in foreign exchange swaps and forwards, as defined by the CEA and as described in this proposed determination, tend to be large entities. Accordingly, a regulatory flexibility analysis is not required. Notwithstanding this certification,

[31] In this regard, Treasury notes that, in other swaps transactions, the parties may, by agreement, physically settle their obligations.

[32] In addition, Treasury notes that section 753 of the Dodd-Frank Act amends section 6(c) of the CEA to provide, in relevant part, that "it shall be unlawful for any person, directly or indirectly, to manipulate or attempt to manipulate the price of any swap, or of any commodity in interstate commerce, or for future delivery on or subject to the rules of any registered entity." 7 U.S.C. 9, 15.

Treasury invites comments on the impact on small entities.

**IV. Proposed Determination**

For the reasons set forth in sections I and II, which are incorporated into and made part of this section IV, the Secretary proposes to issue a determination, as follows:

*(a) Authority and purpose.* This determination is issued under section 1a(47)(E) and 1b of the Act in order to implement the provisions of the Act relating to the treatment of foreign exchange swaps and foreign exchange forwards as swaps under the Act.

*(b) Findings and exemption*—(1) *Considerations.* The Secretary has considered—

(i) Whether the required trading and clearing of foreign exchange swaps and foreign exchange forwards would create systemic risk, lower transparency, or threaten the financial stability of the United States, and finds that the required trading and clearing of these instruments would introduce new challenges and could result in negative consequences, without improving transparency;

(ii) Whether foreign exchange swaps and foreign exchange forwards are already subject to a regulatory scheme that is materially comparable to that established by this Act for other classes of swaps, and finds that the regulatory scheme for foreign exchange swaps and foreign exchange forwards applicable in the U.S., as well as the regulatory schemes in other jurisdictions, have required specific actions that address settlement risk, mitigate counterparty credit risk, and manage other risks associated with foreign exchange swaps and forwards;

(iii) The extent to which bank regulators of participants in the foreign exchange market provide adequate supervision, including capital and margin requirements, and finds that regulators are adequately supervising these participants, in part by requiring the implementation of risk-management and operational processes, including the use of payment-versus-payment settlement arrangements for settling transactions and the adoption of credit support annexes with counterparties;

(iv) The extent of adequate payment and settlement systems, and finds that these systems are adequate for foreign exchange swaps and foreign exchange forwards, particularly because a specialized settlement system, which is subject to Federal oversight, has proven capabilities to settle the majority of all global foreign exchange transactions in multiple currencies; and

(v) The use of a potential exemption of foreign exchange swaps and foreign exchange forwards to evade otherwise applicable regulatory requirements, and finds that foreign exchange swaps and foreign exchange forwards, as defined under the Act, are distinguished from other derivatives, widely used by supervised banks for bona fide funding transactions, and not likely to be used to evade otherwise applicable regulatory requirements because of operational and transactions costs associated with potentially transforming these instruments into other derivatives that are subject to regulatory requirements under the Act.

*(2) Exemption.* Upon consideration of each of the factors set forth in section 1b of the Act, the Secretary finds that—

(i) Foreign exchange swaps and foreign exchange forwards should not be regulated as swaps under the Act; and

(ii) Foreign exchange swaps and foreign exchange forwards are not structured to evade the requirements of the Dodd-Frank Act, in violation of any rule promulgated by the Commission, pursuant to section 721(c) of the Dodd-Frank Act (15 U.S.C. 8321)— and, accordingly, hereby determines that any foreign exchange swap or foreign exchange forward hereby is exempt from the definition of the term "swap" under the Act.

(c) *Scope*—As provided in sections 1a(47)(E) and 1b(c) of the Act—

(1) *Reporting.* Notwithstanding this determination, all foreign exchange swaps and foreign exchange forwards shall be reported to a either a swap data repository or, if there is no swap data repository that would accept such swaps or forwards, to the Commission, pursuant to section 4r of the Act (7 U.S.C. 6r) within such time period as the Commission may by rule or regulation prescribe.

(2) *Business standards.* Notwithstanding this determination, any party to a foreign exchange swap or forward that is a swap dealer or major swap participant (as such terms are defined under the Act or under section 721(c) of the Dodd-Frank Act (15 U.S.C. 8321)) shall conform to the business conduct standards contained in section 4s(h) of the Act (7 U.S.C. 6s(h)).

(3) *Effect of determination.* This determination shall not exempt any foreign exchange swap or foreign exchange forward traded on a designated contract market or swap execution facility from any applicable antimanipulation provision of the Act.

*(d) Definitions.* For the purposes of this determination, the following definitions apply:

(1) *Act* means the Commodity Exchange Act.

(2) *Commission* means the Commodity Futures Trading Commission.

(3) *Dodd-Frank Act* means the Dodd-Frank Wall Street Reform and Consumer Protection Act.

(4) *Foreign exchange forward* shall have the same meaning as in section 1a(24) of the Act.

(5) *Foreign exchange swap* shall have the same meaning as in section 1a(25) of the Act.

(6) *Swap* shall have the same meaning as in section 1a(47) of the Act.

Dated: April 29, 2011.

**Alastair Fitzpayne,**

*Deputy Chief of Staff and Executive Secretary.*

[FR Doc. 2011–10927 Filed 5–4–11; 8:45 am]

**BILLING CODE 4810–25–P**

---

## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Financial Management Service; Proposed Collection of Information: List of Data (A) and List of Data (B)

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Notice and Request for comments.

**SUMMARY:** The Financial Management Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection. By this notice, the Financial Management Service solicits comments concerning the form "List of Data (A) and List of Data (B)."

**DATES:** Written comments should be received on or before July 5, 2011.

**ADDRESSES:** Direct all written comments to Financial Management Service, 3700 East West Highway, Records and Information Management Branch, Room 135, Hyattsville, Maryland 20782.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of form(s) and instructions should be directed to Rose Miller, Manager, Surety Bond Branch, 3700 East West Highway, Room 632F, Hyattsville, MD 20782, (202) 874–1427.

**SUPPLEMENTAL INFORMATION:** Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below:

*Title:* List of Data (A) and List of Data (B) *OMB Number:* 1510–0047.

*Form Number:* TFS 2211.

*Abstract:* This information is collected from insurance companies to assist Treasury Department in determining acceptability of the companies applying for a Certificate of Authority to write or reinsure Federal surety bonds.

*Current Actions:* Extension of currently approved collection.

*Type of Review:* Regular.

*Affected Public:* Business or other for-profit.

*Estimated Number of Respondents:* 30.

*Estimated Time per Respondent:* 18 hours.

*Estimated Total Annual Burden Hours:* 540.

*Comments*: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record.

*Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: APR 27 2011.

**Linda S. Kimberling,**

*Assistant Commissioner, Management (CFO).*

[FR Doc. 2011–10775 Filed 5–4–11; 8:45 am]

BILLING CODE 4810–35–M

## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds; Name Change: Odyssey America Reinsurance Corporation

**AGENCY:** Financial Management Service, Fiscal Service, Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** This is Supplement No. 9 to the Treasury Department Circular 570, 2010 Revision, published July 1, 2010, at 75 FR 38192.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–6850.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that Odyssey America Reinsurance Corporation (NAIC #23680) has changed its name to Odyssey Reinsurance Company effective February 18, 2011. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 ("Circular"), 2010 Revision, to reflect this change.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: April 22, 2011.

**Laura Carrico,**

*Director, Financial Accounting and Services Division.*

[FR Doc. 2011–10773 Filed 5–4–11; 8:45 am]

BILLING CODE 4810–35–M

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### Identification of Thirty Entities as Governemnt of Libya Entities Pursuant to Executive Order 13566

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

**ACTION:** Notice.

**SUMMARY:** The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the names of 16 entities identified on March 15, 2011 and 14 entities identified on March 22, 2011, as persons whose property and interests in property are blocked pursuant to Section 2 of Executive Order 13566 of February 25, 2011, "Blocking Property and Prohibiting Certain Transactions Related to Libya."

**DATES:** The identification by the Director of OFAC of the 16 and 14 entities pursuant to Section 2 of Executive Order 13566 of February 25, 2011, went into effect on March 15, 2011, and March 22, 2011, respectively.

**FOR FURTHER INFORMATION CONTACT:** Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, Tel.: 202/622–2490.

**SUPPLEMENTARY INFORMATION:**

**Electronic and Facsimile Availability**

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, *Tel.:* 202/622–0077.

**Background**

On February 25, 2011, the President issued Executive Order 13566, "Blocking Property and Prohibiting Certain Transactions Related to Libya" (the "Order") pursuant to, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–06).

Section 2 of the Order blocks all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, including any overseas branch, of the Government of Libya, its agencies, instrumentalities, and controlled entities, and the Central Bank of Libya.

On March 15, 2011 and March 22, 2011, the Director of OFAC, identified for sanctions, pursuant to Section 2 of the Order, thirty entities whose property and interests in property are blocked. The listing for entities is as follows:

**Entities**

*March 15, 2011 Identifications*

1. AFRIQIYAH AIRWAYS, 1st Floor, Waha Building, 273, Omar Almokhtar Street, Ali Khalifa Zaidi Street, Tripoli, Libya; 273 Omar Al Mokhtar Street, P.O. Box 83428, Tripoli, Libya; E mail Address *afriqiyah@afriqiyah.aero;* alt. E-mail Address *cargo@afriqiyah.aero;* Website www.afriqiyah.aero; Telephone No. (218) 214442622; Telephone No. (218) 214444408; Telephone No. (218) 214444409; Telephone No. (218) 214449734; Telephone No. (218) 214449743; Fax No. (218) 213341181; Fax No. (218) 214449128; Fax No. (218) 213614102 [LIBYA2]
2. AGRICULTURAL BANK (a.k.a. AL MASRAF AL ZIRAE; a.k.a. LIBYAN AGRICULTURAL BANK), El Ghayran Area, Ganzor El Sharqya, P.O. Box 1100, Tripoli, Libya; Al Jumhouria Street, East Junzour, Al Gheran, Tripoli, Libya; E-mail Address *agbank@agribank-ly.org;* SWIFT/BIC AGRULYLT (Libya); Telephone No. (218) 214870586; Telephone No. (218) 214870714; Telephone No. (218) 214870745; Telephone No. (218) 213338366; Telephone No. (218) 213331533; Telephone No. (218) 213333541; Telephone No. (218) 213333544;

Telephone No. (218) 213333543; Telephone No. (218) 213333542; Fax No. (218) 214870747; Fax No. (218) 214870767; Fax No. (218) 214870777; Fax No. (218) 213330927; Fax No. (218) 213333545 [LIBYA2]

3. AL WAFA BANK (a.k.a. MASSRAF AL WAFA), Dat El Imad Administrative Complex, Al Thawra Street, P.O. Box 84212, Tripoli, Libya; E-mail Address *info@alwafabank.com;* Telephone No. (218) 214815123; Fax No. (218) 214801247 [LIBYA2]
4. FIRST GULF LIBYAN BANK, The 7th of November Street, P.O. Box 81200, Tripoli, Libya; SWIFT/BIC FGLBLYLT (Libya); Telephone No. (218) 213622262; Fax No. (218) 213622205 [LIBYA2]
5. GUMHOURIA BANK (f.k.a. AL OUMMA BANK; a.k.a. JAMAHIRIYA BANK; f.k.a. MASRAF AL GUMHOURIA; f.k.a. UMMA BANK), Umar Al Mukhtar Street, Tripoli, Libya; Al Shohadaa Building, Mehammed El Magrif, P.O. Box 3224, Tripoli, Libya; SWIFT/BIC JAMBLYLT (Libya); Telephone No. (218) 21333553; Telephone No. (218) 21333555; Telephone No. (218) 213332888; Telephone No. (218) 214442541; Fax No. (218) 213333793; Fax No. (218) 214442476 [LIBYA2]
6. LIBYA AFRICA INVESTMENT PORTFOLIO (a.k.a. LAIP; a.k.a. LAP), Jumhoria Street, P.O. Box 91330, Tarabulus, Tripoli, Libya; E-mail Address *info@lap.ly;* Web site *http://www.lap.ly* [LIBYA2]
7. LIBYAN AFRICAN INVESTMENT COMPANY (a.k.a. LAAICO; a.k.a. LAICO; a.k.a. LIBYAN ARAB AFRICAN INVESTMENT COMPANY; a.k.a. THE LAICO GROUP), Janzoor (neighborhood), Tripoli, Libya; P.O. Box 81370, Tarabulus, Tripoli, Libya; E-mail Address *info@laaico.com;* Web site *http://www.laaico.com* [LIBYA2]
8. LIBYAN ARAB FOREIGN BANK LIMITED (a.k.a. LAFB; a.k.a. LIBYAN ARAB FOREIGN BANK; a.k.a. LIBYAN FOREIGN BANK), P.O. Box 2542 Tower 2, Dat Al-Imad Complex, Tripoli, Libya; Dat Elemad Administrative Complex, Tower No. 2, Tripoli, Libya; Web site *http://www.lafbank.com;* alt. Web site *http://www.lfbank.ly;* Telephone No. (218) 213350160; Telephone No. (218) 213350161; Telephone No. (218) 213350155; Fax No. (218) 213350164 [LIBYA2]
9. LIBYAN ARAB FOREIGN INVESTMENT COMPANY (a.k.a. LAFICO; a.k.a. LIBYAN FOREIGN INVESTMENT COMPANY), Libyan Arab Foreign Investment Company Building, Al Tharwa Street, P.O. Box 4538, Gharyan Area, Tarabulus, Tripoli, Libya; E-mail Address *info@lafico.ly;* Web site *http://www.lafico.ly* [LIBYA2]
10. LIBYAN INVESTMENT AUTHORITY (a.k.a. LIA; a.k.a. LIBYAN INVESTMENT CORPORATION), Office No. 99, 9th Floor, Bourj Al Fatih Tower, Tripoli, Libya; E-mail Address *info@libyaninvestment.com;* Web site *http://www.lia.ly;* Telephone No. (218) 213351034; Telephone No. (218) 213362091; Telephone No. (218) 213362085; Fax No. (218) 213351035; Fax No. (218) 213362082; Fax No. (218) 213362084 [LIBYA2]
11. NATIONAL BANKING CORPORATION, Al Dhahra Area, Near Qasr Libya Hotel, P. O. Box 80930, Tripoli, Libya; SWIFT/BIC NBCLLYLT (Libya); Telephone No. (218) 214444524; Telephone No. (218) 214444870; Telephone No. (218) 21902524510; Telephone No. (218) 214444267; Fax No. (218) 213330896 [LIBYA2]
12. NATIONAL COMMERCIAL BANK (a.k.a. BANK WATANI; a.k.a. NATIONAL COMMERCIAL BANK SAL), Orouba Street, Al Baida, P.O. Box 543, Tripoli, Libya; SWIFT/BIC LNCBLYLT (Libya); Telephone No. (218) 213612267; Telephone No. (218) 213612429; Telephone No. (218) 213610306; Telephone No. (218) 213617977; Telephone No. (218) 214441168; Telephone No. (218) 214446019; Fax No. (218) 213610306; Fax No. (218) 214448878 [LIBYA2]
13. NATIONAL OIL CORPORATION (a.k.a. LIBYA NATIONAL OIL CORPORATION; a.k.a. LNOC; a.k.a. NATIONAL OIL CORPORATION—LIBYA; a.k.a. NOC), National Oil Corporation Building, Bashir Al Saadawi Street, P.O. Box 2655, Tarabulus, Tripoli, Libya [LIBYA2]
14. SAHARA BANK, 1st of September Street No. 10, P.O. Box 270, Tripoli, Libya; SWIFT/BIC SABKLYLT (Libya); Telephone No. (218) 214448066; Telephone No. (218) 213330724; Telephone No. (218) 213339390; Telephone No. (218) 214443061; Fax No. (218) 213337922; Fax No. (218) 213330068 [LIBYA2]
15. SAVINGS AND REAL ESTATE INVESTMENT BANK (a.k.a. EDDEKHAR BANK), Al Sreem Street—Abu Miliana Street, Al Masera Al Kobra Street, P.O. Box 2289, Tripoli, Libya; Khalifa Alzaidi Street, P.O. Box 2289, Tripoli, Libya; E-mail Address *edara@eddekharbank.com;* Telephone No. (218) 214449306; Telephone No. (218) 214449308; Telephone No. (218) 214449310; Telephone No. (218) 213330434; Telephone No. (218) 213330561; Telephone No. (218) 213331746; Telephone No. (218) 213344631; Telephone No. (218) 213344632; Telephone No. (218) 213344633; Telephone No. (218) 213344634; Fax No. (218) 214449309 [LIBYA2]
16. THE ECONOMIC AND SOCIAL DEVELOPMENT FUND COMPANY (a.k.a. ECONOMIC SOCIAL AND DEVELOPMENT FUND; a.k.a. SOCIAL AND ECONOMIC DEVELOPMENT FUND; a.k.a. "ESDF"), ESDF Building, Qaser Bin Ghasher Road, Salaheddine Cross, Tripoli, Libya; E-mail Address *info@esdf.ly;* Web-site *http://www.esdf.ly;* Telephone No. (218) 214908893; Fax No. (218) 214918893; Fax No. (218) 214918894 [LIBYA2]

*March 22, 2011 Identifications*

1. ARABIAN GULF OIL COMPANY (a.k.a. AGOCO), AGOCO Building, P.O. Box 263, Al Kish, Benghazi, Libya [LIBYA2]
2. AZZAWIYA OIL REFINING COMPANY (a.k.a. AZAWIYA OIL; a.k.a. AZZAWIYA OIL REFINING COMPANY INC; a.k.a. ZAWIA OIL REFINING COMPANY; a.k.a. "ARC"), Azzawiya Oil Refining Building, 45 Km West of Tripoli, Al Harsha Area, Azzawiya, Libya; Azzawiya Oil Refining Building, Al harsha Area, P.O. Box 15715, Az Zawiyah, Libya [LIBYA2]
3. BREGA PETROLEUM MARKETING COMPANY (a.k.a. BPMC; a.k.a. BREGA MARKETING COMPANY), P.O. Box 402, Tripoli, Libya; Coast Road, P.O. Box 16649, Az Zawiyah, Libya; Ben Shatwan Street, P.O. Box 1278, Benghazi, Libya [LIBYA2]
4. HAROUGE OIL OPERATIONS (a.k.a. HAROUGE; f.k.a. VEBA OIL LIBYA GMBH), Al Magharba Street, P.O. Box 690, Tripoli, Libya [LIBYA2]
5. JAMAHIRIYA OIL WELL FLUIDS AND EQUIPMENT (a.k.a. JOWEF OIL TECHNOLOGY; a.k.a. JOWFE; a.k.a. JOWFE CO. FOR OIL TECHNOLOGY; a.k.a. JOWFE OIL TECHNOLOGY COMPANY), Ganfouda area, 15 Km Qaminis Road, P.O. Box 9019, Benghazi, Libya; 15 Km Qaminis Road, Benghazi, Libya [LIBYA2]
6. MEDITERRANEAN OIL SERVICES COMPANY (a.k.a. MEDITERRANEAN SEA OIL

SERVICES COMPANY), Bashir El Saadawy Street, P.O. Box 2655, Tripoli, Libya [LIBYA2]

7. MEDITERRANEAN OIL SERVICES GMBH (a.k.a. MED OIL OFFICE DUSSELDORF; a.k.a. MEDOIL), Werdener Str. 8, Dusseldorf, Nordhein-Westfalen 40227, Germany [LIBYA2]

8. NATIONAL OIL FIELDS AND TERMINALS CATERING COMPANY, Airport Road Km 3, Tripoli, Libya [LIBYA2]

9. NATIONAL OIL WELLS DRILLING AND WORKOVER COMPANY (a.k.a. NATIONAL OIL WELLS CHEMICAL AND DRILLING AND WORKOVER EQUIPMENT CO.; a.k.a. NATIONAL OIL WELLS DRILLING AND WORKOVER EQUIPMENT CO.), National Oil Wells Drilling and Workover Company Building, Omar Al Mokhtar Street, P.O. Box 1106, Tripoli, Libya [LIBYA2]

10. NORTH AFRICAN GEOPHYSICAL EXPLORATION COMPANY (a.k.a. NAGECO; a.k.a. NORTH AFRICAN GEOPHYSICAL EXPLORATION), Airport Road, Ben Ghasir 6.7 KM, Tripoli, Libya [LIBYA2]

11. RAS LANUF OIL AND GAS PROCESSING COMPANY (a.k.a. RASCO; a.k.a. RASLANUF OIL AND GAS REFINARY OIL COMPANY), Ras Lanuf Oil and Gas Processing Company Building, P.O. Box 2323, Ras Lanuf City, Libya; P.O. Box 2323, GSPLAJ, Tripoli, Libya; P.O. Box 1971, GSPLAJ, Benghazi, Libya [LIBYA2]

12. SIRTE OIL COMPANY FOR PRODUCTION MANUFACTURING OF OIL AND GAS (a.k.a. SIRTE OIL COMPANY; a.k.a. SIRTE OIL COMPANY (SOC) FOR PRODUCTION MANUFACTURING OF SIRTE OIL COMPANY; a.k.a. SIRTE OIL COMPANY FOR PRODUCTION AND MANUFACTURING OF OIL AND GAS LTD; a.k.a. SOC), Sirte Oil Company Building, Marsa Al Brega Area, P.O. Box 385, Tripoli, Libya [LIBYA2]

13. WAHA OIL COMPANY (a.k.a. OASIS OIL COMPANY; a.k.a. WAHA), Waha Oil Company Building, Airport Road, Al Akwakh Street, P.O. Box 395, Tripoli, Libya [LIBYA2]

14. ZUEITINA OIL COMPANY (a.k.a. ZOC; a.k.a. ZUEITINA), Zueitina Oil Building, Sidi Issa Street, Al Dahra Area, P.O. Box 2134, Tripoli, Libya [LIBYA2]

**Adam Szubin,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2011–10926 Filed 5–4–11; 8:45 am]

BILLING CODE 4811–AL–P

# FEDERAL REGISTER

Vol. 76 Thursday,

No. 87 May 5, 2011


Part II

## Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 476
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 412, 413, and 476**

**[CMS–1518–P]**

**RIN 0938–AQ24**

# Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates

**AGENCY:** Centers for Medicare and Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems and to implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. These changes would be applicable to discharges occurring on or after October 1, 2011. We also are setting forth the proposed update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The proposed updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2011.

We are proposing to update the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implement certain statutory changes made by the Affordable Care Act. These changes would be applicable to discharges occurring on or after October 1, 2011.

**DATES:** *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EDT on June 20, 2011.

**ADDRESSES:** When commenting, please refer to file code CMS–1518–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" and enter the file code CMS–1518–P to submit comments on this proposed rule.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1518–P, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1518–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Bridget Dickensheets, (410) 786–8670, Rebasing and Revising of the Market Basket for LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Inpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Elizabeth Goldstein, (410) 786–6665, Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions at that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

## Electronic Access

This **Federal Register** document is also available from the **Federal Register**

online database through *GPO Access,* a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web, (the Superintendent of Documents' home Web page address is *http://www.gpoaccess.gov/*), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

**Tables Available Only Through the Internet on the CMS Web Site**

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this proposed rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables will no longer be published as part of the annual IPPS/LTCH PPS proposed and final rules. Instead, these tables will be available only through the Internet. The IPPS tables for this proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, "FY 2012 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download". The LTCH PPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–P. For complete details on the availability of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule. Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786–4487.

**Acronyms**

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASC Ambulatory surgical center
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
CoP [Hospital] condition of participation
CPI Consumer price index
CRNA Certified Registered Nurse Anesthetist
CY Calendar year
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
ECI Employment cost index
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
FAH Federation of Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FQHC Federally qualified health center
FTE Full-time equivalent
FY Fiscal year
GAAP Generally Accepted Accounting Principles
GAF Geographic Adjustment Factor
GME Graduate medical education
HACs Hospital-acquired conditions
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MA Medicare Advantage
MAC Medicare Administrative Contractor
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MCV Major cardiovascular condition
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NQF National Quality Forum
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991 (Public Law 104–113)
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB Executive Office of Management and Budget
OPM U.S. Office of Personnel Management
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPACA Patient Protection and Affordable Care Act, Public Law 111–148
PPI Producer price index
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PS&R Provider Statistical and Reimbursement (System)
QIG Quality Improvement Group, CMS
QIO Quality Improvement Organization
RCE Reasonable compensation equivalent
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SFY State fiscal year
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSO Short-stay outlier
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
UHDDS Uniform hospital discharge data set

## Table of Contents

I. Background
A. Summary
1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)
2. Hospitals and Hospital Units Excluded From the IPPS
3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)
4. Critical Access Hospitals (CAHs)
5. Payments for Graduate Medical Education (GME)
B. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) Applicable to FY 2012
C. Major Contents of This Proposed Rule
1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights
2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals
3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs
4. Proposed FY 2012 Policy Governing the IPPS for Capital-Related Costs
5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages
6. Proposed Changes to the LTCH PPS
7. Proposed Changes to the Electronic Prescribing (eRx) Incentive Program
8. Determining Proposed Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals
9. Determining Proposed Prospective Payments Rates for LTCHs
10. Impact Analysis
11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services
12. Discussion of Medicare Payment Advisory Commission Recommendations
II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights
A. Background
B. MS–DRG Reclassifications
1. General
2. Yearly Review for Making MS–DRG Changes
C. Adoption of the MS–DRGs in FY 2008
D. Proposed FY 2012 MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount
1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90
2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Public Law 110–90
3. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Pub. L. 110–90
4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data
5. Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act
6. Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90
7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates
8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years
9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount
E. Refinement of the MS–DRG Relative Weight Calculation
1. Background
2. Summary of the RTI Study of Charge Compression and CCR Refinement
3. Summary of Policy Changes Made in FY 2011
4. Discussion for FY 2012
F. Preventable Hospital-Acquired Conditions (HACs), Including Infections
1. Background
a. Statutory Authority
b. HAC Selection
c. Collaborative Process
d. Application of HAC Payment Policy to MS–DRG Classifications
e. Public Input Regarding Selected and Potential Candidate HACs
f. POA Indicator Reporting
2. Proposed Additions and Revisions to the HAC Policy for FY 2012
a. Contrast-Induced Acute Kidney Injury
b. New Diagnosis Codes Proposed To Be Added to Existing HACs
c. Revision to HAC Subcategory Title
d. Conclusion
3. RTI Program Evaluation Summary
a. Background
b. FY 2009 Data Analysis
c. FY 2010 Data Analysis
G. Proposed Changes to Specific MS–DRG Classifications
1. Pre-Major Diagnostic Categories (Pre-MDCs)
a. Noninvasive Mechanical Ventilation
b. Debridement With Mechanical Ventilation Greater Than 96 Hours With Major Operating Room (O.R.) Procedure
c. Autologous Bone Marrow Transplant
2. MDC 1 (Diseases and Disorders of the Nervous System): Rechargeable Dual Array Deep Brain Stimulation System
3. MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth, and Throat): Skull Based Surgeries

4. MDC 5 (Diseases and Disorders of the Circulatory System)
a. Percutaneous Mitral Valve Repair With Implant
b. Aneurysm Repair Procedure Codes
5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)
a. Artificial Discs
b. Major Joint Replacement or Reattachment of Lower Extremities
c. Combined Anterior/Posterior Spinal Fusion
6. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast): Excisional Debridement of Wound, Infection, or Burn
7. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)
a. Nutritional and Metabolic Diseases: Update of MS–DRG Titles
b. Sleeve Gastrectomy Procedure for Morbid Obesity
8. MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period): Discharge Status Code 66 (Discharged/Transferred to Critical Access Hospital (CAH))
9. Proposed Medicare Code Editor (MCE) Changes
10. Surgical Hierarchies
11. Complications or Comorbidity (CC) Exclusions List
a. Background
b. Proposed CC Exclusions List for FY 2012
12. Review of Procedure Codes in MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989
a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs
b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989
c. Adding Diagnosis or Procedure Codes to MDCs
13. Changes to the ICD–9–CM Coding System, Including Discussion of the Replacement of the ICD–9–CM System With the ICD–10–CM and ICD–10–PCS Systems in FY 2014
a. ICD–9–CM Coding System
b. Code Freeze
c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims
d. ICD–10 MS–DRGs
14. Other Issues
a. O.R./Non-O.R. Status of Procedures
b. IPPS Recalled Device Policy Clarification
H. Recalibration of MS–DRG Weights
I. Proposed Add-On Payments for New Services and Technologies
1. Background
2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments
3. FY 2012 Status of Technologies Approved for FY 2011 Add-On Payments
a. Spiration® IBV Valve System
b. Cardio West™ Temporary Artificial Heart System (Cardio West™ TAH-t)
c. Auto Laser Interstitial Thermal Therapy (AutoLITT™) System
4. FY 2012 Applications for New Technology Add-On Payments
a. AxiaLIF® 2L+™ System
b. Champion™ HF Monitoring System
c. PerfectCLEAN With Micrillon®
III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals
A. Background
B. Core-Based Statistical Areas for the Hospital Wage Index
C. Proposed Occupational Mix Adjustment to the FY 2012 Wage Index
1. Development of Data for the Proposed FY 2012 Occupational Mix Adjustment Based on the 2007–2008 Occupational Mix Survey
2. New 2010 Occupational Mix Survey for the FY 2013 Wage Index
3. Calculation of the Proposed Occupational Mix Adjustment for FY 2012
D. Worksheet S–3 Wage Data for the Proposed FY 2012 Wage Index
1. Included Categories of Costs
2. Proposal for Changes to the Reporting Requirements for Pension Costs for the Medicare Wage Index
a. Background
b. Proposal for Allowable Pension Cost for the Medicare Wage Index
3. Excluded Categories of Costs
4. Use of Wage Index Data by Providers Other Than Acute Care Hospitals Under the IPPS
E. Verification of Worksheet S–3 Wage Data
F. Method for Computing the Proposed FY 2012 Unadjusted Wage Index
1. Steps for Computation
2. Expiration of the Imputed Floor Policy
3. Proposed FY 2012 Puerto Rico Wage Index
G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2012 Occupational Mix Adjusted Wage Index
H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications
1. General
2. Effects of Reclassification/Redesignation
3. FY 2012 MGCRB Reclassifications
a. FY 2012 Reclassification Requirements and Approvals
b. Applications for Reclassifications for FY 2013
4. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act
5. Reclassifications Under Section 1886(d)(8)(B) of the Act
6. Reclassifications Under Section 508 of Public Law 108–173
7. Waiving Lugar Redesignation for the Out-Migration Adjustment
8. Other Geographic Reclassification Issues
a. Requested Reclassification for Single Hospital MSAs
b. Requests for Exceptions to Geographic Reclassification Rules
I. Proposed FY 2012 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees
J. Process for Requests for Wage Index Data Corrections
K. Labor-Related Share for the Proposed FY 2012 Wage Index
IV. Other Proposed Decisions and Changes to the IPPS for Operating Costs and GME Costs
A. Hospital Inpatient Quality Reporting Program
1. Background
a. Overview
b. Statutory History and History of Measures Adopted for the Hospital IQR Program
c. Maintenance of Technical Specifications for Quality Measures
d. Public Display of Quality Measures
2. Retirement of Hospital IQR Program Measures
a. Considerations in Retiring Quality Measures from the Hospital IQR Program
b. Proposed Retirement of Quality Measures under the Hospital IQR Program for the FY 2014 Payment Determination and Subsequent Years
3. Proposed Quality Measures for the FY 2014 and FY 2015 Payment Determinations
a. Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program
b. Proposed Hospital IQR Program Quality Measures for the FY 2014 Payment Determination
c. Proposed Hospital IQR Program Quality Measures for the FY 2015 Payment Determination
4. Possible New Quality Measures and Measure Topics for Future Years
5. Form, Manner, and Timing of Quality Data Submission
a. Background
b. Proposed Procedural Requirements for FY 2013 and Subsequent Years
c. Proposed General Data Collection and Submission Requirements
d. Proposed Data Submission Requirements for Chart-Abstracted Measures
e. Proposed Sampling and Case Thresholds
f. Proposed HCAHPS Requirements for the FY 2013, FY 2014, and FY 2015 Payment Determinations
g. Proposed Procedures for Claims-Based Measures
h. Proposed Data Submission Requirements for Structural Measures
i. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN
6. Proposed Chart Validation Requirements for Chart-Abstracted Measures
a. Proposed Chart Validation Requirements and Methods for the FY 2012 Payment Determination
b. Proposed Supplements to the Chart Validation Process for the FY 2013 Payment Determination and Subsequent Years
7. Proposed QIO Regulation Changes for Provider Medical Record Deadlines Possibly Including Serious Reportable Events
8. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2012 Payment Determination and Subsequent Years
9. Proposed Public Display Requirements for the FY 2013 Payment Determination and Subsequent Years
10. Proposed Reconsideration and Appeal Procedures for the FY 2012 Payment Determination

11. Proposed Hospital IQR Program Disaster Waivers
12. Electronic Health Records
a. Background
b. HITECH Act EHR Provisions
B. Hospital Value-Based Purchasing (VBP) Program
1. Background
2. Overview of the Hospital VBP Program Proposed Rule
3. Proposed FY 2014 Hospital VBP Program Measures
a. Background
b. Proposed Efficiency Measure—Medicare Spending per Beneficiary Measure—for the FY 2014 Hospital VBP Program
4. Proposed Efficiency Domain (Medicare Spending per Beneficiary Measure) Performance Period and Baseline Period
C. Hospital Readmission Reduction Program
1. Background
a. Overview
b. Statutory Basis for the Hospital Readmission Reduction Program
2. Implementation of the Hospital Readmission Reduction Program
a. Overview
b. Proposed Provisions in the FY 2012 IPPS/LTCH PPS Rulemaking
c. Proposed Provisions To Be Included in the FY 2013 IPPS/LTCH PPS Proposed Rule
d. Proposed Expansion of the Applicable Conditions To Be Included in the Future Rulemaking
3. Proposed Provisions of the Hospital Readmission Reduction Program
a. Proposed Applicable Conditions for FY 2013 Hospital Readmission Reduction Program
b. Proposed Definition of "Readmissions"
c. Proposed Readmission Measures and Related Methodology
D. Rural Referral Centers (RRCs) (§ 412.96)
1. Case-Mix Index (CMI)
2. Discharges
E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)
1. Background
2. Temporary Changes for FYs 2011 and 2012
3. Proposed Discharge Data Source to Identify Qualifying Low-Volume Hospitals and Calculate the Payment Adjustment (Percentage Increase) for FY 2012
F. Indirect Medical Education (IME) Adjustment
1. Background
2. IME Adjustment Factor for FY 2012
G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)
1. Background
2. Proposed Policy Change Relating to Exclusion of Hospice Beds and Patient Days From the Medicare DSH Calculation
H. Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)
1. Background
2. Extension of the MDH Program
I. Certified Register Nurse Anesthetists (CRNA) Services Furnished in Rural Hospitals and CAHs (§ 412.113)
J. Additional Payments for Qualifying Hospitals with Lowest per Enrollee Medicare Spending
1. Background
2. Method for Identifying Qualifying Hospitals and Eligible Counties
3. Determination of Annual Payment Amounts
4. Eligible Counties and Qualifying Hospitals
5. Payment Determination and Distributions for FY 2011 and FY 2012
K. Proposed Changes in the Inpatient Hospital Update
1. FY 2012 Inpatient Hospital Update
2. FY 2012 Puerto Rico Hospital Update
3. Productivity Adjustment
L. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)
M. Proposal for Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes
1. Background
2. Proposal for Allowable Defined Benefit Pension Plan Cost for Medicare Cost-Finding Purposes
N. Rural Community Hospital Demonstration Program
1. Background
2. Changes to the Demonstration Program Made by the Affordable Care Act
3. Proposed FY 2012 Budget Neutrality Adjustment
a. Component of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated Demonstration Program Costs of the "Pre-Expansion" Participating Hospitals
b. Portion of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs for Hospitals Newly Selected to Participate in the Demonstration Program
c. Portion of the Proposed FY 2012 Budget Neutrality Adjustment to Offset the Amount by Which the Costs of the Demonstration Program in FYs 2007 and 2008 Exceeded the Amount That Was Identified in the FYs 2007 and 2008 IPPS Final Rules as the Budget Neutrality Offset for FYs 2007 and 2008
O. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window
1. Background
2. Establishment of Condition Code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services)
3. Applicability of the Payment Window Policy to Services Furnished at Physicians' Practices
P. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy
Q. Hospital Services Furnished under Arrangements
V. Proposed Changes to the IPPS for Capital-Related Costs
A. Overview
B. Exception Payments
C. New Hospitals
D. Hospitals Located in Puerto Rico
E. Proposed Changes for FY 2012: MS–DRG Documentation and Coding Adjustment
F. Other Proposed Changes for FY 2012
VI. Proposed Changes for Hospitals Excluded From the IPPS
A. Excluded Hospitals
B. Critical Access Hospital (CAH) Payment for Ambulance Services
1. Background
2. Requirement for CAH Ambulance Within a 35-Mile Location of a CAH or Entity
VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2012
A. Background of the LTCH PPS
1. Legislative and Regulatory Authority
2. Criteria for Classification as a LTCH
a. Classification as a LTCH
b. Hospitals Excluded From the LTCH PPS
3. Limitation on Charges to Beneficiaries
4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance
B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights
1. Background
2. Patient Classifications into MS–LTC–DRGs
a. Background
b. Proposed Changes to the MS–LTC–DRGs for FY 2012
3. Development of the Proposed FY 2012 MS–LTC–DRG Relative Weights
a. General Overview of the Development of the MS–LTC–DRG Relative Weights
b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2012
c. Data
d. Hospital-Specific Relative Value (HSRV) Methodology
e. Proposed Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights
f. Proposed Low-Volume MS–LTC–DRGs—Steps for Determining the Proposed FY 2012 MS–LTC–DRG Relative Weights
C. Proposed Quality Reporting Program for LTCHs
1. Background and Statutory Authority
2. Proposed Quality Measures for the LTCH Quality Reporting Program for FY 2014
a. Considerations in the Selection of the Proposed Quality Measures
b. Proposed LTCH Quality Measures for FY 2014 Payment Determination
3. Possible LTCH Quality Measures under Consideration for Future Years
4. Proposed Data Submission Methods and Timelines
a. Proposed Method of Data Submission for HAIs
b. Proposed Timeline for Data Reporting Related to HAIs
c. Proposed Method of Data Collection and Submission for the Pressure Ulcer Measure Data
d. Proposed Timeline for Data Reporting Related to Pressure Ulcers
5. Public Reporting and Availability of Data Submitted
D. Proposed Rebasing and Revising of the Market Basket Used Under the LTCH PPS
1. Background

2. Overview of the Proposed FY 2008–Based RPL Market Basket
3. Proposed Rebasing and Revising of the RPL Market Basket
a. Development of Cost Categories
b. Final Cost Category Computation
c. Selection of Price Proxies
d. Proposed Methodology for Capital Portion of the RPL Market Basket
e. Proposed FY 2012 Market Basket Update for LTCHs
f. Proposed Labor-Related Share
E. Proposed Changes to the LTCH Payment Rates and Other Proposed Changes to the FY 2012 LTCH PPS
1. Overview of Development of the LTCH Payment Rates
2. Proposed FY 2012 LTCH PPS Annual Market Basket Update
a. Overview
b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act
c. Proposed Market Basket Under the LTCH PPS for FY 2012
d. Productivity Adjustment
e. Proposed Annual Market Basket Update for LTCHs for FY 2012
3. Proposed Budget Neutrality Adjustment for the Changes to the Area Wage Level Adjustment
4. Proposed Budget Neutrality Adjustment for the Changes to the Area Wage Level Adjustment
5. Greater Than 25 Day Average Length of Stay Requirement for LTCHs
a. Determining the Average Length of Stay When There Is a Change of Ownership
b. Inclusion of Medicare Advantage (MA) Days in the Average Length of Stay Calculation
F. Proposed Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(2) of Public Law 110–173
VIII. MedPAC Recommendations
IX. Other Required Information
A. Requests for Data From the Public
B. Collection of Information Requirements
1. Legislative Requirement for Solicitation of Comments
2. ICRs for Add-On Payments for New Services and Technologies
3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program
4. ICRs for the Occupational Mix Adjustment to the Proposed FY 2012 Index (Hospital Wage Index Occupational Mix Survey)
5. Hospital Applications for Geographic Reclassifications by the MGCRB
6. ICRs for the Proposed Quality Reporting Program for LTCHs
C. Response to Public Comments
Regulation Text
Addendum—Proposed Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2011
I. Summary and Background
II. Proposed Changes to the Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2012
A. Calculation of the Proposed Adjusted Standardized Amount
B. Proposed Adjustments for Area Wage Levels and Cost-of-Living
C. Proposed MS–DRG Relative Weights
D. Calculation of the Proposed Prospective Payment Rates
III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2012
A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update
B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2012
C. Capital Input Price Index
IV. Proposed Changes to Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages for FY 2012
V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2012
A. Proposed LTCH PPS Standard Federal Rate for FY 2012
B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2012
C. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases
D. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2012
VI. Tables Referenced in This Proposed Rulemaking and Available Through the Internet on the CMS Web Site
Appendix A—Regulatory Impact Analysis
I. Overall Impact
II. Objectives of the IPPS
III. Limitations of Our Analysis
IV. Hospitals Included in and Excluded From the IPPS
V. Effects on Hospitals and Hospital Units Excluded From the IPPS
VI. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs
A. Basis and Methodology of Estimates
B. Analysis of Table I
C. Impact Analysis of Table II
VII. Effects of Other Proposed Policy Changes
A. Effects of Proposed Policy on HACs, Including Infections
B. Effects of Proposed Policy Changes Relating to New Medical Service and Technology Add-On Payments
C. Effects of Requirements for Hospital Inpatient Quality Reporting (IQR) Program
D. Effects of Additional Proposed Hospital Value-Based Purchasing (VBP) Program Requirements
E. Effects of Proposed Requirements for Hospital Readmissions Reduction Program
F. Effects of Proposed Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)
G. Effects of the FY 2012 Low-Volume Hospital Payment Adjustment
H. Effects of Proposed Changes Relating to MDHs
I. Effects of Proposed Policy Relating to CRNA Services Furnished in Rural Hospitals and CAHs
J. Effects of Proposed Changes Relating to ESRD Add-On Payment
K. Effects of Proposed Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding and Wage Reporting Purposes
L. Effects of Implementation of Rural Community Hospital Demonstration Program
M. Effects of Proposed Changes to List of MS–DRGs Subject to the Postacute Care Transfer and DRG Special Pay Policy
N. Effects of Proposed Changes Relating to Hospital Services Furnished Under Arrangements
O. Effects of Proposed Change Relating to CAH Payment for Ambulance Services
VIII. Effects of Proposed Changes in the Capital IPPS
A. General Considerations
B. Results
IX. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS
A. Introduction and General Considerations
B. Impact on Rural Hospitals
C. Anticipated Effects of Proposed LTCH PPS Payment Rate Change and Policy Changes
D. Effect on the Medicare Program
E. Effect on Medicare Beneficiaries
X. Alternatives Considered
XI. Overall Conclusion
A. Acute Care Hospitals
B. LTCHs
XII. Accounting Statements
A. Acute Care Hospitals
B. LTCHs
XIII. Executive Order 12866
Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services
I. Background
II. Inpatient Hospital Update for FY 2012
A. Proposed FY 2012 Inpatient Hospital Update
B. Proposed Update for SCHs and MDHs for FY 2012
C. Proposed FY 2012 Puerto Rico Hospital Update
D. Proposed Update for Hospitals Excluded From the IPPS
III. Secretary's Recommendation
IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

## I. Background

### *A. Summary*

#### 1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system (PPS). Under these PPSs, Medicare payment

for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2012, an MDH will receive the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services "in accordance with a prospective payment system established by the Secretary." The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs per discharge.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on

reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

*B. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) Applicable to FY 2012*

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111–148 and Pub. L. 111–152 are collectively referred to as the "Affordable Care Act.") A number of the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010 and 2011 were implemented in the following documents:

On June 2, 2010, we issued in the **Federal Register** a notice (75 FR 31118) that contained the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables, effective for the FY 2010 IPPS and the RY 2010 LTCH PPS, which were required by or directly resulted from implementation of provisions of the Affordable Care Act.

On August 16, 2010, we issued in the **Federal Register** a final rule (75 FR 50042) that implemented provisions of the Affordable Care Act applicable to the IPPS and LTCH/PPS for FY 2011.

In this proposed rule, we are proposing to implement the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS and LTCH PPS for FY 2012:

- Section 3001 of Public Law 111–148, which provides for establishment of a hospital value-based purchasing program and applicable measures for value-based incentive payments with respect to discharges occurring during FY 2013.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data for LTCHs in order to receive the full annual update to the payment rates and the establishment of quality data measures.
- Section 3025 of Public Law 111–148, which provides for a hospital readmissions reduction program and related quality data reporting measures.
- Section 3124 of Public Law 111–148, which provides for extension of the Medicare-dependent, small rural hospital (MDH) program through FY 2012.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity improvements into the market basket updates for IPPS hospitals and LTCHs.

In addition, we are proposing to continue in FY 2012 to implement the following provisions, which were initiated in FY 2011:

- Section 10324 of Public Law 111–148, which provided for a wage adjustment for hospitals located in frontier States.
- Sections 3401 and 10319 of Public Law 111–148 and section 1105 of Public Law 111–152, which revise certain market basket update percentages for IPPS and LTCH PPS payment rates for FY 2012.
- Sections 3125 and 10314 of Public Law 111–148, which provides for temporary percentage increases in payment adjustments to low-volume hospitals for discharges occurring in FY 2012.
- Section 1109 of Public Law 111–152, which provides for additional payments in FY 2012 for qualifying hospitals in the lowest quartile of per capita Medicare spending.

*C. Major Contents of This Proposed Rule*

In this proposed rule, we are setting forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2012. We also are setting forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis.

In addition, in this proposed rule, we are setting forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012.

Below is a summary of the major changes that we are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review.
- Proposed application of the documentation and coding adjustment for FY 2012 resulting from implementation of the MS–DRG system.
- A discussion of the Research Triangle International, Inc. (RTI) reports and recommendations relating to charge compression.
- Proposed recalibrations of the MS–DRG relative weights.
- Proposed changes to hospital-acquired conditions (HACs) and a listing and discussion of HACs, including infections, that would be subject to the statutorily required quality adjustment in MS–DRG payments for FY 2012.

We discussed the FY 2012 status of new technologies approved for add-on payments for FY 2011 and present our evaluation and analysis of the FY 2012 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include the following:

- The proposed FY 2012 wage index update using wage data from cost reporting periods beginning in FY 2008.
- Analysis and implementation of the proposed FY 2012 occupational mix adjustment to the wage index for acute care hospitals, including discussion of the 2010 occupational mix survey.
- A proposal to change the reporting requirements for pension costs for the Medicare wage index.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.
- The proposed adjustment to the wage index for acute care hospitals for FY 2012 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- The timetable for reviewing and verifying the wage data used to compute the proposed FY 2012 hospital wage index.
- Determination of the labor-related share for the proposed FY 2012 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of this proposed rule, we discuss a number of the provisions of the regulations in 42 CFR parts 412, 413, and 476, including the following:

- The reporting of hospital quality data under the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full annual payment update increase.
- The proposed implementation of the Hospital Value-Based Purchasing Program measures.
- The proposed establishment of hospital readmisssion measures for reporting of hospital quality data.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2012.
- Proposed payment adjustment for low-volume hospitals.
- Proposal for counting hospice days in the formula for determining the payment adjustment for disproportionate share hospitals.
- Proposal for making additional payments for qualifying hospitals with lowest per enrollee Medicare spending for FY 2012.
- Proposal to clarify ESRD add-on payment requirements based on cost report requirements.
- Proposal relating to changes to the reporting requirements for pension costs for Medicare cost-finding purposes.
- Proposal to implement statutory change to the hospital payment update, including incorporation of a productivity adjustment.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Discussion of August 2010 interim final rule with comment period and further proposed changes relating to the 3-day payment window for payments for services provided to outpatients who are later admitted as inpatients.

4. Proposed FY 2012 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2012 and the proposed MS–DRG documentation and coding adjustment for FY 2012.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss proposed changes to payments to certain excluded hospitals. In addition, we discuss proposed changes relating to payment for TEFRA services furnished under arrangements and payment for ambulance services furnished by CAH-owned and operated entities.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012, including the annual update of the MS–LTC–DRG classifications and relative weights for use under the LTCH PPS for FY 2012, the proposed documentation and coding adjustment under the LTCH PPS for FY 2012, and the proposed rebasing and revising of the market basket for LTCHs. In addition, we are setting forth proposals for implementing the quality data reporting program for LTCHs. We also are proposing to clarify two policies regarding the calculation of the average length of stay requirement for LTCHs, and proposing a policy to address a LTCH moratorium issue.

7. Determining Proposed Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also are proposing to establish the threshold amounts for outlier cases. In addition, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2012 for certain hospitals excluded from the IPPS.

8. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective standard Federal rate. We also are proposing to establish the proposed adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

9. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals and LTCHs.

10. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2012 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The standard Federal rate for hospital inpatient services furnished by LTCHs.

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 1 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2011 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and

capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2011 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov.*

## II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

### *A. Background*

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

### *B. MS–DRG Reclassifications*

#### 1. General

As discussed in the preamble to the FY 2008 IPPS final rule with comment period (72 FR 47138), we focused our efforts in FY 2008 on making significant reforms to the IPPS consistent with the recommendations made by MedPAC in its "Report to the Congress, Physician-Owned Specialty Hospitals" in March 2005. MedPAC recommended that the Secretary refine the entire DRG system by taking severity of illness into account and applying hospital-specific relative value (HSRV) weights to DRGs.[1] We began this reform process by adopting cost-based weights over a 3-year transition period beginning in FY 2007 and making interim changes to the DRG system for FY 2007 by creating 20 new CMS DRGs and modifying 32 other DRGs across 13 different clinical areas involving nearly 1.7 million cases. As described in more detail below, these refinements were intermediate steps towards comprehensive reform of both the relative weights and the DRG system as we undertook further study. For FY 2008, we adopted 745 new Medicare Severity DRGs (MS–DRGs) to replace the CMS DRGs. We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system, based on severity levels of illness, was established (72 FR 47141).

Currently, cases are classified into MS–DRGs for payment under the IPPS based on the following information reported by the hospital: The principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. (We refer readers to section II.G.11.c. of this proposed rule for a discussion of our efforts to increase our internal systems capacity to process diagnosis and procedures on hospital claims to 25 diagnosis codes and 25 procedure codes prior to the use of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10 PCS) for inpatient hospital procedure coding, effective October 1, 2013.) In a small number of MS–DRGs, classification is also based on the age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) prior to October 1, 2013. We refer readers to section II.G.11.b. of this proposed rule for a reference to the replacement of ICD–9–CM, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting, Volume 3, with the ICD–10–CM and ICD–10–PCS, including the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting, effective October 1, 2013 (FY 2014).

The process of developing the MS–DRGs was begun by dividing all possible principal diagnoses into mutually exclusive principal diagnosis areas, referred to as Major Diagnostic Categories (MDCs). The MDCs were formulated by physician panels to ensure that the DRGs would be clinically coherent. The diagnoses in each MDC correspond to a single organ system or etiology and, in general, are associated with a particular medical specialty. Thus, in order to maintain the requirement of clinical coherence, no final MS–DRG could contain patients in different MDCs. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). For FY 2011, cases were assigned to one of 747 MS–DRGs in 25 MDCs. The table below lists the 25 MDCs.

[1] Medicare Payment Advisory Commission: *Report to the Congress, Physician-Owned Specialty Hospitals,* March 2005, page viii.

| | Major Diagnostic Categories (MDCs) |
|---|---|
| 1 | Diseases and Disorders of the Nervous System |
| 2 | Diseases and Disorders of the Eye |
| 3 | Diseases and Disorders of the Ear, Nose, Mouth, and Throat |
| 4 | Diseases and Disorders of the Respiratory System |
| 5 | Diseases and Disorders of the Circulatory System |
| 6 | Diseases and Disorders of the Digestive System |
| 7 | Diseases and Disorders of the Hepatobiliary System and Pancreas |
| 8 | Diseases and Disorders of the Musculoskeletal System and Connective Tissue |
| 9 | Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast |
| 10 | Endocrine, Nutritional and Metabolic Diseases and Disorders |
| 11 | Diseases and Disorders of the Kidney and Urinary Tract |
| 12 | Diseases and Disorders of the Male Reproductive System |
| 13 | Diseases and Disorders of the Female Reproductive System |
| 14 | Pregnancy, Childbirth, and the Puerperium |
| 15 | Newborns and Other Neonates with Conditions Originating in the Perinatal Period |
| 16 | Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders |
| 17 | Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms |
| 18 | Infectious and Parasitic Diseases (Systemic or Unspecified Sites) |
| 19 | Mental Diseases and Disorders |
| 20 | Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders |
| 21 | Injuries, Poisonings, and Toxic Effects of Drugs |
| 22 | Burns |
| 23 | Factors Influencing Health Status and Other Contacts with Health Services |
| 24 | Multiple Significant Trauma |
| 25 | Human Immunodeficiency Virus Infections |

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to an MS–DRG. However, under the most recent version of the Medicare GROUPER (Version 28.0), there are 13 MS–DRGs to which cases are directly assigned on the basis of ICD–9–CM procedure codes. These MS–DRGs are for heart transplant or implant of heart assist systems; liver and/or intestinal transplants; bone marrow transplants; lung transplants; simultaneous pancreas/kidney transplants; pancreas transplants; and tracheostomies. Cases are assigned to these MS–DRGs before they are classified to an MDC. The table below lists the 13 current pre-MDCs.

| Pre-Major Diagnostic Categories (Pre-MDCs) | |
|---|---|
| MS-DRG 001 | Heart Transplant or Implant of Heart Assist System with MCC |
| MS-DRG 002 | Heart Transplant or Implant of Heart Assist System without MCC |
| MS-DRG 003 | ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R. |
| MS-DRG 004 | Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R. |
| MS-DRG 005 | Liver Transplant with MCC or Intestinal Transplant |
| MS-DRG 006 | Liver Transplant without MCC |
| MS-DRG 007 | Lung Transplant |
| MS-DRG 008 | Simultaneous Pancreas/Kidney Transplant |
| MS-DRG 009 | Bone Marrow Transplant |
| MS-DRG 010 | Pancreas Transplant |
| MS-DRG 011 | Tracheostomy for Face, Mouth, and Neck Diagnoses with MCC |
| MS-DRG 012 | Tracheostomy for Face, Mouth, and Neck Diagnoses with CC |
| MS-DRG 013 | Tracheostomy for Face, Mouth, and Neck Diagnoses without CC/MCC |

Once the MDCs were defined, each MDC was evaluated to identify those additional patient characteristics that would have a consistent effect on hospital resource consumption. Because the presence of a surgical procedure that required the use of the operating room would have a significant effect on the type of hospital resources used by a patient, most MDCs were initially divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age (0 to 17 years of age or greater than 17 years of age). Some surgical and medical DRGs are further differentiated based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

Generally, nonsurgical procedures and minor surgical procedures that are not usually performed in an operating room are not treated as O.R. procedures. However, there are a few non-O.R. procedures that do affect MS–DRG assignment for certain principal diagnoses. An example is extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones. Lithotripsy procedures are not routinely performed in an operating room. Therefore, lithotripsy codes are not classified as O.R. procedures. However, our clinical advisors believe that patients with urinary stones who undergo extracorporeal shock wave lithotripsy should be considered similar to other patients who undergo O.R. procedures. Therefore, we treat this group of patients similar to patients undergoing O.R. procedures.

Once the medical and surgical classes for an MDC were formed, each diagnosis class was evaluated to determine if complications or comorbidities would consistently affect hospital resource consumption. Each diagnosis was categorized into one of three severity levels. These three levels include a major complication or comorbidity (MCC), a complication or comorbidity (CC), or a non-CC. Physician panels classified each diagnosis code based on a highly iterative process involving a combination of statistical results from test data as well as clinical judgment. As stated earlier, we refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system was established based on severity levels of illness (72 FR 47141).

A patient's diagnosis, procedure, discharge status, and demographic information is entered into the Medicare claims processing systems and subjected to a series of automated screens called the Medicare Code Editor (MCE). The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS–DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS–DRG on the basis of the diagnosis and procedure codes and, for a limited number of MS–DRGs, demographic information (that is, sex, age, and discharge status).

After cases are screened through the MCE and assigned to an MS–DRG by the GROUPER, the PRICER software calculates a base MS–DRG payment. The PRICER calculates the payment for each case covered by the IPPS based on the MS–DRG relative weight and additional factors associated with each hospital, such as IME and DSH payment adjustments. These additional factors increase the payment amount to hospitals above the base MS–DRG payment.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible MS–DRG classification changes and to recalibrate the MS–DRG weights. However, in the FY 2000 IPPS final rule (64 FR 41499 and 41500), we discussed a process for considering non-MedPAR data in the recalibration process. We stated that for use of non-MedPAR data

to be feasible for purposes of DRG recalibration and reclassification, the data must, among other things: (1) Be independently verified; (2) reflect a complete set of cases (or a representative sample of cases); and (3) enable us to calculate appropriate DRG relative weights and ensure that cases are classified to the "correct" DRG, and to one DRG only, in the recalibration process. Further, in order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. The time necessary to do so depend upon the nature and quality of the non-MedPAR data submitted. Generally, however, a significant sample of the non-MedPAR data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule. This date allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete non-MedPAR database should be submitted by early December for consideration in conjunction with the next year's proposed rule.

As we indicated above, for FY 2008, we made significant improvements in the DRG system to recognize severity of illness and resource usage by adopting MS–DRGs that were reflected in the FY 2008 GROUPER, Version 25.0, and were effective for discharges occurring on or after October 1, 2007. Our MS–DRG analysis for this FY 2012 proposed rule is based on data from the September 2010 update of the FY 2010 MedPAR file, which contained hospital bills received through September 30, 2010, for discharges occurring through September 30, 2010.

2. Yearly Review for Making MS–DRG Changes

Many of the changes to the MS–DRG classifications we make annually are the result of specific issues brought to our attention by interested parties. We encourage individuals with comments about MS–DRG classifications to submit these comments no later than early December of each year so they can be carefully considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. Therefore, similar to the timetable for interested parties to submit non-MedPAR data for consideration in the MS–DRG recalibration process, comments about MS–DRG classification issues should be submitted no later than early December in order to be considered and possibly included in the next annual proposed rule updating the IPPS.

The actual process of forming the MS–DRGs was, and will likely continue to be, highly iterative, involving a combination of statistical results from test data combined with clinical judgment. In the FY 2008 IPPS final rule (72 FR 47140 through 47189), we described in detail the process we used to develop the MS–DRGs that we adopted for FY 2008. In addition, in deciding whether to make further modification to the MS–DRGs for particular circumstances brought to our attention, we considered whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluated patient care costs using average charges and lengths of stay as proxies for costs and relied on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we considered both the absolute and percentage differences in average charges between the cases we selected for review and the remainder of cases in the MS–DRG. We also considered variation in charges within these groups; that is, whether observed average differences were consistent across patients or attributable to cases that were extreme in terms of charges or length of stay, or both. Further, we considered the number of patients who will have a given set of characteristics and generally preferred not to create a new MS–DRG unless it would include a substantial number of cases.

*C. Adoption of the MS–DRGs in FY 2008*

In the FY 2006, FY 2007, and FY 2008 IPPS final rules, we discussed a number of recommendations made by MedPAC regarding revisions to the DRG system used under the IPPS (70 FR 47473 through 47482; 71 FR 47881 through 47939; and 72 FR 47140 through 47189). As we noted in the FY 2006 IPPS final rule, we had insufficient time to complete a thorough evaluation of these recommendations for full implementation in FY 2006. However, we did adopt severity-weighted cardiac DRGs in FY 2006 to address public comments on this issue and the specific concerns of MedPAC regarding cardiac surgery DRGs. We also indicated that we planned to further consider all of MedPAC's recommendations and thoroughly analyze options and their impacts on the various types of hospitals in the FY 2007 IPPS proposed rule.

For FY 2007, we began this process. In the FY 2007 IPPS proposed rule, we proposed to adopt Consolidated Severity DRGs (CS DRGs) for FY 2008 (if not earlier). Based on public comments received on the FY 2007 IPPS proposed rule, we decided not to adopt the CS DRGs. In the FY 2007 IPPS final rule (71 FR 47906 through 47912), we discussed several concerns raised by public commenters regarding the proposal to adopt CS DRGs. We acknowledged the many public comments suggesting the logic of Medicare's DRG system should continue to remain in the public domain as it has since the inception of the PPS. We also acknowledged concerns about the impact on hospitals and software vendors of moving to a proprietary system. Several commenters suggested that CMS refine the existing DRG classification system to preserve the many policy decisions that were made over the last 20 years and were already incorporated into the DRG system, such as complexity of services and new device technologies. Consistent with the concerns expressed in the public comments, this option had the advantage of using the existing DRGs as a starting point (which was already familiar to the public) and retained the benefit of many DRG decisions that were made in recent years. We stated our belief that the suggested approach of incorporating severity measures into the existing DRG system was a viable option that would be evaluated.

Therefore, we decided to make interim changes to the existing DRGs for FY 2007 by creating 20 new DRGs involving 13 different clinical areas that would significantly improve the CMS DRG system's recognition of severity of illness. We also modified 32 DRGs to better capture differences in severity. The new and revised DRGs were selected from 40 existing CMS DRGs that contained 1,666,476 cases and represented a number of body systems. In creating these 20 new DRGs, we deleted 8 existing DRGs and modified 32 existing DRGs. We indicated that these interim steps for FY 2007 were being taken as a prelude to more comprehensive changes to better account for severity in the DRG system by FY 2008.

In the FY 2007 IPPS final rule (71 FR 47898), we indicated our intent to pursue further DRG reform through two initiatives. First, we announced that we were in the process of engaging a contractor to assist us with evaluating alternative DRG systems that were raised as potential alternatives to the CMS DRGs in the public comments. Second, we indicated our intent to review over 13,000 ICD–9–CM diagnosis codes as part of making further refinements to the current CMS DRGs to better recognize severity of illness based

on the work that CMS (then HCFA) did in the mid-1990's in connection with adopting severity DRGs. We describe below the progress we have made on these two initiatives and our actions for FYs 2008, 2009, 2010, and 2011, and our proposed actions for FY 2012 based on our continued analysis of reform of the DRG system. We note that the adoption of the MS–DRGs to better recognize severity of illness has implications for the outlier threshold, the application of the postacute care transfer policy, the measurement of real case-mix versus apparent case-mix, and the IME and DSH payment adjustments. We discuss these implications for FY 2012 in other sections of this preamble and in the Addendum to this proposed rule.

In the FY 2007 IPPS proposed rule, we discussed MedPAC's recommendations to move to a cost-based HSRV weighting methodology using HSRVs beginning with the FY 2007 IPPS proposed rule for determining the DRG relative weights. Although we proposed to adopt the HSRV weighting methodology for FY 2007, we decided not to adopt the proposed methodology in the final rule after considering the public comments we received on the proposal. Instead, in the FY 2007 IPPS final rule, we adopted a cost-based weighting methodology without the HSRV portion of the proposed methodology. The cost-based weights were adopted over a 3-year transition period in ⅓ increments between FY 2007 and FY 2009. In addition, in the FY 2007 IPPS final rule, we indicated our intent to further study the HSRV-based methodology as well as other issues brought to our attention related to the cost-based weighting methodology adopted in the FY 2007 final rule. There was significant concern in the public comments that our cost-based weighting methodology does not adequately account for charge compression—the practice of applying a higher percentage charge markup over costs to lower cost items and services and a lower percentage charge markup over costs to higher cost items and services. Further, public commenters expressed concern about potential inconsistencies between how costs and charges are reported on the Medicare cost reports and charges on the Medicare claims. In the FY 2007 IPPS final rule, we used costs and charges from the cost reports to determine departmental level cost-to-charge ratios (CCRs) which we then applied to charges on the Medicare claims to determine the cost-based weights. The commenters were concerned about potential distortions to the cost-based weights that would result from inconsistent reporting between the cost reports and the Medicare claims. After publication of the FY 2007 IPPS final rule, we entered into a contract with RTI International (RTI) to study both charge compression and the extent, if any, to which our methodology for calculating DRG relative weights is affected by inconsistencies between how hospitals report costs and charges on the cost reports and how hospitals report charges on individual claims. Further, as part of its study of alternative DRG systems, the RAND Corporation analyzed the HSRV cost-weighting methodology. We refer readers to section II.E. of the preamble of this proposed rule for a discussion of the issue of charge compression and the cost-weighting methodology for FY 2012.

We believe that revisions to the DRG system to better recognize severity of illness and changes to the relative weights based on costs rather than charges are improving the accuracy of the payment rates in the IPPS. We agree with MedPAC that these refinements should be pursued. Although we continue to caution that any prospective payment system based on grouping cases will always present some opportunities for providers to specialize in cases they believe have higher margins, we believe that the changes we have adopted and the continuing reforms we are proposing to make in this proposed rule for FY 2012 will improve payment accuracy and reduce financial incentives to create specialty hospitals.

We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full discussion of how the MS–DRG system was established based on severity levels of illness (72 FR 47141).

*D. Proposed FY 2012 MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount*

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

As we discussed earlier in this preamble, we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 747 MS–DRGs, and we are proposing 4 additional MS–DRGs for FY 2012.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90. Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009. Section 7(a) of Public Law 110–90 did not adjust the FY 2010 −1.8 percent documentation and coding adjustment promulgated in the FY 2008 IPPS final rule with comment period. To comply with section 7(a) of Public Law 110–90, we promulgated a final rule on November 27, 2007 (72 FR 66886) that modified the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 payment rates, factors, and thresholds accordingly. These revisions were effective on October 1, 2007.

For FY 2009, section 7(a) of Pub. L. 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final

rule with comment period. As discussed in the FY 2009 IPPS final rule (73 FR 48447) and required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amount. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

3. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 precisely matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we indicated in the FY 2009 IPPS final rule (73 FR 48450) that we planned a thorough retrospective evaluation of our claims data. We stated that the results of this evaluation would be used by our actuaries to determine any necessary payment adjustments to the standardized amounts under section 1886(d) of the Act to ensure the budget neutrality of the MS–DRGs implementation for FY 2008 and FY 2009, as required by law. In the FY 2009 IPPS proposed rule (73 FR 23541 through 23542), we described our preliminary plan for a retrospective analysis of inpatient hospital claims data and invited public input on our proposed methodology.

In that proposed rule, we indicated that we intended to measure and corroborate the extent of the overall national average changes in case-mix for FY 2008 and FY 2009. We expected that the two largest parts of this overall national average change would be attributable to underlying changes in actual patient severity of illness and to documentation and coding improvements under the MS–DRG system. In order to separate the two effects, we planned to isolate the effect of shifts in cases among base DRGs from the effect of shifts in the types of cases within base DRGs.

The MS–DRGs divide the base DRGs into three severity levels (with MCC, with CC, and without CC); the previously used CMS DRGs had only two severity levels (with CC and without CC). Under the CMS DRG system, the majority of hospital discharges had a secondary diagnosis which was on the CC list, which led to the higher severity level. The MS–DRGs significantly changed the code lists of what was classified as an MCC or a CC. Many codes that were previously classified as a CC are no longer included on the MS–DRG CC list because the data and clinical review showed these conditions did not lead to a significant increase in resource use. The addition of a new level of high severity conditions, the MCC list, also provided a new incentive to code more precisely in order to increase the severity level. We anticipated that hospitals would examine the MS–DRG MCC and CC code lists and then work with physicians and coders on documentation and coding practices so that coders could appropriately assign codes from the highest possible severity level. We note that there have been numerous seminars and training sessions on this particular coding issue. The topic of improving documentation practices in order to code conditions on the MCC list was also discussed extensively by participants at the March 11–12, 2009 ICD–9–CM Coordination and Maintenance Committee meeting. Participants discussed their hospitals' efforts to encourage physicians to provide more precise documentation so that coders could appropriately assign codes that would lead to a higher severity level. Because we expected most of the documentation and coding changes under the MS–DRG system would occur in the secondary diagnoses, we believed that the shifts among base DRGs were less likely to be the result of the MS–DRG system and the shifts within base DRGs were more likely to be the result of the MS–DRG system. We also anticipated evaluating data to identify the specific MS–DRGs and diagnoses that contributed significantly to the documentation and coding payment effect and to quantify their impact. This step entailed analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs.

In the FY 2009 IPPS proposed rule, we solicited public comments on the analysis plans described above, as well as suggestions on other possible approaches for performing a retrospective analysis to identify the amount of case-mix changes that occurred in FY 2008 and FY 2009 that did not reflect real increases in patient severity of illness.

A few commenters, including MedPAC, expressed support for the analytic approach described in the FY

2009 IPPS proposed rule. A number of other commenters expressed concerns about certain aspects of the approach and/or suggested alternate analyses or study designs. In addition, one commenter recommended that any determination or retrospective evaluation by the actuaries of the impact of the MS–DRGs on case-mix be open to public scrutiny prior to the implementation of the payment adjustments beginning in FY 2010.

We took these comments into consideration as we developed our proposed analysis plan, and in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we solicited public comment on our methodology and analysis. For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008. Based on this evaluation, our actuaries determined that implementation of the MS–DRG system resulted in a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772), we responded to comments on our methodology for the retrospective evaluation of FY 2008 claims data. We refer readers to that final rule for a detailed description of our analysis and prior responses to comments.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068), we performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims. We note that, in the FY 2011 IPPS/LTCH PPS proposed rule, we performed this analysis using FY 2009 claims paid through December 2009. In the FY 2011 IPPS/LTCH PPS final rule, we updated the analysis with FY 2009 claims paid through March 2010, as we discussed in the proposed rule. We note that, for all IPPS hospitals, other than those in Puerto Rico, the estimates were unchanged from those in the proposed rule. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068) for a detailed description of our analysis and prior responses to comments. The results of the analysis for the FY 2011 proposed and final rules provided additional support for our conclusion that the proposed 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system.

As in prior years, the FY 2008 and FY 2009 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effect. Interested individuals may still order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

5. Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

Based on our evaluation of FY 2008 Medicare claims data that were most current at the time of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, the estimated 2.5 percent change in FY 2008 case-mix due to changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 exceeded the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24096), we solicited public comment on our proposal to make a −1.9 percent prospective adjustment to the standardized amounts under section 1886(d) of the Act to address the effects of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, in response to public comments, we indicated that we fully understood that our proposed adjustment of −1.9 percent would reduce the increase in payments that affected hospitals would have received in FY 2009 in the absence of the adjustment, and we determined that it would be appropriate to postpone adopting documentation and coding adjustments as authorized under section 7(a) of Public Law 110–90 and section 1886(d)(3)(A)(vi) of the Act until a full analysis of case-mix changes could be completed. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43767 through 43777) for a detailed description of our proposal, responses to comments, and finalized policy.

After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an "appropriate" adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believe we have some discretion as to the manner in which we apply the prospective adjustment of −3.9 percent. We indicated that applying the full prospective adjustment of −3.9 percent for FY 2011, in combination with the proposed recoupment adjustment of −2.9 percent in FY 2011 (discussed below) would require an aggregate adjustment of −6.8 percent. As we discuss elsewhere in this section II.D., and more extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. As we also discuss below in this section II.D., we are required to implement the remaining adjustment in section 7(b)(1)(B) of Public Law 110–90 no later than the FY 2012 rulemaking period, and accordingly, in the FY 2011 IPPS/LTCH PPS proposed rule, we proposed a recoupment adjustment under section 7(b)(1)(B) of −2.9 percent for FY 2011 (75 FR 23870 and 23871). Therefore, we stated that we believed it was appropriate to not implement any or all of the −3.9 percent prospective adjustment in FY 2011. Accordingly, we did not propose a prospective

adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870) for FY 2011. We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) would be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We also noted that payments in FY 2010 were also expected to be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90, which our actuaries estimated increased aggregate payments by approximately $4 billion in FY 2010.

Because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it is imperative that we propose a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we are proposing a −3.15 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described below in section II.D.6. of this preamble), and after considering other payment adjustments to FY 2012 rates proposed elsewhere within this proposed rule, we believe that the proposed −3.15 percent adjustment will allow for a significant reduction in potential unrecoverable overpayments, yet will maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. We recognize that an additional adjustment of −0.75 (3.9 minus 3.15) percent will be required in future rule making to complete the necessary −3.9 adjustment to meet CMS' statutory requirement under section 7(b)(1)(A) of Public Law 110–90. We are not at this time proposing a timeline to implement the remainder of this prospective adjustment.

6. Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As discussed in section II.D.1. of this preamble, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43773), we estimated a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008, exceeding the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. We stated that our actuaries had estimated that this 1.9 percentage point increase resulted in an increase in aggregate payments of approximately $2.2 billion in FY 2008. We did not propose to make an adjustment to the FY 2010 average standardized amounts to offset, in whole or in part, the estimated increase in aggregate payments for discharges occurring in FY 2008, but stated in the proposed rule that we intended to address this issue in future rulemaking. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43774), we stated that because we would not receive all FY 2009 claims data prior to publication of the final rule, we would address any increase or decrease in FY 2009 payments in future rulemaking for FY 2011 and 2012 after we performed a retrospective evaluation of the FY 2009 claims data. In response to public comments in FY 2010, we indicated that we recognized that any adjustment to account for the documentation and coding effect observed in the FY 2008 and FY 2009 claims data may result in significant future payment reductions for providers. However, we indicated that we are required under section 7(b)(1)(B) of Pub. L. 110–90 to recover the difference of actual documentation and coding effect in FY 2008 and FY 2009 that is greater than the prior adjustments. We agreed with the commenters who requested that CMS delay any adjustment and, for the reasons stated above, indicated that we expected to address this issue in the FY 2011 rulemaking. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777) for a detailed description of our proposal, responses to comments, and finalized policy.

As we indicated in the FY 2011 IPPS/LTCH PPS final rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110–90 for those 2 years, respectively, by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 (1.9 plus 3.9) percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we noted that there may be a need to actuarially adjust the recoupment adjustment to accurately reflect accumulated interest. Therefore, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009. In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23871), we stated that we intended to take into account the need to reflect accumulated interest in proposing a recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS proposed rule, we proposed to make an adjustment to the standardized amount of −2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude would allow us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012).

Unlike the permanent prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, and, therefore, would be removed for subsequent fiscal years

once we have completely offset the increase in aggregate payments for discharges for FY 2008 and FY 2009 expenditures. In keeping with our practice of moderating payment adjustments when necessary, we stated that we anticipated that the proposal of phasing in the recoupment adjustment will have an additional, and significant, moderating effect on implementing the requirements of section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

In the FY 2011 IPPS/LTCH PPS proposed rule, we sought public comment on our proposal to offset part of the total 5.8 percent increase in aggregate payments (including interest) for discharges occurring in FY 2008 and FY 2009 resulting from the adoption of the MS–DRGs in FY 2011, noting that this proposal would result in a −2.9 percent adjustment to the standardized amount. We received numerous comments on our proposal, especially from national and regional hospital associations, hospital systems, and individual hospitals. MedPAC also commented on our proposal. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50055 through 50073) for a detailed description of our analysis and prior responses to comments, and finalized policy.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50068), we finalized the proposed adjustment to the standardized amount of −2.9 percent, which represented approximately half of the aggregate recoupment adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. We were persuaded by both MedPAC's analysis, and our own review of the methodologies recommended by various commenters, that the methodology we employed to determine the required recoupment adjustment was sound. Since the statute required that we implement the entire recoupment adjustment no later than FY 2012, we have sought, as we commonly do, to moderate the potential impact on hospitals by phasing in the required adjustment over more than one year. As we stated in prior rulemaking, a major advantage of making the −2.9 percent adjustment to the standardized amount in FY 2011 was that, because the required recoupment adjustment is not cumulative, we anticipated removing the FY 2011 −2.9 percent adjustment from the rates (in other words, making a positive 2.9 percent adjustment to the rates) in FY 2012, at the same time that the law required us to apply the remaining approximately −2.9 percent adjustment required by section 7(b)(1)(B) of Public Law 110–90. These two steps in FY 2012, restoring the FY 2011 −2.9 percent adjustment and then applying the remaining adjustment of approximately −2.9 percent, would effectively cancel each other out. The result of these two steps would be an aggregate adjustment of approximately 0.0 percent. While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, for FY 2012, pursuant to the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we are proposing to complete the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011. Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals.

**FY 2012 MS-DRG Documentation and Coding Adjustment**

| | Required Prospective Adjustment for FYs 2008-2009 | Remaining Required Recoupment Adjustment for FYs 2008-2009 | Total Remaining Adjustment | Proposed Prospective Adjustment for FY 2012 | Proposed Recoupment Adjustment to FY 2012 Payments | Remaining Prospective Adjustment If proposals are Finalized |
|---|---|---|---|---|---|---|
| Level of Adjustments | -3.9% | -2.9% | -6.8% | -3.15% | -2.9% | -0.75% |

The table above summarizes the proposed adjustments for FY 2012 for documentation and coding for IPPS hospitals.

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs per discharge. In the FY 2008 IPPS final rule with comment period (72 FR 47152 through 47188), we established a policy of applying the documentation and coding adjustment to the hospital-specific rates. In that final rule with comment period, we indicated that because SCHs and MDHs use the same DRG system as all other hospitals, we believe they should be equally subject to the budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. In establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the Act, which provides us with the authority to adjust "the standardized amount" to eliminate the effect of changes in coding or classification that do not reflect real change in case-mix.

However, in the final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we rescinded the application of the

documentation and coding adjustment to the hospital-specific rates retroactive to October 1, 2007. In that final rule, we indicated that, while we still believe it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, upon further review, we decided that the application of the documentation and coding adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting "the standardized amount" under section 1886(d) of the Act and does not mention adjusting the hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that we continued to have concerns about this issue. Because hospitals paid based on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. In section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rates should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment provision authorizes us to provide "for such other exceptions and adjustments to [IPPS] payment amounts * * * as the Secretary deems appropriate." In the FY 2009 IPPS final rule (73 FR 48448 through 48449), we indicated that, for the FY 2010 rulemaking, we planned to examine our FY 2008 claims data for hospitals paid based on the hospital-specific rate. We further indicated that if we found evidence of significant increases in case-mix for patients treated in these hospitals that do not reflect real changes in case-mix, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS proposed rule, we stated in the FY 2009 IPPS final rule that we would consider whether such a proposal was warranted for FY 2010. To gather information to evaluate these considerations, we indicated that we planned to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we found that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 was warranted, we indicated that we would propose to make such an adjustment in the FY 2010 IPPS proposed rule.

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule and final rule (74 FR 24098 through 24100 and 74 FR 43775 through 43776, respectively), we discussed our retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology described earlier for other IPPS hospitals. We found that, independently for both SCHs and MDHs, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 slightly exceeded the proposed 2.5 percent result discussed earlier for other IPPS hospitals, but did not significantly differ from that result. We refer readers to those rules for a more complete discussion.

Therefore, consistent with our statements in prior IPPS rules, we proposed to use our authority under section 1886(d)(5)(I)(i) of the Act to prospectively adjust the hospital-specific rates by the proposed −2.5 percent in FY 2010 to account for our estimated documentation and coding effect in FY 2008 that does not reflect real changes in case-mix. We proposed to leave this adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments for SCHs and MDHs not reflective of an increase in real case-mix. The proposed −2.5 percent adjustment to the hospital-specific rates exceeded the −1.9 percent adjustment to the national standardized amount under section 7(b)(1)(A) of Public Law 110–90 because, unlike the national standardized rates, the FY 2008 hospital-specific rates were not previously reduced in order to account for anticipated changes in documentation and coding that do not reflect real changes in case-mix resulting from the adoption of the MS–DRGs.

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24100), we solicited public comment on this proposal. Consistent with our approach for IPPS hospitals discussed earlier, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we also delayed adoption of a documentation and coding adjustment to the hospital-specific rate until FY 2011. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As we have noted previously, because SCHs and MDHs use the same MS–DRG system as all other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. We believe the documentation and coding estimates for all subsection (d) hospitals should be the same. While the findings for the documentation and coding effect for all IPPS hospitals are similar to the effect for SCHs and slightly different to the effect for MDHs, we continue to believe that this is the appropriate policy so as to neither advantage or disadvantage different types of providers. As we discuss in section II.D.4. of this preamble, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011, we had not made any previous adjustments to the hospital-specific rates paid to SCHs and MDHs to account for documentation and coding changes. Therefore, the entire −5.4 percent recoupment adjustment needed to be made, as opposed to a −3.9 percent remaining adjustment for IPPS hospitals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50068 through 50071), we made an adjustment to the standardized amount for IPPS hospitals of −2.9 percent under section 7(b)(1)(B) of

Public Law 110–90, for FY 2011. As we noted in the FY 2011 IPPS/LTCH PPS final rule, in determining the level and pace of adjustments to account for such documentation and coding changes, we believe that it is important to maintain, as much as possible, both consistency and equity among these classes of hospitals. Therefore, we finalized a prospective adjustment of −2.9 percent to the hospital-specific rates paid to SCHs and MDHs. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As discussed earlier in this section II.D., we are proposing a net −3.15 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−3.15 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2010). The proposed IPPS adjustment exceeds the remaining −2.5 percent documentation and coding adjustment for hospitals receiving a hospital-specific rate (that is, the entire −5.4 percent adjustment, minus the −2.9 percent adjustment finalized for FY 2011). As we indicated in the FY 2011 IPPS/LTCH PPS proposed rule and final rule, we are continuing, as much as possible, consistent with section 7(b)(1) of Public Law 110–90 and section 1886(d)(5)(I)(i) of the Act, to take such consistency and equity into account in developing future proposals for implementing documentation and coding adjustments. We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we are proposing a −2.5 percent payment adjustment to the hospital-specific rate. We believe that proposing the entire remaining prospective adjustment of −2.5 percent allows CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG. As discussed below, we took a similar approach in finalizing an adjustment to the Puerto-Rico specific rate in FY 2011.

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the Secretary the authority to adjust "the standardized amounts computed under this paragraph" to eliminate the effect of changes in coding or classification that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act. In calculating the FY 2008 payment rates, we made an inadvertent error and applied the FY 2008 –0.6 percent documentation and coding adjustment to the Puerto Rico-specific standardized amount, relying on our authority under section 1886(d)(3)(A)(vi) of the Act. However, section 1886(d)(3)(A)(vi) of the Act authorizes application of a documentation and coding adjustment to the national standardized amount and does not apply to the Puerto Rico specific standardized amount. In the FY 2009 IPPS final rule (73 FR 48449), we corrected this inadvertent error by removing the –0.6 percent documentation and coding adjustment from the FY 2008 Puerto Rico-specific rates (that is, we made a positive 0.6 percent adjustment, increasing the Puerto Rico-specific rates).

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs and MDHs that are paid based on the hospital-specific rate, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. Consistent with the approach described for SCHs and MDHs, in the FY 2009 IPPS final rule (73 FR 48449), we indicated that we planned to examine our FY 2008 claims data for hospitals in Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR 23541) that if we found evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing to apply documentation and coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act.

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 claims data for Puerto Rico hospitals using the same methodology described earlier for IPPS hospitals paid under the national standardized amounts under section 1886(d) of the Act. We found that, for Puerto Rico hospitals, the increase in payments for discharges occurring during FY 2008 due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 was approximately 1.1 percent. However, as we note earlier for IPPS hospitals and hospitals receiving hospital-specific rates, if the estimated documentation and coding effect determined based on a full analysis of FY 2009 claims data was more or less than our then current estimates, it would change, possibly lessen, the anticipated cumulative adjustments that we had estimated we would have to make for the FY 2008 and FY 2009 combined adjustment. Therefore, we believed that it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY 2009 claims data for Puerto Rico hospitals.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43777), we indicated that, given these documentation and coding increases, consistent with our statements in prior IPPS rules, we would use our authority under section 1886(d)(5)(I)(i) of the Act to adjust the Puerto Rico-specific rate and solicited public comment on the proposed −1.1 percent prospective adjustment. However, in parallel to our decision to postpone adjustments to the Federal standardized amount, we also indicated that we were adopting a similar policy for the Puerto Rico-specific rate for FY 2010 and would consider the phase-in of this adjustment over an appropriate time period through future rulemaking. We noted that, as with the hospital-specific rates, the Puerto Rico-specific standardized amount had not previously been adjusted based on estimated changes in documentation and coding associated with the adoption of the MS–DRGs.

Consistent with our approach for IPPS hospitals for FY 2010, we indicated that

we would address in the FY 2011 rulemaking cycle any change in FY 2009 case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009.

As we have noted above, similar to SCHs and MDHs, hospitals in Puerto Rico use the same MS–DRG system as all other hospitals and we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to the prospective budget neutrality adjustment that we intend to apply to prospective payment rates for IPPS hospitals, including SCHs and MDHs, in order to eliminate the full effect of the documentation and coding changes associated with implementation of the MS–DRG system.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that, for documentation and coding that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. As we stated above, we believe it important to maintain both consistency and equity among all hospitals paid on the basis of the same MS–DRG system. At the same time, however, we recognize that the estimated cumulative impact on aggregate payment rates resulting from implementation of the MS–DRG system was smaller for Puerto Rico hospitals as compared to IPPS hospitals and SCHs and MDHs. Therefore, in the FY 2011 IPPS LTCH PPS proposed rule (75 FR 23876), we proposed an adjustment to eliminate the full effect of the documentation and coding changes on the portion of future payments to Puerto Rico hospitals based on the Puerto Rico-specific rate. We stated that we believed that a full prospective adjustment was the most appropriate means to take into full account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates. We noted that our updated data analysis in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073) final rule showed that this adjustment would be −2.6 percent. The previous estimate in the proposed rule was a −2.4 percent adjustment.

One reason we proposed the full prospective adjustment for the Puerto Rico-specific rate in FY 2011 was to maintain equity as much as possible in the documentation and coding adjustments applied to various hospital rates in FY 2011. Because our proposal was to make an adjustment that represents the full adjustment that is warranted for the Puerto Rico-specific rate, we indicated that we did not anticipate proposing any additional adjustments to the this rate for documentation and coding effects.

Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we are proposing no further adjustment in this proposed rule for FY 2012.

### *E. Refinement of the MS–DRG Relative Weight Calculation*

#### 1. Background

In the FY 2009 IPPS final rule (73 FR 48450), we continued to implement significant revisions to Medicare's inpatient hospital rates by completing our 3-year transition from charge-based relative weights to cost-based relative weights. Beginning in FY 2007, we implemented relative weights based on cost report data instead of based on charge information. We had initially proposed to develop cost-based relative weights using the hospital-specific relative value cost center (HSRVcc) methodology as recommended by MedPAC. However, after considering concerns expressed in the public comments we received on the proposal, we modified MedPAC's methodology to exclude the hospital-specific relative weight feature. Instead, we developed national CCRs based on distinct hospital departments and engaged a contractor to evaluate the HSRVcc methodology for future consideration. To mitigate payment instability due to the adoption of cost-based relative weights, we decided to transition cost-based weights over 3 years by blending them with charge-based weights beginning in FY 2007. (We refer readers to the FY 2007 IPPS final rule for details on the HSRVcc methodology and the 3-year transition blend from charge-based relative weights to cost-based relative weights (71 FR 47882 through 47898).)

In FY 2008, we adopted severity-based MS–DRGs, which increased the number of DRGs from 538 to 745. Many commenters raised concerns as to how the transition from charge-based weights to cost-based weights would continue with the introduction of new MS–DRGs. We decided to implement a 2-year transition for the MS–DRGs to coincide with the remainder of the transition to cost-based relative weights. In FY 2008, 50 percent of the relative weight for each DRG was based on the CMS DRG relative weight and 50 percent was based on the MS–DRG relative weight.

In FY 2009, the third and final year of the transition from charge-based weights to cost-based weights, we calculated the MS–DRG relative weights based on 100 percent of hospital costs. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a more detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

#### 2. Summary of the RTI Study of Charge Compression and CCR Refinement

As we transitioned to cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single CCR is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to RTI to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. RTI issued an interim draft report in January 2007 with its findings on charge compression (which was posted on the CMS Web site at: *http://www.cms.hhs.gov/reports/downloads/Dalton.pdf*). In that report, RTI found that a number of factors contribute to charge compression and affect the accuracy of the relative weights. RTI's findings demonstrated that charge compression exists in several CCRs, most notably in the Medical Supplies and Equipment CCR.

In its interim draft report, RTI offered a number of recommendations to mitigate the effects of charge compression, including estimating regression-based CCRs to disaggregate the Medical Supplies Charged to Patients, Drugs Charged to Patients, and Radiology cost centers, and adding new cost centers to the Medicare cost report, such as adding a "Devices, Implants and Prosthetics" line under "Medical

Supplies Charged to Patients" and a "CT Scanning and MRI" subscripted line under "Radiology-Diagnostics". Despite receiving public comments in support of the regression-based CCRs as a means to immediately resolve the problem of charge compression, particularly within the Medical Supplies and Equipment CCR, we did not adopt RTI's recommendation to create additional regression-based CCRs. (For more details on RTI's findings and recommendations, we refer readers to the FY 2009 IPPS final rule (73 FR 48452).) RTI subsequently expanded its analysis of charge compression beyond inpatient services to include a reassessment of the regression-based CCR models using both outpatient and inpatient charge data. This interim report was made available in April 2008 during the public comment period on the FY 2009 IPPS proposed rule and can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200804.pdf* . The IPPS-specific chapters, which were separately displayed in the April 2008 interim report, as well as the more recent OPPS chapters, were included in the July 3, 2008 RTI final report entitled, "Refining Cost-to-Charge Ratios for Calculating APC [Ambulatory Payment Classification] and DRG Relative Payment Weights," that became available at the time of the development of the FY 2009 IPPS final rule. The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf.*

RTI's final report found that, under the IPPS and the OPPS, accounting improvements to the cost reporting data reduce some of the sources of aggregation bias without having to use regression-based adjustments. In general, with respect to the regression-based adjustments, RTI confirmed the findings of its March 2007 report that regression models are a valid approach for diagnosing potential aggregation bias within selected services for the IPPS and found that regression models are equally valid for setting payments under the OPPS.

RTI also noted that cost-based weights are only one component of a final prospective payment rate. There are other rate adjustments (wage index, IME, and DSH) to payments derived from the revised cost-based weights, and the cumulative effect of these components may not improve the ability of final payment to reflect resource cost. RTI endorsed short-term regression-based adjustments, but also concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in hospital cost-based weights. For a more detailed summary of RTI's findings, recommendations, and public comments we received on the report, we refer readers to the FY 2009 IPPS final rule (73 FR 48452 through 48453).

3. Summary of Policy Changes Made in FY 2011

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, and because of RAND's finding that regression-based adjustments to the CCRs do not significantly improve payment accuracy, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." (We refer readers to the Web site: *http://www.rand.org/pubs/working_papers/WR560/,* and the FY 2009 IPPS/LTCH PPS final rule for details on the RAND report (73 FR 48453 through 48457).) We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS/LTCH PPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining what should be reported in these respective cost centers, we adopted the commenters' recommendation that hospitals should use revenue codes established by AHA's National Uniform Billing Committee to determine what should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. Accordingly, a new subscripted line 55.30 for "Implantable Devices Charged to Patients" was created in July 2009 as part of CMS' Transmittal 20 update to the existing cost report Form CMS–2552–96. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRI, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI found that the costs and charges of CT scans, MRI, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. CMS issued the new hospital cost report Form CMS–2552–10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10.* Once at this Web site, users should double click on "Chapter 40."

4. Discussion for FY 2012

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new "Implantable Devices Charged to Patients" cost center to develop a CCR for Implantable Devices Charged to Patients in the FY 2012 or FY 2013 IPPS rulemaking cycle. Specifically, we stated, "Because there is approximately a 3-year lag between the availability of cost report data for IPPS and OPPS rate-setting purposes in a given fiscal year, we may be able to derive two distinct CCRs, one for medical supplies and one for devices, for use in calculating the FY 2012 or FY 2013 IPPS relative weights and the CY 2012 or CY 2013 OPPS relative weights" (73 FR 48468). However, as noted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552–10,

a new CCR for Implantable Devices Charged to Patients may not be available until FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for MRI, CT scans, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). That is, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077), we stated that the data from the standard cost centers for MRI, CT scans, and cardiac catheterization, respectively, would not even be available for possible use in calculating the relative weights earlier than 3 years after Form CMS–2552–10 becomes available. We further stated that, at that time, we would analyze the data and determine if it is appropriate to use those data to create distinct CCRs from these cost centers for use in the relative weights for the respective payment systems. We also reassured public commenters that there was no need for immediate concern regarding possible negative payment impacts on MRI and CT scans under the IPPS and the OPPS because the cost report data that would be used for the calculation of the relative weights were at least 3 years from being available. We stated that we will first thoroughly analyze and run impacts on the data and provide the public with the opportunity to comment before distinct CCRs for MRI and CT scans would be finalized for use in the calculation of the relative weights. We also urged all hospitals to properly report their costs and charges for MRI, CT scans, and all other services so that, in several years' time, we will have reliable data from all hospitals on which to base a decision as to whether to incorporate additional CCRs into the relative weight calculation (75 FR 50077).

Accordingly, in preparation for this FY 2012 IPPS/LTCH PPS proposed rule, we have assessed the availability of data in the "Implantable Devices Charged to Patients" cost center. In order to develop a robust analysis regarding the use of cost data from the "Implantable Devices Charged to Patients" cost center, it is necessary to have a critical mass of cost reports filed with data in this cost center. The cost center for "Implantable Devices Charged to Patients" is effective for cost reporting periods beginning on or after May 1, 2009. We have checked the availability of FY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which is the latest upload of FY 2009 cost report data that we could use for this proposed rule. We have determined that there are only 437 hospitals (out of approximately 3,500 IPPS hospitals) that have completed the "Implantable Devices Charged to Patients" cost center. We do not believe that this is a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we are not proposing to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for Implantable Devised Charged to Patients for use in calculating the MS–DRG relative weights for FY 2012. We will reassess the availability of data for the "Implantable Devices Charged to Patients" cost center, and the "MRI, CT Scans, and Cardiac Catheterization" cost centers, for the FY 2013 IPPS rulemaking cycle and, if appropriate, we will propose to create a distinct CCR at that time.

*F. Preventable Hospital-Acquired Conditions (HACs), Including Infections*

1. Background

a. Statutory Authority

Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not POA. Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS–DRG rate. Under the HAC payment policy, all CCs/MCCs on the claim must be HACs in order to generate a lower MS–DRG payment. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA.

The POA indicator reporting requirement and the HAC payment provision apply to IPPS hospitals only. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, hospitals in Maryland operating under waivers, rural health clinics, federally qualified health centers, RNHCIs, and Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting and the HAC payment provision. Throughout this section, the term "hospital" refers to an IPPS hospital.

The HAC provision found in section 1886(d)(4)(D) of the Act is part of an array of Medicare value-based purchasing (VBP) tools that we are using to promote increased quality and efficiency of care. Those tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through Quality Improvement Organization (QIO) activities. The application of VBP tools, such as this HAC provision, is transforming Medicare from a passive payer to an active purchaser of higher value health care services. We are applying these strategies for inpatient hospital care and across the continuum of care for Medicare beneficiaries.

These VBP tools are highly compatible with the underlying purposes as well as existing structural features of Medicare's IPPS. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of certain conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may

generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS–DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS–DRG system, there are currently 259 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. The presence of a CC or an MCC generally results in a higher payment. However, since we implemented the HAC provisions, if a secondary diagnosis acquired during a hospital stay is a HAC and no other CCs or MCCs are present, the hospital receives a payment under the MS–DRGs as if the HACs were not present. (We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a discussion of DRG reforms (72 FR 47141).)

b. HAC Selection

Beginning in FY 2007, we have proposed, solicited, and responded to public comments and have implemented section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, we direct readers to the following publications: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); and the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080). A complete list of the 10 current categories of HACs is included in section II.F.2. of this preamble.

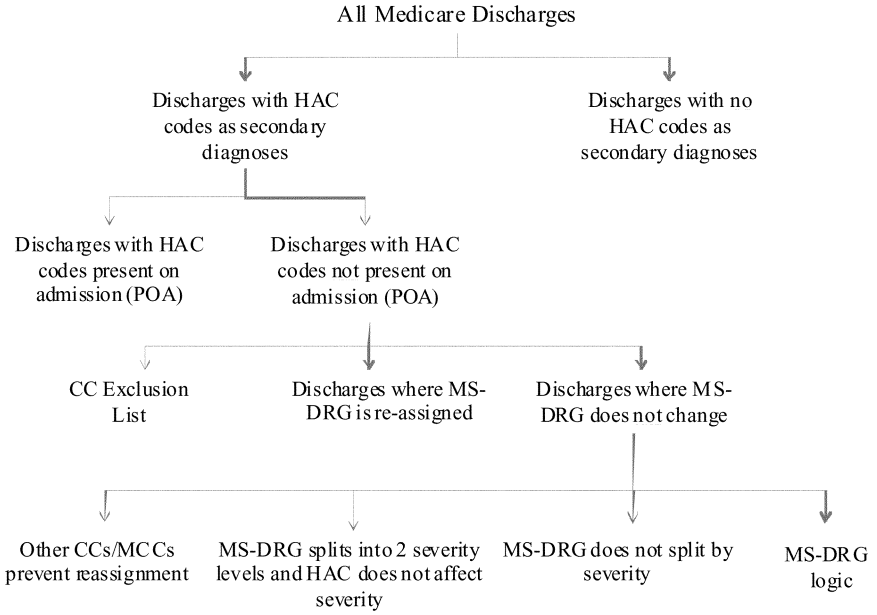
In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add any additional HACs or make any changes to policies already established under the authority of section 1886(d)(4)(D) of the Act.

c. Collaborative Process

In establishing the HAC payment policy under section 1886(d)(4)(D) of the Act, our experts have worked closely with public health and infectious disease professionals from across the Department of Health and Human Services, including CDC, the Agency for Healthcare Research and Quality (AHRQ), and the Office of Public Health and Science (OPHS), to identify the candidate preventable HACs, review comments, and select HACs. CMS and CDC also have collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on IPPS hospital Medicare claims and on the payment implications of the various POA reporting options. In addition, as discussed below, we have used rulemaking and Listening Sessions to obtain public input.

d. Application of HAC Payment Policy to MS–DRG Classifications

As described above, in certain cases, application of the HAC payment policy provisions can result in MS–DRG reassignment to a lower paying MS–DRG. The following diagram portrays the logic of the HAC payment policy provision as adopted in the FY 2008 IPPS final rule with comment period (72 FR 47200) and in the FY 2009 IPPS final rule (73 FR 48471):




e. Public Input Regarding Selected and Potential Candidate HACs

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add or remove categories of HACs, nor did we make any changes to previously established policies. However, we continue to encourage public dialogue about refinement of the HAC list.

Given the timeliness of the HAC discussion, particularly when considered within the context of recent legislative health care reform initiatives, we remain eager to engage in an ongoing public dialogue about the various aspects of this policy. We plan to continue to include updates and findings from the RTI evaluation on CMS' Hospital-Acquired Conditions and Present on Admission Indicator Web site available at: *http://www.cms.hhs.gov/HospitalAcqCond/.*

f. POA Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In the FY 2011 IPPS/LTCH PPS proposed rule, we listed the instructions and change requests that were issued to IPPS hospitals and also to non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims (75 FR 23381). We also indicated that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* We reiterate that additional information regarding POA indicator reporting and application of the POA reporting options is available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/.* Historically, we have not provided coding advice. Rather, we collaborate with the American Hospital Association (AHA) through the *Coding Clinic for ICD–9–CM.* We will continue to collaborate with the AHA to promote the *Coding Clinic for ICD–9–CM* as the source for coding advice about the POA indicator.

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting:*

| Indicator | Descriptor |
|---|---|
| **Y** | Indicates that the condition was present on admission. |
| **W** | Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred. |
| **N** | Indicates that the condition was not present on admission. |
| **U** | Indicates that the documentation is insufficient to determine if the condition was present at the time of admission. |
| **1** | Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD-9-CM diagnosis codes is available in the ICD-9-CM Official Guidelines for Coding and Reporting. |

In the FY 2009 IPPS final rule (73 FR 48486 through 48487), we adopted final payment policies to: (1) Pay the CC/MCC MS–DRGs for those HACs coded with "Y" and "W" indicators; and (2) not pay the CC/MCC MS–DRGs for those HACs coded with "N" and "U" indicators.

Beginning on or after January 1, 2011, hospitals are required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of "1" for codes that are exempt from POA reporting. However, for claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of "1" is still necessary because of reporting restrictions from the use of the 4010 electronic transmittal standards format.

Hospitals that began reporting with the 5010 format on and after January 1, 2011, can no longer report a POA indicator of "1" for POA exempt codes. The POA field should instead be left blank for codes exempt from POA reporting. We have issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100–20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010. These instructions, entitled *5010 Implementation-Changes to Present on Admission (POA) Indicator "1" and the K3 Segment,* can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf.*

We are continuing our efforts to clarify instructions regarding use of the POA indicator. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50088), we received public comments in response to the FY 2011 IPPS/LTCH PPS proposed rule that expressed concern about the accuracy of reporting of POA indicators for HACs related to intracranial injury with loss of consciousness. The codes for loss of consciousness are listed in the Falls and Trauma HAC category, within the "Intracranial Injury" subcategory. Because loss of consciousness is a component of intracranial injuries rather than a separate condition, we agreed that the POA guidelines that instructed coders to assign an "N" indicator if any part of the combination code was not present on admission did not apply to the loss of consciousness codes. As a member of the Editorial Advisory Board for the *Coding Clinic for ICD–9–CM,* we worked with the American Hospital Association (AHA), American Health Information Management Association (AHIMA), and the Centers for Disease Control and Prevention (CDC) to provide additional clarification on how these conditions should be reported. Additional guidance on how these cases should be reported can be found in AHA's *Coding Clinic for ICD–9–CM,* 2nd Quarter 2010, "Frequently Asked POA Questions" section. That publication clarified the POA reporting for patients in whom a single code captures the fact that the patient was admitted as a result of a head injury and then subsequently lost consciousness after the admission. For these cases, we clarified that the POA indicator assigned should be "Y," indicating that the head injury and resulting loss of consciousness occurred prior to (and was present on) admission.

We expect that this clarification will lead to greater consistency and accuracy in POA indicator reporting for these conditions. We look forward to continuing our efforts as part of the AHA's Editorial Advisory Board for *Coding Clinic for ICD–9–CM* to provide guidance on accuracy of coding and the reporting of POA indicators. Hospitals look to this publication to provide detailed guidance on ICD–9–CM coding and POA reporting. We encourage

hospitals to send any other questions about ICD–9–CM codes or POA indicator selection to the AHA so that the Editorial Advisory Board can continue its role of providing instruction on the accurate selection and reporting of both ICD–9–CM codes and POA indicators.

2. Proposed Additions and Revisions to the HAC Policy for FY 2012

a. Contrast-Induced Acute Kidney Injury

We discuss below our analysis for a proposed new condition as a possible candidate for selection for FY 2012 under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1.a. of this preamble, each HAC must be: (1) High cost, high volume, or both; (2) assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (3) could reasonably have been prevented through the application of evidence-based guidelines. We also discuss other considerations relating to the selection of a HAC, including any administrative or operational issues associated with a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC or an MCC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. We invite public comment on clinical, coding, and prevention issues on our proposal to add contrast-induced acute kidney injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011).

Contrast-induced acute kidney injury is a significant complication of the use of iodinated contrast media and accounts for a large number of cases of hospital-acquired acute kidney injury cases. A published study has shown that renal failure associated with contrast administration is correlated with up to 11 percent of cases of renal failure that occur in hospitals (Nash, *et al.:* American Journal on Kidney Disease, 2002, Vol. 39, pp. 930–936). Patients who experience acute kidney injury have an increased risk of inhospital mortality even after adjustments for disease comorbidities (McCullough, J.: American College of Cardiology, 2008, pp. 1419 through 1428). Data suggest that the risk for mortality extends beyond the period of hospitalization, resulting in 1-year and 5-year mortality rates significantly higher than those patients who have not developed acute kidney injury. In addition, contrast-induced acute kidney injury is associated with an increased incidence of myocardial infarction, bleeding requiring transfusion, and prolonged hospital stays (McCullough, J.: American Journal of Medicine, 1997, Vol. 103, pp. 368 through 375). We note that "acute kidney injury" is a new terminology endorsed by the National Kidney Foundation to replace "acute renal failure."

There is not a unique code that identifies kidney injury. However, kidney injury can be identified as a subset of discharges with ICD–9–CM diagnosis code 584.9 (Acute kidney failure, unspecified). Our clinical advisors believe that diagnosis code 584.9, in combination with the associated procedure codes below, can accurately identify contrast-induced acute kidney injury:

- 88.40 (Arteriography using contrast material, unspecified site)
- 88.41 (Arteriography of cerebral arteries)
- 88.42 (Aortography)
- 88.43 (Arteriography of pulmonary arteries)
- 88.44 (Arteriography of other intrathoracic vessels)
- 88.45 (Arteriography of renal arteries)
- 88.46 (Arteriography of placenta)
- 88.47 (Arteriography of other intra-abdominal arteries)
- 88.48 (Arteriography of femoral and other lower extremity arteries)
- 88.49 (Arteriography of other specified sites)
- 88.50 (Angiocardiography, not otherwise specified)
- 88.51 (Angiocardiography of venae cavae)
- 88.52 (Angiocardiography of right heart structures)
- 88.53 (Angiocardiography of left heart structures)
- 88.54 (Combined right and left heart angiocardiography)
- 88.55 (Coronary arteriography using a single catheter)
- 88.56 (Coronary arteriography using two catheters)
- 88.57 (Other and unspecified coronary arteriography)
- 88.58 (Negative-contrast cardiac roentgenography)
- 88.59 (Intra-operative coronary fluorescence vascular angiography)
- 88.60 (Phlebography using contrast material, unspecified site)
- 88.61 (Phlebography of veins of head and neck using contrast material)
- 88.62 (Phlebography of pulmonary veins using contrast material)
- 88.63 (Phlebography of other intrathoracic veins using contrast material)
- 88.64 (Phlebography of the portal venous system using contrast material)
- 88.65 (Phlebography of other intra-abdominal veins using contrast material)
- 88.66 (Phlebography of femoral and other lower extremity veins using contrast material)
- 88.67 (Phlebography of other specified sites using contrast material)
- 87.71 (C.A.T. of kidney)
- 87.72 (Other nephrotomogram)
- 87.73 (Intravenous pyelogram)
- 87.74 (Retrograde pyelogram)
- 87.75 (Percutaneous pyelogram)

We are proposing to identify contrast-induced acute kidney injury with diagnosis code 584.9 in combination with one or more of the above associated procedure codes.

We also considered identifying contrast-induced acute kidney injury through the use of external injury codes, or E-codes. Code E947.8 (Other drugs and medicinal substances) has an inclusion term "Contrast media used for diagnostic x-ray procedures" to identify the use of contrast. However, we note that we do not currently require the reporting of E-codes for the HAC payment provisions under the IPPS. Therefore, we would be unable to rely on the identification of contrast-induced acute kidney injury through E-codes on Medicare IPPS HAC claims.

Section 1886(d)(4)(D) of the Act requires that a HAC be a condition that is "high cost, high volume, or both." In FY 2009, there were 38,324 inpatient discharges coded with acute renal failure as specified by ICD–9–CM diagnosis code 584.9 reported as not present on admission (POA status = N) when reported with one of the above procedure codes submitted through Medicare claims. The cases had an average charge of $29,122 for the entire hospital stay. Studies suggest the additional average cost per day for a patient who has acquired contrast-induced acute kidney injury is $2,654. Other data report patients stays increases by 3.75 days once they have acquired the diagnosis (Subramanian, *et al.: Journal of Medical Economics,* 2007, Vol. 10, pp. 119 through 134).

There are widely recognized guidelines for the prevention of acute kidney injury that address the prevention of contrast-induced acute kidney injury, and we believe the condition is reasonably preventable. One of these guidelines can be found at: *http://www.renal.org/Clinical/*

*GuidelineSection/ AcuteKidneyInjury.aspx.*

The condition of contrast-induced acute kidney injury as specified in our proposal is a CC under the MS DRGs.

We have not identified any additional administrative or operational difficulties with proposing this condition as a HAC. We invite public comment on whether contrast-induced acute kidney injury meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011). We are particularly interested in receiving comments on the degree to which contrast-induced acute kidney injury is reasonably preventable through the application of evidence-based guidelines.

b. New Diagnosis Codes Proposed to be Added to Existing HACs

As changes to diagnosis codes and new diagnosis codes are proposed and finalized for the list of CCs and MCCs, we modify the list of selected HACs to reflect these changes. Included in Table 6A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, are five new ICD–9–CM diagnosis codes that we are proposing to add to three of the current HAC categories. We are proposing to add two new codes for the Falls and Trauma HAC category, two new codes for the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category, and one new code for the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category. The two new diagnosis codes that we are proposing to add to the Falls and Trauma HAC category are code 808.44 (Multiple closed pelvic fractures without disruption of pelvic circle) and code 808.54 (Multiple open pelvic fractures without disruption of pelvic circle). These codes fall within the range of the fracture code subcategory (800 through 829). The two new diagnosis codes that we are proposing to add to the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category are code 539.01 (Infection due to gastric band procedure) and code 539.81 (Infection due to other bariatric procedure). We believe these diagnosis codes are appropriate for inclusion in the existing category when reported as a secondary diagnosis with the specified principal diagnosis code of morbid obesity (code 278.01) and one of the designated bariatric procedure codes (code 44.38, 44.39, or 44.95). Lastly, the one new diagnosis code that we are proposing to add to the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category is code 415.13 (Saddle embolus of pulmonary artery). Diagnosis code 415.13 would be applicable when reported along with one of the following procedures codes describing certain orthopedic procedures: 00.85 through 00.87, 81.51, 81.52, or 81.54. Shown in the table below are these five new diagnosis codes with their corresponding descriptions and their proposed CC/MCC designations.

| ICD-9-CM Code | Code Descriptor | Proposed CC/MCC Designation |
|---|---|---|
| 539.01 | Infection due to gastric band procedure | CC |
| 539.81 | Infection due to other bariatric procedure | CC |
| 415.13 | Saddle embolus of pulmonary artery | MCC |
| 808.44 | Multiple closed pelvic fractures without disruption of pelvic circle | CC |
| 808.54 | Multiple open pelvic fractures without disruption of pelvic circle | MCC |

We are inviting public comments on the proposed adoption of theses five new ICD–9–CM diagnosis codes as CC/MCCs that are listed above, which, if finalized, would be added to the current Falls and Trauma HAC category, Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category and Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category and would be subject to the HAC payment provision for FY 2012.

c. Revision to HAC Subcategory Title

After publication of the FY 2011 IPPS/LTCH PPS final rule, we received a comment stating that the subcategory title "Electric Shock" that is included in the Falls and Trauma HAC category was misleading. The commenter stated that this subcategory title did not accurately describe the CC/MCC ICD–9–CM diagnoses codes (991 through 994) contained within this subcategory. The commenter requested that CMS develop a new title that would more accurately describe this group of codes.

We agree with the commenter that the HAC subcategory title "Electric Shock" is potentially misleading because the codes included within these ranges contain a variety of injuries, including the following:

- Category 991 (Effects of Reduced Temperature)
- Category 992 (Effects of Heat and Light)
- Category 993 (Effects of Air Pressure)
- Category 994 (Effects of Other External Causes)

We are proposing to change the title of this HAC subcategory from "Electric Shock" to "Other Injuries" because it includes a variety of injury codes. The subcategory will continue to include the codes within the 991–994 code ranges appearing on the CC/MCC list. We are proposing no changes to the list of codes in this subcategory; we are simply proposing to rename the subcategory title. We invite public comments on this proposed title change to the HAC subcategory from "Electric Shock" to "Other Injuries" for FY 2012.

d. Conclusion

The following table lists the current HAC categories and the ICD–9–CM codes that identify the conditions and have been finalized through FY 2011. For FY 2012, we are proposing that these conditions continue to be subject to the HAC payment provision, along with the creation of a new HAC category for Contrast-Induced Acute Kidney Injury as discussed in section II.F.2.a. of this preamble. In addition, we are proposing to add five new ICD–9–CM diagnosis codes and to revise the title of the "Electric Shock" subcategory in the Falls and Trauma HAC category.

BILLING CODE 4120–01–P

| HAC | CC/MCC (ICD-9-CM Code) |
|---|---|
| Foreign Object Retained After Surgery | 998.4 (CC)<br>998.7 (CC) |
| Air Embolism | 999.1 (MCC) |
| Blood Incompatibility | 999.60 (CC)<br>999.61 (CC)<br>999.62 (CC)<br>999.63 (CC)<br>999.69 (CC) |
| Pressure Ulcer Stages III & IV | 707.23 (MCC)<br>707.24 (MCC) |
| Falls and Trauma:<br><br>- Fracture<br>- Dislocation<br>- Intracranial Injury<br>- Crushing Injury<br>- Burn<br>- Electric Shock | Codes within these ranges on the CC/MCC list:<br>800-829<br>830-839<br>850-854<br>925-929<br>940-949<br>991-994 |
| Catheter-Associated Urinary Tract Infection (UTI) | 996.64 (CC)<br><br>Also excludes the following from acting as a CC/MCC:<br>112.2 (CC)<br>590.10 (CC)<br>590.11 (MCC)<br>590.2 (MCC)<br>590.3 (CC)<br>590.80 (CC)<br>590.81 (CC)<br>595.0 (CC)<br>597.0 (CC)<br>599.0 (CC) |
| Vascular Catheter-Associated Infection | 999.31 (CC) |
| Manifestations of Poor Glycemic Control | 250.10-250.13 (MCC)<br>250.20-250.23 (MCC)<br>251.0 (CC)<br>249.10-249.11 (MCC)<br>249.20-249.21 (MCC) |
| **Surgical Site Infections** | |
| Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG) | 519.2 (MCC)<br>And one of the following procedure codes:<br>36.10–36.19 |

| | |
|---|---|
| Surgical Site Infection Following Certain Orthopedic Procedures | 996.67 (CC)<br>998.59 (CC)<br>And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85 |
| Surgical Site Infection Following Bariatric Surgery for Obesity | *Principal Diagnosis* – 278.01<br>998.59 (CC)<br>And one of the following procedure codes: 44.38, 44.39, or 44.95 |
| Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures | 415.11 (MCC)<br>415.19 (MCC)<br>453.40-453.42 (CC)<br>And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54 |

BILLING CODE 4120–01–C

We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS final rule (73 FR 48474 through 48486) for detailed analyses supporting the selection of each of the HACs selected through FY 2011.

3. RTI Program Evaluation Summary

a. Background

On September 30, 2009, a contract was awarded to Research Triangle Incorporated (RTI) to evaluate the impact of the Hospital-Acquired Condition-Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection.

RTI's evaluation of the HAC–POA provisions is divided into several parts. In the FY 2011 IPPS/LTCH PPS final rule (50085 through 50101), we summarized the analyses by RTI that had been completed at that time. These RTI analyses of POA indicator reporting, frequencies and net savings associated with current HACs, and frequencies of previously considered candidate HACs reflected MedPAR claims from October 2008 through September 2009.

b. FY 2009 Data Analysis

As we describe above, we have provided instructions to IPPS hospitals and non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims (75 FR 23381) and note that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* After publication of the FY 2011 IPPS/LTCH PPS final rule, we identified a discrepancy between the claims data that hospitals submitted and the CMS data file used to calculate the HAC measures. Specifically, this error led to incorrect HAC assignments in cases where a hospital reported an external cause of injury (E-code). Since then, we have corrected this error in the data file.

As a result, the RTI analysis of the HAC–POA program that was conducted using FY 2009 claims data will be updated using the corrected data file. We do not expect the corrected data to have a material impact on our previous findings for FY 2009. Revised data tables will be made publicly available on the CMS Web site at *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and the RTI Web site at *http://www.rti.org/reports/cms/* soon after publication of this proposed rule.

c. FY 2010 Data Analysis

RTIs analysis of the FY 2010 MedPAR data file for the HAC–POA program evaluation was not fully complete in time for publication in this proposed rule. We will provide the results from the study on the CMS Web site at *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and on the RTI Web site at *http://www.rti.org/reports/cms/* when available. We anticipate that the examination of FY 2010 MedPAR data will be completed soon after publication of this proposed rule. We invite public comment on RTI's analysis of the FY 2010 MedPAR data for the HAC–POA program.

*G. Proposed Changes to Specific MS–DRG Classifications*

In this proposed rule, we are inviting public comment on each of the MS–DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS–DRG classifications, which are also discussed below. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Noninvasive Mechanical Ventilation

We received a request from the National Association for Medical Direction of Respiratory Care (NAMDRC) which suggested that we

create a new MS–DRG for patients with certain respiratory conditions who receive noninvasive mechanical ventilation (NIV). The requestor stated that patients who receive NIV are almost always placed within an intensive care unit (ICU) or an emergency department and use the resources available in those areas. The requestor recommended that this new MS–DRG recognize current practice and allow for appropriate reimbursement for the technical complexity and monitoring required for NIV as a form of acute life support. According to the requestor, NIV has evolved to become first-line supportive therapy for several forms of acute respiratory failure. Lastly, the requestor recommended that the new MS–DRG identify NIV usage of approximately 6 to 12 hours to account for the "legitimate but very short term use of this therapy."

Historically, the concept of mechanical ventilation for critically ill patients included establishment of an artificial airway, invasively, through endotracheal intubation or a tracheostomy. According to the requestor, a significant portion of these patients can now be treated through noninvasive mechanical ventilation with the use of a face or nasal mask. In the ICD–9–CM classification system, NIV is described by procedure code 93.90 (Noninvasive mechanical ventilation), while invasive mechanical ventilation is described by procedure codes 96.70 (Continuous invasive mechanical ventilation of unspecified duration), 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours), and 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). The requestor submitted external data to illustrate trends in NIV use over the past decade. These data were derived from a survey conducted during 2002–2003 of several hospitals located in Massachusetts and Rhode Island. The requestor believed that these data indicate patients with exacerbation of chronic obstructive pulmonary disease (COPD), acute pulmonary edema, or worsening congestive heart failure are successfully managed with NIV.

We analyzed FY 2010 MedPAR claims data that are representative of the respiratory conditions the requestor identified when reported with NIV. We found 14 MS–DRGs reporting procedure code 93.90 using the above specifications. The MS–DRGs are as follows:

Pre-MDC MS–DRGs:

- MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck with Major O.R.)
- MS–DRG 004 (Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck without Major O.R.) MS–DRGs:
- MS–DRG 189 (Pulmonary Edema & Respiratory Failure)
- MS–DRG 190 (Chronic Obstructive Pulmonary Disease with MCC)
- MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC)
- MS–DRG 192 (Chronic Obstructive Pulmonary Disease without CC/MCC)
- MS–DRG 204 (Respiratory Signs & Symptoms)
- MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours)
- MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours)
- MS–DRG 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC)
- MS–DRG 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC)
- MS–DRG 291 (Heart Failure & Shock with MCC)
- MS–DRG 292 (Heart Failure & Shock with CC)
- MS–DRG 293 (Heart Failure & Shock without CC/MCC)

As shown in the list above and in the chart below, the MS–DRGs identified also include those that describe invasive mechanical ventilation. The ICD–9–CM coding convention instructs the reporting of both types of mechanical ventilation when patients are admitted on noninvasive mechanical ventilation that subsequently requires invasive mechanical ventilation therapy.

The data demonstrate that, in certain MS–DRGs, for example, MS–DRGs 003, 004, and 222 that the cases with NIV primarily have shorter lengths of stay and lower average costs compared to all the cases in those MS–DRGs. Alternatively, the data for MS–DRGs 189, 190, 191, and 192 demonstrate that the cases with NIV have an increased length of stay and higher average costs, but a relatively low volume compared to all the cases in those MS–DRGs. Combining the current surgical and medical MS–DRGs into a single, new MS–DRG would include noninvasive mechanical ventilation cases with a wide range of costs for several indications with varying levels of severity. The average costs for these cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. We believe the cases are more appropriately assigned and reimbursed in the MS–DRGs to which they are currently assigned.

BILLING CODE 4120–01–P

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 003 – All cases | 18,223 | 34.7 | $103,492 |
| MS-DRG 003 - Cases with code 93.90 without code 96.70, 96.71, or 96.72 | 58 | 33.3 | $95,940 |
| MS-DRG 004 – All cases | 19,599 | 25.79 | $63,022 |
| MS-DRG 004 – Cases with code 93.90 without code 96.70, 96.71, or 96.72 | 170 | 25.43 | $58,500 |
| MS-DRG 189 – All cases | 87,668 | 5.36 | $8,317 |
| MS-DRG 189 – Cases with code 93.90 without code 96.70, 96.71, or 96.72 | 22,023 | 6.07 | $10,383 |
| MS-DRG 190 – All cases | 130,731 | 5.30 | $7,140 |
| MS-DRG 190 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 8,450 | 6.78 | $11,207 |
| MS-DRG 191 – All cases | 135,851 | 4.49 | $6,236 |
| MS-DRG 191 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 4,563 | 5.41 | $8,819 |
| MS-DRG 192 – All cases | 115,153 | 3.52 | $4,621 |
| MS-DRG 192 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 2,334 | 4.25 | $6,803 |
| MS-DRG 204 – All cases | 21,049 | 2.61 | $4,310 |
| MS-DRG 204 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 265 | 4.17 | $7,591 |
| MS-DRG 207 – All cases | 32,752 | 14.61 | $32,897 |
| MS-DRG 207 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 0 | 0 | 0 |
| MS-DRG 208 – All cases | 67,724 | 6.98 | $14,742 |
| MS-DRG 208 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 0 | 0 | 0 |
| MS-DRG 222 – All cases | 2,279 | 11.98 | $57,478 |
| MS-DRG 222 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 52 | 11.79 | $55,011 |
| MS-DRG 223 – All cases | 3,230 | 6.17 | $41,754 |
| MS-DRG 223 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 19 | 11.05 | $47,064 |
| MS-DRG 291 – All cases | 170,399 | 6.05 | $9,585 |
| MS-DRG 291 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 14,274 | 6.95 | $12,320 |
| MS-DRG 292 – All cases | 220,031 | 4.72 | $6,584 |
| MS-DRG 292 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 5,171 | 5.58 | $9,180 |
| MS-DRG 293 – All cases | 98,134 | 3.20 | $4,410 |
| MS-DRG 293 – Cases with code 93.90 without code 96.70, 96.71 or 96.72 | 1,381 | 3.43 | $5,794 |

BILLING CODE 4120–01–C

As mentioned in the requestor's comments, and our clinical advisors agree, NIV encompasses a broad range of interventions and utilizes periods of time that range from a few hours to a few days of continuous chronic use. Resource requirements are vastly different for the various intended indications. For example, as also noted by the requestor, respiratory failure can have many forms. Our clinical advisors provided three subsets of patients as an example: Those that are given oxygen support, those that are given pressure (rate) support, and those that are intubated. There is overlap between the three subsets in that a patient may require one, two, or all three types of therapy and there are multiple options for any given patient. Our clinical advisors stated that these various subsets of patients can require significantly different resources. Lastly, respiratory failure reflects the severity of the diagnosis (it is a complication) while NIV is a therapeutic option. Unlike a major surgical intervention where the intervention creates morbidity, NIV merely reflects the severity of the underlying respiratory failure.

The requestor further noted in its comments that a significant number of patients who receive NIV fail this therapy and must be intubated and subsequently placed on a ventilator. However, those patients who require both noninvasive and invasive mechanical ventilation are already accounted for in the invasive mechanical ventilation MS–DRGs. Similar to patients with respiratory failure, patients with heart failure and shock have a comparable severity of illness where each condition reflects the severity of the diagnosis (it is a complication). Therefore, the cost is already reflected in the high resource expenditure estimates for MS–DRGs 222, 223, 291, 292, and 293, as are all other severity-correlated resource costs.

In conclusion, we believe that the data do not support the creation of a single MS–DRG to identify NIV cases. As stated previously, the average costs for the NIV cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. If created, this single MS–DRG would include patients with a wide range in average costs. We believe the cases are more appropriately captured in their current MS–DRGs. In addition to the clinical points raised by our clinical advisors and outlined above, the volume and length of stay data for cases where NIV was reported with the specified respiratory conditions further support their present MS–DRG assignments. Therefore, we are not proposing to create a new MS–DRG for patients receiving NIV. We invite public comment on our proposal not to create a new MS–DRG for patients receiving NIV for FY 2012.

b. Debridement With Mechanical Ventilation Greater Than 96 Hours With Major Operating Room (O.R.) Procedure

We received a comment concerning the use of excisional debridement in cases with complications that lead to the need for extended mechanical ventilation. The commenter stated that patients undergoing procedures such as excisional debridement may also develop extensive complications such as respiratory failure and sepsis. The commenter indicated that these patients tend to use significant resources. The commenter stated that these cases are currently assigned to MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) or MS–DRG 870 (Septicemia with or Severe Sepsis with Mechanical Ventilation 96+ Hours). The commenter expressed a concern that the operating room (OR) procedure of the excisional debridement was not fully recognized through either of these two medical MS–DRGs. The commenter requested that a new MS–DRG be created that would include mechanical ventilation of greater than 96 hours with the presence of an additional major OR procedure.

We agree that patients with long-term mechanical ventilation greater than 96 hours and a major OR procedure utilize extensive resources. However, we point out that these patient cases are not currently assigned to MS–DRG 207 or MS–DRG 870 as the commenter stated. Many of these long-term mechanical ventilation patient cases are instead assigned to MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or PDX, Excluding Face, Mouth & Neck with Major Operating Room Procedure). Cases that require mechanical ventilation for greater than 96 hours, that have a tracheostomy performed, and that have a procedure on the major O.R. list (including excisional debridement) are assigned to MS–DRG 003. We specifically created MS–DRG 003 to capture these complicated patients on long-term mechanical ventilation who also have a major O.R. procedure. Therefore, we are not proposing to create a second MS–DRG to capture these patients at this time. We welcome public comments on our proposal not to create a new MS–DRG for these patients for FY 2012.

c. Autologous Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), effective October 1, 2011, we deleted MS–DRG 009 (Bone Marrow Transplant) and created two new MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 015 (Autologous Bone Marrow Transplant). We created new MS–DRGs 014 and 015 because of differences in costs associated with these procedures. During the comment period for the FY 2011 IPPS/LTCH PPS proposed rule, two commenters who supported the proposed reclassification of the bone marrow transplant MS–DRGs requested further refinement to account for severity of illness. At that time, we did not subdivide MS–DRG 014 and MS–DRG 015 based on severity of illness because they did not meet our criteria for subdivision (75 FR 50102).

As we outlined in our FY 2008 IPPS/LTCH PPS final rule with comment period (72 FR 47169), in designating an MS–DRG as one that would be subdivided into subgroups based on the presence of a CC or an MCC, we developed a set of criteria to facilitate our decision-making process. The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule, 71 FR 47882). In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

- A reduction in variance of cost of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average cost between subgroups.
- There is a $2,000 difference in average cost between subgroups.

We examined FY 2010 MedPAR claims data for these newly created MS–DRGs, and based on these criteria, we identified MS–DRG 015 as a possible MS–DRG that would require further subdivision. MS–DRG 014 was not identified, as this MS–DRG did not meet the criteria stated above for possible subdivision. Autologous bone marrow transplantation utilizes the patient's own bone marrow or stem cells in the treatment of certain cancers and bone marrow diseases. These procedures restore stem cells that have been destroyed either by chemotherapy and/or radiation treatment.

In our analysis, we found 1,338 total cases assigned to MS–DRG 015 with average costs of approximately $38,608

and an average length of stay of approximately 18.8 days. There were 1,092 cases that had a secondary diagnosis code reported on the claim that was designated as a CC or an MCC with average costs of approximately $40,974 and an average length of stay of approximately 19.7 days. There were 246 cases without a secondary diagnosis code reported on the claim that had a CC or an MCC designation with average cost of approximately $28,105 and an average length of stay of approximately 14.6 days. The following table illustrates our findings:

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 015 - All cases | 1,338 | 18.8 | $38,608 |
| MS-DRG 015 - Cases with MCC/CC | 1,092 | 19.7 | $40,974 |
| MS-DRG 015 - Cases without MCC/CC | 246 | 14.6 | $28,105 |

We found that the cases reported with a secondary diagnosis code of a CC or an MCC were more costly and had a longer average length of stay than both the overall cases assigned to MS–DRG 015 and the cases without a CC or an MCC. The cases without a CC or an MCC were less costly and had a shorter average length of stay than both the cases with a CC or an MCC and the overall cases assigned to that MS–DRG. Based on our analysis, all five criteria for a subgroup division were met, thereby supporting a 2-level severity split for MS–DRG 015. Therefore, we are proposing to delete MS–DRG 015 and create two new MS–DRGs:

- Proposed MS–DRG 016 (Autologous Bone Marrow Transplant with MCC/CC); and
- Proposed MS–DRG 017 (Autologous Bone Marrow Transplant without MCC/CC).

We invite public comment on our proposal to delete MS–DRG 015 and create two new MS–DRGs 016 and 017 for autologous bone marrow transplant for FY 2012.

2. MDC 1 (Diseases and Disorders of the Nervous System): Rechargeable Dual Array Deep Brain Stimulation System

We received a public comment in response to the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for rechargeable dual array deep brain neurostimulators. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128), we indicated that we considered this comment outside of the scope of the proposed rule as we did not propose any changes for these procedures for FY 2011. However, we are addressing this issue in this FY 2012 proposed rule.

Deep brain stimulation is a surgical treatment that involves the implantation of a neurostimulator, used in the treatment of essential tremor, Parkinson's disease, dystonia, and chronic pain. The commenter recommended that CMS assign the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, procedure code 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and procedure code 86.98 (Insertion or replacement of dual array rechargeable neurostimulator pulse generator) to MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant) and MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC).

The commenter stated that this recommendation would allow all full system dual array deep brain stimulation cases to be appropriately grouped to the same MS–DRGs. Currently, procedure codes 02.93 and 86.98 are assigned to MS–DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), MS–DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and MS–DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC), while the procedure codes for the nonrechargeable dual array systems, procedure codes 02.93 and 86.95 (Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable), are already assigned to MS–DRGs 023 and 024. The commenter stated that the procedures to implant the rechargeable and nonrechargeable dual array systems are similar clinically as well as comparable in resource utilization.

We analyzed FY 2010 MedPAR data and found a total of 16 full system rechargeable dual array deep brain stimulation systems reported with procedure codes 02.93 and 86.98 assigned to MS–DRGs 025 through 027. We found one case assigned to MS–DRG 025 and one case assigned to MS–DRG 026. The majority of the cases, 14, were assigned to MS–DRG 027, with average costs of approximately $23,870 and an average length of stay of approximately 2.2 days. We found that the deep brain stimulation cases assigned to MS–DRG 027 had higher average costs than the overall cases assigned to MS–DRG 027 of approximately $14,200. However, the average length of stay was shorter for these cases than the overall length of stay for MS–DRG 027 cases of approximately 3.7 days.

We also examined the data for the nonrechargeable dual array systems to assess the commenter's assumption that both the rechargeable and nonrechargeable dual array systems are similar in resource use. We found 155 total nonrechargeable dual array systems (procedure codes 02.93 and 86.95) assigned to MS–DRGs 023 and 024. There were 5 cases assigned to MS–DRG 023, with average costs of approximately $36,159 and an average length of stay of approximately 10 days. We found that the majority of the cases, 150, were assigned to MS–DRG 024, with average costs of approximately $25,855 and an average length of stay of approximately 2.2 days. We believe that these data support the commenter's statement that, for the majority of these cases, the resource use is similar for both systems.

For comparison purposes, if we propose the changes that the commenter suggested, those deep brain stimulation cases currently assigned to MS–DRG 027 and the one case assigned to MS–DRG 026 (with average costs of approximately $27,836) would be reassigned to MS–DRG 024. The average costs of approximately $23,870 of these deep brain stimulation cases assigned to MS–DRG 027 are similar to the overall average costs of approximately $23,249 for MS–DRG 024. The one case assigned to MS–DRG 025 (with average costs of approximately $29,361) would be reassigned to MS–DRG 023 (with average costs of approximately $34,168). The following table illustrates our findings:

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 023 - All cases | 4,238 | 11.8 | $34,168 |
| MS-DRG 023 - Cases with codes 02.93 and 86.95 | 5 | 10.0 | $36,159 |
| MS-DRG 024 - All cases | 1,592 | 7.6 | $23, 249 |
| MS-DRG 024 - Cases with codes 02.93 and 86.95 | 150 | 2.2 | $25,855 |
| MS-DRG 025 - All cases | 11,505 | 11.0 | $29,524 |
| MS-DRG 025 - Cases with codes 02.93 and 86.98 | 1 | 2.0 | $29, 361 |
| MS-DRG 026 - All cases | 9,782 | 7.0 | $19,125 |
| MS-DRG 026 - Cases with codes 02.93 and 86.98 | 1 | 3.0 | $27,836 |
| MS-DRG 027 - All cases | 10,936 | 3.7 | $14,200 |
| MS-DRG 027 - Cases with codes 02.93 and 86.98 | 14 | 2.2 | $23,870 |

Based on our findings, we believe that the data support reassigning the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, code 02.93 and code 86.98, to MS–DRGs 023 and 024. Our clinical advisors support this reassignment. Therefore, we are proposing to assign rechargeable dual array systems for deep brain stimulation cases identified by reporting both procedure codes 02.93 and 86.98 to MS–DRGs 023 and 024 for FY 2012. We invite public comment on our proposal to assign these cases to MS–DRG 023 and 024 for FY 2012.

3. MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth, and Throat): Skull Based Surgeries

We received a request from a commenter recommending that CMS reclassify skull-based surgical procedures that are currently assigned to MS–DRGs 135 and 136 (Sinus and Mastoid Procedures with CC/MCC and without CC/MCC, respectively) and reassign them to MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter stated that the current MS–DRG assignment does not reflect the resource utilization and technical complexity of these difficult procedures when performed for anterior skull base tumors.

Skull (or cranial) based surgery is performed for a variety of serious medical conditions including esthesioneuroblastomas, which are rare, malignant tumors that arise from the epithelium overlying the olfactory bulb; sinonasal melanomas, which are malignant melanomas that may develop in the mucosa of the nose and sinuses; and sinonasal undifferentiated carcinomas, which are rapidly growing malignant tumors arising in the nasal cavity and/or sinuses. These types of conditions are generally identified by the following ICD–9–CM diagnosis codes:

- 160.0 (Malignant neoplasm of nasal cavities)
- 160.1 (Malignant neoplasm of auditory tube, middle ear, and mastoid air cells)
- 160.2 (Malignant neoplasm of maxillary sinus)
- 160.3 (Malignant neoplasm of ethmoidal sinus)
- 160.4 (Malignant neoplasm of frontal sinus)
- 160.5 (Malignant neoplasm of sphenoidal sinus)
- 160.8 (Malignant neoplasm of other accessory sinuses)
- 160.9 (Malignant neoplasm of accessory sinus, unspecified)
- 210.7 (Benign neoplasm of nasopharynx)
- 212.0 (Benign neoplasm of nasal cavities, middle ear, and accessory sinuses)

According to the commenter, procedure code 22.63 (Ethmoidectomy) describes the type of surgery being performed for these patients and is currently assigned to MS–DRGs 135 and 136.

Using the FY 2010 MedPAR file, we examined data on cases identified by procedure code 22.63 when reported with one of the above listed diagnosis codes in MS–DRGs 135 and 136. We found a total of 402 cases in MS–DRG 135 with an average length of stay of 6.30 days and average costs of $12,869. We found only 23 cases in MS–DRG 135 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 3.96 days and average costs of $10,510. In MS–DRG 136, there were a total of 320 cases with an average length of stay of 2.36 days and average costs of $6,683. We found only 27 cases in MS–DRG 136 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 2.04 days and average costs of $6,844. As shown in the table below, the cases reporting procedure code 22.63 in MS–DRGs 135 and 136 have a lower volume, a shorter length of stay, and primarily lower average costs compared to all cases in MS–DRGs 135 and 136. The data demonstrate that these cases are appropriately assigned to their current MS–DRG classifications.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 135 - All cases | 402 | 6.30 | $12,869 |
| MS-DRG 135 -Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0 | 23 | 3.96 | $10,510 |
| MS-DRG 136 -All cases | 320 | 2.36 | $6,683 |
| MS-DRG 136 - Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0 | 27 | 2.04 | $6,844 |

We also analyzed claims data for MS–DRGs 25 through 27. We determined that if the cases identified by procedure code 22.63 were to be reassigned to MS–DRGs 25–27, they would be significantly overpaid. As shown in the table below, we found that the average costs for these MS–DRGs range from $14,200 to $29,524.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 025 - All cases | 11,505 | 10.95 | $29,524 |
| MS-DRG 026 - All cases | 9,782 | 7.00 | $19,125 |
| MS-DRG 027 - All cases | 10,936 | 3.71 | $14,200 |

In summary, the data do not support moving cases with procedure code 22.63 when reported with one of the previously listed diagnosis codes from MS–DRGs 135 and 136 to MS–DRGs 25, 26 and 27. We invite public comment on our proposal not to make any MS–DRG modifications for these codes for FY 2012.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair With Implant

Procedure code 35.97 (Percutaneous mitral valve repair with implant) was created for use beginning October 1, 2010 (FY 2011) after the concept of a percutaneous valve repair was presented and approved at the February 2010 ICD–9–CM Coordination and Maintenance Committee Meeting. Procedure code 35.97 was created at that time to describe the MitraClip™ device and any other percutaneous mitral valve repair devices currently on the market. This procedure code is assigned to the following MS–DRGs: 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC); and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC).

According to the Food and Drug Administration's (FDA's) terms of the clinical trial for MitraClip™, the device is to be implanted in patients without any additional surgeries performed. Therefore, based on these terms, we believe that the most likely MS–DRG assignments would be MS–DRGs 250 and 251, as described above. However, because procedure code 35.97 has only been in use since October 1, 2010, there are no claims data in the most recent MedPAR update file with which to evaluate any alternative MS–DRG assignments. Therefore, we are not proposing to make any MS–DRG changes for procedure code 35.97 for FY 2012. We are proposing to keep procedure code 35.97 in its current MS–DRG assignments. We invite public comment on this proposal.

b. Aneurysm Repair Procedure Codes

Thoracic aorta defects, such as aneurysm, dissection, or injury, are uncommon but serious conditions that may arise from a disease or an accident. Some patients can be medically managed but most patients are treated with surgery. Often these defects result in death if they are not diagnosed and treated promptly. Currently, there are two techniques used for repair of aortic defects; both are O.R. procedures performed in an inpatient hospital setting. These two procedures are described by ICD–9–CM procedure codes 38.45 (Resection of vessel with replacement, thoracic vessel) and 39.73 (Endovascular implantation of graft in thoracic aorta). Both procedure codes 38.45 and 39.73 are currently assigned to MS–DRGs 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) and 238 (Major Cardiovascular Procedures without MCC).

We received a request that we consider the reassignment of procedure codes 38.45 and 39.73 within the MS–DRG structure by removing the procedure codes from MS–DRGs 237 and 238 and adding them to a more clinically coherent set of MS–DRGs reflecting higher resource consumption. The requestors believed that, based on their analysis of MedPAR claims data of

MS–DRGs 237 and 238, the resource utilization of both the endovascular and open repairs of the abdominal and thoracic aortas are higher than the overall average resource utilization for the MS–DRGs to which these procedures are currently assigned. The requestors also believed that an unusually high number of cases probably fall into cost outlier status.

We reviewed the MedPAR claims data for these two procedure codes. Our findings are shown in the following two tables.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 237 - All cases | 20,680 | 10.03 | $34,268 |
| MS-DRG 237 - Cases with procedure code 39.73 | 1,851 | 7.73 | $41,033 |
| MS-DRG 237 - Cases without procedure code 39.73 | 18,829 | 10.26 | $33,603 |
| MS-DRG 238 - All cases | 35,705 | 4.08 | $20,597 |
| MS-DRG 238 - Cases with procedure code 39.73 | 0 | 0 | 0 |
| MS-DRG 238 - Cases without procedure code 39.73 | 35,705 | 4.08 | $20,597 |

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 237 - All cases | 20,680 | 10.03 | $34,268 |
| MS-DRG 237 - Cases with procedure code 38.45 | 448 | 13.29 | $51,953 |
| MS-DRG 237 - Cases without procedure code 38.45 | 20,234 | 9.96 | $33,878 |
| MS-DRG 238 - All cases | 35,705 | 4.08 | $20,597 |
| MS-DRG 238 - Cases with procedure code 38.45 | 466 | 7.29 | $30,219 |
| MS-DRG 238 - Cases without procedure code 38.45 | 35,239 | 4.03 | $20,465 |

Our findings of the analysis of the cases with procedure code 39.73 showed that the average costs are substantially higher than those costs for the cases overall in both MS–DRGs 237 and 238. We found that the average length of stay for the 1,851 cases identified in MS–DRG 237 is somewhat lower at 7.73 days than the average length of stay of 10.26 days in cases not containing procedure code 39.73.

Our findings of the analysis of the cases with procedure code 38.45 showed that both the average costs and the average length of stay are considerably higher than the average costs and the average length of stay for those cases without procedure code 38.45.

In addition, we reviewed the cases in which both procedure codes 38.45 and 39.73 were documented during the same admission. As can be seen in the charts below, we found 22 cases in which both procedure codes 38.45 and 39.73 were reported. Therefore, the sum of the values in the next two charts below will differ from the charts above because of the cases containing both procedure codes that have been removed and the data have been reworked.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 237 - All cases | 20,680 | 10.03 | $34,268 |
| MS-DRG 237 - Cases with procedure code 39.73 and without procedure code 38.45 | 1,829 | 7.68 | $40,862 |
| MS-DRG 237 - Cases with procedure code 38.45 and without procedure code 39.73 | 424 | 13.36 | $51,783 |
| MS-DRG 238 - All cases | 35,705 | 4.08 | $20,597 |
| MS-DRG 238 - Cases with procedure code 39.73 and without procedure code 38.45 | 0 | 0 | 0 |
| MS-DRG 238 - Cases with procedure code 38.45 and without procedure code 39.73 | 466 | 7.29 | $30,219 |

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 237 - All cases | 20,680 | 10.03 | $34,268 |
| MS-DRG 237 - Cases with procedure code 38.45 and with procedure code 39.73 | 22 | 11.86 | $55,243 |
| MS-DRG 237 - Cases without procedure code 38.45 or procedure code 39.73 | 18,405 | 10.19 | $33,184 |
| MS-DRG 238 - All cases | 35,705 | 4.08 | $20,597 |
| MS-DRG 238 - Cases with procedure code 38.45 and with procedure code 39.73 | 0 | 0 | 0 |
| MS-DRG 238 - Cases without procedure code 38.45 or procedure code 39.73 | 35,239 | 4.03 | $20,465 |

We found in our analysis of the claims data for cases with both procedure codes 38.45 and 39.73 that the average costs are substantially higher than those costs for the cases overall in MS–DRG 237. In addition, we found that the average length of stay for the 22 cases with both procedure codes 38.45 and 39.73 is higher at 11.86 days than the average length of stay of 10.03 days for all cases in MS–DRG 237.

Our analysis of the claims data for the procedure codes in MDC 5 showed that procedure code 34.85 is also assigned to MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), and 230 (Other Cardiothoracic Procedures without CC/MCC) when it occurs in combination with procedure code 38.44 (Resection of vessel with replacement, aorta, abdominal). We found that when procedure code 39.73 is not assigned to MS–DRGs 228 through 230, there are no cases reported.

The table below shows our findings of the average costs and the average length of stay for procedure code 38.45 in combination with procedure code 38.44 in MS–DRGs 228 through 230 and the average costs and the average length of stay in all cases in MS–DRGs 228 through 230 when both procedure codes 38.45 and 38.44 are not assigned.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 228 - All cases | 2,084 | 13.79 | $49,488 |
| MS-DRG 228 - Cases with procedure code 38.45 and procedure code 38.44 | 276 | 15.18 | $56,246 |
| MS-DRG 228 - Cases without procedure code 38.45 and without procedure code 38.44 | 1,808 | 13.58 | $48,456 |
| MS-DRG 229 - All cases | 2,354 | 8.31 | $31,148 |
| MS-DRG 229 - Cases with procedure code 38.45 and procedure code 38.44 | 157 | 10.68 | $37,723 |
| MS-DRG 229 - Cases without procedure code 38.45 and without procedure code 38.44 | 2,197 | 8.14 | $30,678 |
| MS-DRG 230 - All cases | 628 | 5.45 | $24,236 |
| MS-DRG-230 - Cases with procedure code 38.45 and procedure code 38.44 | 34 | 7.18 | $27,054 |
| MS-DRG 230 - Cases without procedure code 38.45 and without procedure code 38.44 | 594 | 5.35 | $24,075 |

Our findings show that both the average length of stay and average costs are higher in those cases containing procedure code 34.85 than those cases without this procedure code in MS–DRGs 228 through 230.

We then analyzed the 1,851 cases containing procedure code 39.73 in MS–DRGs 237 and 238 and the 912 cases containing procedure code 38.45 in MS–DRGs 237 and 238 to determine if they would meet the established criteria for a 3-way severity of illness split. This criterion is described in section III.G.1.c. of this preamble. The chart below shows our findings, with MS–DRG 237 acting as a severity of illness proxy for all cases, as there were no cases in MS–DRG 238. In the chart, the extensions "–1," "–2," and "–3" correspond to severity levels, with "–1" representing cases with MCC, "–2" representing cases with CC, and "–3" representing cases without CC/MCC.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 237-1 - All cases | 20,680 | 10.03 | $34,268 |
| MS-DRG 237-1 - Cases with procedure code 39.73 | 637 | 12.14 | $57,834 |
| MS-DRG 237-1 - Cases with procedure code 38.45 | 446 | 13.29 | $51,954 |
| MS-DRG 237-2 - All cases | 17,356 | 5.73 | $22,083 |
| MS-DRG 237-2 - Cases with procedure code 39.73 | 659 | 6.89 | $38,673 |
| MS-DRG 237-2 - Cases with procedure code 38.45 | 353 | 8.14 | $31,480 |
| MS-DRG 237-3 - All cases | 18,349 | 2.52 | $19,183 |
| MS-DRG 237-3 - Cases with procedure code 39.73 | 555 | 3.65 | $27,993 |
| MS-DRG 237-3 - Cases with procedure code 38.45 | 113 | 6.30 | $26,280 |

Our next step was to analyze the claims data for the cases in the clinically coherent MS–DRGs to which we are proposing to move these cases. These six MS–DRGs are: 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC); 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC); 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC); 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC); and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). For the sake of the grouping algorithm, procedure codes 39.73 and 38.45 must also be added to MS–DRGs 216 through 219. However, if these codes are documented in cases in which a cardiac catheterization occurs, they will be "trumped" by those catheterizations. Therefore, when we reviewed the data in order to make length of stay and cost comparisons, we only used the three MS–DRGs to which procedure codes 39.73 and 38.45 would appear without cardiac catheterization; that is MS–DRGs 219, 220, and 221. Our findings describing these three MS–DRGs are displayed in the following chart:

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 219 | 12,805 | 12.76 | $51,399 |
| MS-DRG 220 | 15,988 | 7.65 | $34,270 |
| MS-DRG 221 | 4,043 | 5.90 | $28,974 |

Our evaluation of the severity levels in the cases containing procedure codes 39.73 and 38.45 using the proxy MS–DRGs 237–1, 237–2, and 237–3 compared to the claims data in the table above with MS–DRGs 219 through 221 demonstrates that the cases are similar in resource consumption. In addition, the cases are clinically coherent.

By proposing to move procedure code 38.45 to MS–DRGs 216 through 221, we do not believe that there is a need for combination codes 38.45 plus 38.44 to be specifically assigned to MS–DRGs 228, 229, and 230. Because MS–DRGs 216 through 221 are higher in the surgical hierarchy for MDC 5 than MS–DRGs 228 through 230, the result of the proposal would be that either procedure code 38.45 by itself or in combination with procedure code 38.44 will always be assigned to MS–DRGs 216 through 221. When reported alone, under our proposal, procedure code 38.44 would continue to be assigned to MS–DRGs 237 and 238, as it has been in the past.

Therefore, for FY 2012, we are proposing to move procedure codes 38.45 and 39.73 from MS–DRGs 237 and 238 and to add these codes to MS–DRGs 216, 217, 218, 219, 220, and 221 based on our findings of similar resource consumption and clinical coherence. To conform to this proposed change, we also are proposing to change the title of MS–DRG 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) by removing the terms "or Thoracic Aortic Aneurysm Repair." Therefore, the new proposed title of MS–DRG 237 would be "Major Cardiovascular Procedures with MCC." We invite public comment on these proposals.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Artificial Discs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received a public comment that was outside of the scope of any proposal in that proposed rule. The commenter urged CMS to reassign procedure code 84.62 (Insertion of total spinal disc prosthesis, cervical) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) into MS–DRGs 471 through 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). In addition, the commenter requested that CMS reassign procedure code 84.65 (Insertion of total spinal disc prosthesis, lumbosacral) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) to MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively). However, the commenter also provided an alternative option to reassigning the procedure codes to different MS–DRGs. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible.

We refer the reader to the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24731 through 24735 and 47226 through 47232) for discussion on the comprehensive evaluation of all the spinal DRGs in the development of the MS–DRG classification system. The modifications made to the spinal DRGs for FY 2008 recognized the similar utilization of resources, differences in levels of severity, and the complexity of the services being performed on patients undergoing the various types of spinal procedures.

We analyzed FY 2010 MedPAR claims data for procedure codes 84.62 and 84.65 in MS–DRG 490 and compared those results to the claims data for MS–DRGs 459, 460, 471, 472, and 473. We found a total of 19,840 cases in MS–DRG 490 with an average length of stay of 4.24 days and average costs of $11,940. As displayed in the chart below, we found 97 cases reporting procedure code 84.62, with an average length of stay of 1.80 days and average costs of $13,194 in MS–DRG 490. We also found 35 cases reporting procedure code 84.65, with an average length of stay of 2.91 days and average costs of $20,753. While average costs for the artificial disc cases were slightly higher ($1,254 for procedure code 84.62 and $8,813 for procedure code 84.65) compared to the average cost for all cases in MS–DRG 490, the artificial disc cases were of extremely low volume and reflected shorter lengths of stay compared to all the cases in MS–DRG 490.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 459 – All cases | 3,650 | 8.92 | $40,218 |
| MS-DRG 460 – All cases | 60,865 | 3.75 | $25,268 |
| MS-DRG 471– All cases | 2,686 | 8.92 | $29,837 |
| MS-DRG 472– All cases | 8,586 | 3.78 | $18,494 |
| MS-DRG 473– All cases | 24,323 | 1.80 | $13,775 |
| MS-DRG 490 – All cases | 19,840 | 4.24 | $11,940 |
| MS-DRG 490 – Cases with code 84.62 | 97 | 1.80 | $13,194 |
| MS-DRG 490 – Cases with code 84.65 | 35 | 2.91 | $20,753 |

We recognize the disparity in average costs for cases reporting the insertion of a cervical or lumbar artificial disc in MS–DRG 490 compared to all the cases in that MS–DRG. However, we do not believe this supports reassignment of procedure codes 84.62 and 84.65 to the MS–DRGs for spinal fusion as the commenter requested. Even with the disparity in costs, clinically, the insertion of an artificial disc is not a spinal fusion. Therefore, reassignment of the artificial disc cases to the fusion MS–DRGs would be clinically inappropriate. In addition, for certain Medicare populations, the insertion of an artificial disc is considered a noncovered procedure.

As stated earlier, the commenter also provided an alternative option to reassigning procedure codes 84.62 and 84.65. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible. In our evaluation of the claims data and as shown above in the data chart, the artificial disc cases are of extremely low volume; therefore, we do not believe the findings warrant the creation of a separate MS–DRG.

We invite public comment on our proposal not to reassign procedure code 84.62 from MS–DRG 490 to MS–DRGs 471 through 473 and procedure code 84.65 from MS–DRG 490 to MS–DRGs 459 and 460. We also invite public comment on our proposal not to create a new, separate MS–DRG for artificial disc procedures (codes 84.62 and 84.65) for FY 2012.

b. Major Joint Replacement or Reattachment of Lower Extremities

We received a request to add an additional severity level for MS–DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) and MS–DRG 470 Major Joint Replacement or Reattachment of Lower Extremity without MCC). We examined FY 2010 MedPAR claims data to determine if we could subdivide the base MS–DRG into three severity levels: With MCC, with CC, and without CC/MCC. We applied the criteria used in the development of the MS–DRGs included in the FY 2008 IPPS final rule with comment period (72 FR 47169). We refer readers to this final rule with comment period for a complete description of these criteria. As discussed earlier, the original criteria were based on average charges. However, subsequent to the FY 2007 IPPS final rule (71 FR 47882), we now use average costs. The five criteria using costs are listed below. In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups

The following table shows our determination of the number of cases and average costs by MCC, CC, and non-CC levels.

| MS-DRGs 469 and 470 | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| Cases with MCC | 25,717 | 7.72 | $21,016 |
| Cases with CC | 179,116 | 3.99 | $14,233 |
| Cases without CC/MCC | 220,739 | 3.21 | $13,250 |
| Total | 425,572 | 3.8 | $14,133 |

We determined that these cases do not meet our five criteria for adding a new severity level. The cases failed to meet criterion four (requiring at least a 20-percent difference in average costs between subgroups) and criterion five (requiring a $2,000 difference in average costs between subgroups). Therefore, we are not proposing the addition of a new severity level for the base MS–DRG. Instead, we are proposing to maintain the two existing severity levels for MS–DRGs 469 and 470. We welcome public comments on our proposal not to add an additional severity level to MS–DRGs 469 and 470.

c. Combined Anterior/Posterior Spinal Fusion

A manufacturer requested that CMS reassign spinal fusion cases utilizing the AxiaLIF technology from MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively) to MS–DRGs 453, 454, and

455 (Combined Anterior/Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). The commenter stated that an anterior lumbar interbody spinal fusion performed with a lateral approach, the extreme lateral interbody fusion (XLIF®), with posterior spinal fixation, can report two codes resulting in assignment to the combined fusion MS–DRGs. The commenter also stated that the AxiaLIF technology, which is also utilized in an anterior lumbar interbody spinal fusion and uses a pre-sacral approach, can only report one code, resulting in assignment to the single fusion MS–DRGs. The commenter expressed concern that the payment incentives are not properly aligned for the recently available minimally invasive spinal fusion technologies. The commenter compared the XLIF® to the AxiaLIF and urged CMS to consider the AxiaLIF technology similar to the XLIF® for purposes of MS–DRG assignment.

Spinal fusion is a surgical procedure that joins two or more vertebrae by the use of bone graft (or bone graft substitute), with the goal of maintaining alignment, providing stability, decreasing pain, and restoring the function of the spinal nerves. Routinely, a spinal fusion also utilizes internal fixation devices (instrumentation) to assist in stabilizing the spine. These fixation devices may include pedicle screws, cages, rods, or plates. Effective October 1, 2010, ICD–9–CM procedure code 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) describes the XLIF® procedure, and code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique) describes the AxiaLIF technology.

The spinal fusion codes and their corresponding MS–DRG assignment include the use of bone graft and internal fixation. The requestor's comment regarding the assignment of one procedure code for one technology versus assigning two procedure codes for another technology indicates that the commenter may not fully understand the MS–DRG GROUPER logic for spinal fusions. For example, if an anterior lumbar interbody fusion is performed and posterior spinal fixation (or instrumentation) is also utilized, this requires one code and results in a single fusion MS–DRG assignment. However, if a posterior spinal fusion (procedure code 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) was performed in addition to an anterior fusion, for example, the XLIF® procedure (procedure code 81.06), that scenario would necessitate the assignment of both codes, resulting in assignment to the combined spinal fusion MS–DRGs (453, 454, or 455). MS–DRGs 453, 454, and 455 were created to capture patients who have both an anterior and posterior fusion. We believe the requestor may have confused the terms "fixation" and "fusion" for MS–DRG assignment in its request.

We analyzed the FY 2010 MedPAR data to evaluate claims reporting procedure codes 81.06, 81.07, and 81.08 in MS–DRGs 456 through 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusions with MCC, with CC and without CC/MCC, respectively) and MS–DRGs 459 and 460. We found a total of 1,115 cases in MS–DRG 456, with an average length of stay of 13.14 days and average costs of $63,856. We found 278 cases reporting procedure code 81.08, with an average length of stay of 12.04 days and average costs of $56,585. Similar results can be seen for procedure code 81.08 in the remaining MS–DRGs as shown in the chart below in terms of volume, length of stay, and average cost. Clearly, the data demonstrate that the AxiaLIF technology (procedure code 81.08) is appropriately assigned to its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06).

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 456 – All cases | 1,115 | 13.14 | $63,856 |
| MS-DRG 456 – Cases with code 81.06 | 54 | 14.37 | $52,392 |
| MS-DRG 456 – Cases with code 81.07 | 22 | 12.32 | $46,828 |
| MS-DRG 456 – Cases with code 81.08 | 278 | 12.04 | $56,585 |
| MS-DRG 457 – All cases | 3,079 | 6.74 | $41,500 |
| MS-DRG 457 – Cases with code 81.06 | 119 | 6.42 | $36,468 |
| MS-DRG 457 – Cases with code 81.07 | 98 | 6.49 | $36,532 |
| MS-DRG 457 – Cases with code 81.08 | 1,194 | 5.73 | $35,272 |
| MS-DRG 458 – All cases | 1,389 | 3.91 | $32,946 |
| MS-DRG 458 – Cases with code 81.06 | 115 | 3.49 | $29,089 |
| MS-DRG 458 – Cases with code 81.07 | 76 | 3.16 | $30,551 |
| MS-DRG 458 – Cases with code 81.08 | 827 | 3.60 | $30,570 |
| MS-DRG 459 – All cases | 3,650 | 8.92 | $40,218 |
| MS-DRG 459 – Cases with code 81.06 | 164 | 9.12 | $40,150 |
| MS-DRG 459 – Cases with code 81.07 | 165 | 8.65 | $37,970 |
| MS-DRG 459 – Cases with code 81.08 | 2,468 | 8.25 | $38,010 |
| MS-DRG 460 – All cases | 60,865 | 3.75 | $25,268 |
| MS-DRG 460 – Cases with code 81.06 | 2,681 | 3.27 | $26,464 |
| MS-DRG 460 – Cases with code 81.07 | 3,709 | 3.67 | $23,334 |
| MS-DRG 460 – Cases with code 81.08 | 46,565 | 3.66 | $24,571 |

We also analyzed data for combinations of the spinal fusion codes that result in assignment to MS–DRGs 453, 454, and 455. We evaluated the following combinations:

- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique).
- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

We further analyzed data with the following combination of spinal fusion codes in MS–DRGs 456, 457, and 458 and MS–DRGs 459 and 460:

- 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

The chart below shows the results of the data analysis for the combination of procedure codes listed above where an anterior and posterior spinal fusion was performed in the same episode of care. There were a total of 1,190 cases in MS–DRG 453, with an average length of stay of 13.08 days and average costs of $71,693. The cases reporting the combination of procedure codes 81.06 and 81.08 in this same MS–DRG totaled 431, with an average length of stay of 11.59 days and average costs of $69,859. Results for the procedure code combination (81.06 and 81.08) in MS–DRGs 454 and 455 with regard to volume of cases, length of stay, and average costs data also support that these spinal fusion procedure code combinations are appropriately placed in their current MS–DRG assignments. Likewise, for MS–DRGs 456, 457, and 458, the data support that the spinal fusion procedure code combinations of 81.07 and 81.08 are appropriately placed in their current MS–DRG assignments. There were a total of 1,115 cases in MS–DRG 456 with an average length of stay of 13.14 days and average costs of $68,856. The cases reporting the combination of procedure codes 81.07 and 81.08 in this same MS–DRG totaled 54, with an average length of stay of 14.37 days and average costs of $52,392. Results for the procedure code combination (81.07 and 81.08) in MS–DRGs 457 and 458 with regard to volume of cases and average length of stay were lower compared to all the cases in those two MS–DRGs. While the data show higher average costs for the procedure code combination of 81.07 and 81.08 in MS–DRGs 457 and 458, as stated previously, the volume was extremely low.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRG 453 – All cases | 1,190 | 13.08 | $71,693 |
| MS-DRG 453 – Cases with codes 81.06 and 81.07 | 8 | 14.00 | $109,089 |
| MS-DRG 453 – Cases with codes 81.06 and 81.08 | 431 | 11.59 | $69,859 |
| MS-DRG 454 – All cases | 3,052 | 6.38 | $48,311 |
| MS-DRG 454 – Cases with codes 81.06 and 81.07 | 47 | 6.83 | $60,743 |
| MS-DRG 454 – Cases with codes 81.06 and 81.08 | 1,825 | 5.71 | $47,144 |
| MS-DRG 455 – All cases | 2,747 | 3.63 | $37,378 |
| MS-DRG 455 – Cases with codes 81.06 and 81.07 | 40 | 4.28 | $47,794 |
| MS-DRG 455 – Cases with codes 81.06 and 81.08 | 2,053 | 3.43 | $37,793 |
| MS-DRG 456 – All cases | 1,115 | 13.14 | $63,856 |
| MS-DRG 456 – Cases with codes 81.07 and 81.08 | 54 | 14.37 | $52,392 |
| MS-DRG 457 – All cases | 3,079 | 6.74 | $41,500 |
| MS-DRG 457 – Cases with codes 81.07 and 81.08 | 29 | 5.97 | $60,820 |
| MS-DRG 458 – All cases | 1,389 | 3.91 | $32,946 |
| MS-DRG 458 – Cases with code 81.07 and 81.08 | 23 | 3.22 | $51,942 |

As the focus of the analysis was to evaluate procedure code 81.08 in comparison to procedure code 81.06, we believe the AxiaLIF technology (procedure code 81.08) is grouped appropriately in its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06). The volume, length of stay, and cost data analyzed demonstrate that the complexity of services and resources utilized for each of these technologies are properly accounted for in their respective MS–DRG assignments. Therefore, the data does not support making changes for procedure code 81.08. As a result, we are not proposing to reassign cases reporting this procedure code to the combined fusion MS–DRGs. We invite public comment on our proposal to not reassign procedure code 81.08 from MS–DRGs 456 through 460 to MS–DRGs 453 through 455 for FY 2012.

6. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast): Excisional Debridement of Wound, Infection, or Burn

We received a request that we remove procedure code 86.22 (Excisional debridement of wound, infection, or burn) from the list of codes considered to be O.R. procedures. The commenter stated that many inpatient excisional debridements are performed in a patient's room instead of in an operating room. The commenter believed that the original assignment of procedure code 86.22 to the O.R. list served to help reflect the resource intensity required by a patient with wounds and ulcers that required an excisional debridement. The commenter stated that, by doing so, the code served as a proxy for severity of illness in the original CMS DRGs prior to the implementation of MS–DRGs in FY 2008. The commenter stated that the creation of the most serious pressure ulcer codes for stage 3 and stage 4 pressure ulcers (codes 707.23 and 707.24) allows these conditions to be classified as MCCs. Therefore, the commenter stated that the need to use procedure code 86.22 to capture severity of illness was no longer needed. The commenter also stated that procedure code 86.22 is a non-O.R. code under the APR–DRGs and does not affect the DRG assignment. The commenter requested that procedure code 86.22 be changed from an O.R. procedure code to a non-O.R. procedure code.

As the commenter stated, excisional debridements are currently captured in procedure code 86.22. Procedure code 88.22 is classified as an O.R. procedure in the current MS–DRGs and, therefore, leads to a surgical MS–DRG assignment. We examined MedPAR claims data on all excisional debridement cases and found that these debridement cases use appreciably fewer resources than other cases in their current surgical DRGs. However, we determined that if we were to classify debridement cases as non-O.R. cases and assign them to medical DRGs, we would significantly underpay these cases. The following chart shows differences in average costs for all excisional debridement cases compared to other cases within their current MS–DRG and compared to medical DRGs to which the patients would be assigned if the procedure were reclassified as a non-O.R. procedure.

| Procedure Code | All Cases with No Other OR Procedure | Average Cost (A) | Average Costs in Surgical DRGs to Which the Patients Are Assigned (B) | Average Costs in Medical DRGs to Which the Patients Would Be Assigned (C) |
|---|---|---|---|---|
| 86.22 | 32,152 | $12,427 | $17,332 | $8,070 |

The chart illustrates that when debridement is the only O.R. procedure, it is assigned to MS–DRGs that have an average cost that is approximately $5,000 more than the actual cost of the debridement ($12,427 versus $17,332). Conversely, if the debridement is made a non-O.R. code, it would, on average, be assigned to MS–DRGs that have an average cost that is approximately $4,000 less than the actual cost of the debridement ($8,070 versus $12,427). Therefore, we believe it would be inappropriate to propose to classify these procedures as a non-O.R. procedure.

We explored alternative approaches to classifying procedure code 86.22 as a non-O.R. procedure. We evaluated the possibility of removing excisional debridements from their current MS–DRG assignments within the following skin-related MS–DRGs, where they are combined with skin grafts, and creating a new set of debridement MS–DRGs. The current MS–DRGs that combine skin grafts and debridements into the same MS–DRGs are as follows:

- MS–DRGs 573 through 575 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).
- MS–DRGs 576 through 578 (Skin Graft &/or Debridement Except for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).

We analyzed MedPAR claims data on the severity level of graft cases without any debridements in these six MS–DRGs. Our findings are shown in the chart below.

## SKIN GRAFTS WITHOUT DEBRIDEMENTS

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| MS-DRGs 573-575 - Cases with severity level of MCC | 751 | 14.56 | $23,975 |
| MS-DRGs 573-575 - Cases with severity level of CC | 1,720 | 10.16 | $14.869 |
| MS-DRGs 573-575 - Cases with severity level of without CC/MCC | 540 | 5.36 | $8,469 |
| MS-DRGs 576-578 - Cases with severity level of MCC | 335 | 10.28 | $22,996 |
| MS-DRGs 576-578 - Cases with severity level of CC | 1,482 | 5.28 | $11,299 |
| MS-DRGs 576-578 - Cases with severity level of without CC/MCC | 1,849 | 3.01 | $6,986 |

We compared these data to a proposed new set of skin-related MS–DRGs that would include only debridements. The results of the findings of the severity levels of debridements without skin grafts in these six MS–DRGs are shown in the chart below.

## DEBRIDEMENTS WITHOUT SKIN GRAFTS

| MS-DRG | Number of Cases | Average Length of Stay | Average costs |
|---|---|---|---|
| MS-DRG 573-575 - Cases with severity level of MCC | 3,177 | 11.73 | $18,381 |
| MS-DRG 573-575 - Cases with severity level of CC | 6,649 | 7.67 | $10,730 |
| MS-DRG 573-575 - Cases with severity level of without CC/MCC | 2,555 | 4.94 | $6,372 |
| MS-DRG 576-578 - Cases with severity level of MCC | 271 | 11.59 | $19,429 |
| MS-DRG 576-578 - Cases with severity level of CC | 638 | 7.61 | $11,913 |
| MS-DRG 576-578 - Cases with severity level of without CC/MCC | 285 | 4.45 | $6,928 |

Our findings indicate that the graft procedure cases have higher average costs than the excisional debridement cases. The average costs for the excisional debridement cases in MS–DRGs 573 through 575 compared to the debridement cases in MS–DRGs 576 through 578 are very similar. We believe that the data support creating a single set of skin-related excisional debridement MS–DRGs composed of cases previously captured in MS–DRGs 573 through 575 as well as MS–DRGs 576 through 578. The following chart illustrates those combined average costs.

## EXCISIONAL DEBRIDEMENTS FROM MS-DRGs 573 THROUGH 578 SPLIT ON SEVERITY LEVEL

| MS-DRGs 573 – 578 | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|
| Combined Excisional Debridement Cases with Severity Level of MCC | 3,448 | 11.71 | $18,463 |
| Combined Excisional Debridement Cases with Severity Level of CC | 7,287 | 7.76 | $10,833 |
| Combined Excisional Debridement Cases with Severity Level of without CC/MCC | 2,840 | 4.89 | $6,428 |

We believe that the data support separating skin graft procedures from excisional debridements by creating a new set of MS–DRGs. This would result in more accurate payment for both skin grafts and debridement. Therefore, we are proposing to remove excisional debridements (procedure code 86.22) from their current MS–DRG assignments within MS–DRGs 573 through 578 for skin grafts and assign them to new excisional debridement MS–DRGs. We are proposing to maintain MS–DRGs 573 through 578 for skin grafts. The following list describes the proposed new and revised MS–DRG titles:

*Proposed new MS–DRGs based on procedure code 86.22:*

- Proposed MS–DRG 570 (Skin Debridement with MCC)
- Proposed MS–DRG 571 (Skin debridement with CC)
- Proposed MS–DRG 572 (Skin Debridement without CC/MCC)

*Proposed Revised MS–DRGs based on codes currently assigned to MS–DRGs 573 through 578, excluding procedure code 86.22:*

- Proposed revised MS–DRG 573 (Skin Graft for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 574 (Skin Graft for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 575 (Skin Graft for Skin Ulcer or Cellulitis without CC/MCC)
- Proposed revised MS–DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 577 (Skin Graft except for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC)

We welcome public comments on our proposal for FY 2012 to create three new debridement MS–DRGs 570, 571, and 572 for skin debridement and to revise MS–DRGs 573 through 578 to include skin grafts only, as indicated above.

7. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

a. Nutritional and Metabolic Diseases: Update of MS–DRG Titles

We received a request to revise the MS–DRG titles for MS–DRGs 640 through 642 to more clearly capture the cases that are currently assigned to these MS–DRGs. The current titles for these MS–DRGs are: MS–DRGs 640 (Nutritional & Miscellaneous Metabolic Disorders with MCC); MS–DRG 641 (Nutritional & Miscellaneous Metabolic Disorders without MCC); and MS–DRG 642 (Inborn Errors of Metabolism). The requestor suggested that we change the titles to: MS–DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes with MCC); MS–DRG 641 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes without MCC); and MS–DRG 642 (Inborn and Other Disorders of Metabolism).

Our clinical advisors support these suggested changes to the titles, as the suggested changes would provide a better description of the diagnoses assigned to MS–DRGs 640, 641, and 642. Therefore, we are proposing to revise the MS–DRG titles for MS–DRGs 640, 641, and 642 as the requested suggested. We invite public comment on our proposal to change the MS–DRG titles for MS–DRGs 640, 641, and 642 for FY 2012.

b. Sleeve Gastrectomy Procedure for Morbid Obesity

Sleeve gastrectomy is a 70 percent to 80 percent greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing Roux-en-Y Gastric Bypass (RYGBP). Sleeve gastrectomy can be performed either as an open or a laparoscopic procedure. Sleeve gastrectomy is currently coded using ICD–9–CM procedure code 43.89 (Other total gastrectomy). Procedure code 43.89 is currently assigned to several MS–DRGs. However, the code is not assigned to MS–DRG 619, 620, or 621 (O.R. Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively).

We received a request for CMS to review MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders) for consistency. Specifically, the requestor questioned why diagnosis code 278.01 (Morbid obesity), when paired on a claim with procedure code 43.89, would be assigned to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, or without CC/MCC, respectively) instead of MS–DRG 619, 620, or 621.

Upon review, we determined that diagnosis code 278.01 is assigned to MDC 10. However, procedure code 43.89 is not assigned to any MS–DRG set in this MDC. Therefore, the cases are assigned to MS–DRGs 981 through 983, reflecting procedures not related to the principal diagnosis. This was an inadvertent oversight on CMS' part when the MS–DRGs were created. Therefore, we are proposing to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621 for FY 2012.

Currently, sleeve gastrectomy is identified in the ICD–9–CM procedure code Index as follows: Gastrectomy (partial) (subtotal) NEC 43.89. At procedure code 43.89 in the ICD–9–CM procedure code Tabular, an inclusion note identifies this code as including sleeve resection of the stomach.

In light of our proposal to add a procedure code or codes to MS–DRGs 619 through 621, we point out that there is an NCD that has precluded coverage of sleeve gastrectomy when performed either open or laparoscopically. This decision may be found in the Medicare National Coverage Determination Manual, Section 100.1, Nationally Non-Covered Indications for Bariatric Surgery for Treatment of Morbid Obesity, effective on February 12, 2009. This manual is available through the CMS Web site through a link at: *http://www.cms.gov/manuals/downloads/mcd103c1_Part2.pdf.* This manual entry affirms that treatment for obesity via use of the open or laparoscopic sleeve gastrectomy is determined to be noncovered for Medicare beneficiaries.

Noncoverage of these cases is determined by the fiscal intermediary or MAC because of the nature of procedure code 43.89, which is a code that identifies several gastrectomy procedures. Therefore, to identify a code describing many procedures in the MCE would be inappropriately restricting other procedures which are covered. However, we have received a request to create specific codes identifying both laparoscopic sleeve gastrectomy and the open procedure, vertical sleeve gastrectomy. We addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011. Should a code or codes be created as a result of this request, we will then be able to add these codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01. The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage.* A summary of the meeting will be available soon after the meeting is held. This summary can be found on CMS' Web site for the ICD–9–CM Coordination and Maintenance Committee at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage* by scrolling down to the .pdf zip files containing the meeting agenda and handouts.

Therefore, for FY 2012, we are proposing to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621. However, we also intend to add any code or codes created at the ICD–9–CM Coordination and Maintenance Committee on March 9, 2011, to the MCE as sleeve gastrectomy, whether open or laparoscopic, is not covered for Medicare beneficiaries. The code or codes would appear in the "Noncovered Procedures" edit of the MCE. As the timing of the development of this proposed rule and the date of the March 2011 meeting of the ICD–9–CM Coordination and Maintenance Committee overlap, it is not possible to determine what those codes might be, or even if they will be created. However, should a code or codes be created, we propose that they will simultaneously be placed in both MS–DRGs 619 through 621 and the MCE. This decision may seem to be counterintuitive, but CMS realizes that our MS–DRGs and the Medicare GROUPER program are used for other beneficiaries and insurance plans rather than strictly for Medicare beneficiaries. A complete description of this issue will be addressed in the final rule. Any new code or codes created as a result of the ICD–9–CM Coordination and Maintenance Committee meeting will only be included in Table 6B, which will be listed in section VI. of the Addendum to the final rule and available via the Internet; we do not have a mechanism to make the codes available prior to the final rule's publication. We invite public comment on this proposal.

8. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period): Discharge Status Code 66 (Discharged/Transferred to Critical Assess Hospital (CAH))

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50236), we finalized our transfer policy regarding transfer of patients from an acute care hospital to a CAH. In that final rule, we stated that hospitals are required to use patient discharge status code 66 on the IPPS claims to identify transfers to CAHs.

With this new requirement, a discharge from an IPPS hospital to a CAH equates to a transfer status. However, discharge status code 66 is currently not included in the MS–DRG GROUPER logic for MS–DRG 789 (Neonate, Died or Transferred to Another Acute Care Facility). Therefore, in this proposed rule, we are proposing to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789. We invite public comment on our proposal to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789 for FY 2012.

9. Proposed Medicare Code Editor (MCE) Changes

As explained under section II.B.1. of the preamble of this proposed rule, the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a MS–DRG. In this proposed rule, we discuss our intention to make the following change to the MCE edits.

In section II.G.7.a. of this preamble, we discuss that the current ICD–9–CM procedure code for sleeve gastrectomy (43.89 (Other partial gastrectomy, other)) is a noncovered code when performed for resection of the stomach in patients with morbid obesity. We also discussed that noncoverage for Medicare beneficiaries of cases containing procedure code 43.89 is determined by the fiscal intermediaries or MACs because of the nature of procedure code 43.89. This code is imprecise and identifies several other gastrectomy procedures in addition to sleeve resection. Therefore, to limit coverage by identifying a code that describes many procedures through the use of the MCE would inappropriately restrict other procedures that are covered by Medicare. In this same section, we also stated that we received a request to create specific codes identifying both laparoscopic sleeve gastrectomy and the open procedure, vertical sleeve gastrectomy. As we stated above, we addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011. If a code or codes should be created as a result of this request, we will then be able to add these codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01 (Morbid obesity).

As the timing of development of this proposed rule and the holding of the ICD–9–CM Coordination and Maintenance Committee meeting on March 9, 2011 overlap, it is not possible to determine what those codes might be, or even if they will be created. However, should a code or codes be created, we propose that any code or codes for laparoscopic or open sleeve resection of the stomach be added to the MCE as a noncovered procedure or procedures, in combination with ICD–9–CM diagnosis code 278.01 (Morbid obesity). The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage*. A complete description of this issue will be addressed in the final rule. Any new code or codes describing sleeve gastrectomy will only be included in Table 6B, which will be listed in section VI. of the Addendum to the final rule and available via the Internet; we do not have a mechanism to make the codes available prior to the final rule's publication. We invite public comments on this proposal.

10. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single MS–DRG (MS–DRG 652) and the class "major bladder procedures" consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 1 and 2 and surgical class B includes MS–DRGs 3, 4, and 5. Assume also that the average costs of MS–DRG 1 is higher than that of MS–DRG 3, but the average costs of MS–DRGs 4 and 5 are higher than the average costs of MS–DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but

are still occasionally performed on patients in the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has a lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2012, as discussed in sections II.G.1. and 6. of this preamble, we are proposing to revise the surgical hierarchy for Pre-MDCs and MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast) as follows:

In Pre-MDCs, we are proposing to reorder proposed new MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and proposed new MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) above MS–DRG 010 (Pancreas Transplant).

In MDC 9, we are proposing to reorder—

- MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC) above proposed new MS–DRG 570 (Skin Debridement with MCC);
- Proposed new MS–DRG 570 above proposed new MS–DRG 571 (Skin Debridement with CC);
- Proposed new MS–DRG 571 above proposed new MS–DRG 572 (Skin Debridement without CC/MCC; and
- Proposed new MS–DRG 572 above MS–DRG 579 (Other Skin, Subcutaneous Tissue, and Breast Procedures with MCC).

11. Complications or Comorbidity (CC) Exclusions List

a. Background

As indicated earlier in the preamble of this proposed rule, under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. We refer readers to section II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47121 through 47152).

b. Proposed CC Exclusions List for FY 2012

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[2]

(1) Proposed Limited Revisions Based on Changes to the ICD–9–CM Diagnosis Codes

For FY 2012, we are proposing to make limited revisions to the CC Exclusions List to take into account the changes made in the ICD–9–CM diagnosis coding system effective October 1, 2011. (We refer readers to section II.G.13. of the preamble of this proposed rule for a discussion of ICD–9–CM changes.) We are proposing to make these changes in accordance with the principles established when we created the CC Exclusions List in 1987. In addition, we are indicating on the CC Exclusions List some changes as a result of updates to the ICD–9–CM codes to reflect the exclusion of codes from being MCCs under the MS–DRG system that we adopted in FY 2008.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2012, comments and suggestions should have been submitted by early December 2010. The following comments were submitted in a timely manner, and are therefore being discussed in this section.

[2] See the FY 1989 final rule (53 FR 38485, September 30, 1988), for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989), for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990), for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992), for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993), for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994), for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995), for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996), for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998), for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000), for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001), for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002), for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003), for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004), for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005), for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions, the FY 2009 final rule (73 FR 48510), the FY 2010 final rule (74 FR 43799); and the FY 2011 final rule (75 FR 50114). In the FY 2000 final rule (64 FR 41490, July 30, 1999, we did not modify the CC Exclusions List because we did not make any changes to the ICD–9–CM codes for FY 2000.

a. Pressure Ulcer Diagnosis Codes

We received a comment recommending that CMS remove diagnosis codes 707.23 (Pressure ulcer, stage III) and 707.24 (Pressure ulcer, stage IV) from the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code for the pressure ulcer site: Diagnosis code 707.00 (Pressure ulcer, unspecified); diagnosis code 707.01 (Pressure ulcer, elbow); diagnosis code 707.02 (Pressure ulcer, upper back); diagnosis code 707.03 (Pressure ulcer, lower back); diagnosis code 707.04 (Pressure ulcer, hip); diagnosis code 707.05 (Pressure ulcer, buttock); diagnosis code 707.06 (Pressure ulcer, ankle); diagnosis code 707.07 (Pressure ulcer, heel); or diagnosis code 707.09 (Pressure ulcer, other site). Currently, when a patient is admitted with a pressure ulcer, the CC Exclusion List prevents a pressure ulcer stage diagnosis code from being designated as an MCC when reported as a secondary diagnosis. The commenter disagreed with this approach and contended that a patient admitted for treatment of a stage III or stage IV pressure ulcer likely requires resources that would qualify the case as a diagnosis with an MCC or, at a minimum, as a CC.

Our clinical advisors agree with the commenter. Therefore, we are proposing to remove diagnosis codes 707.23 and 707.24 from the CC Exclusion List when a principal diagnosis code of one of codes 707.00 through 707.09 is reported. Under this proposal, diagnosis code 707.23 or diagnosis code 707.24 would be an MCC when reported as a secondary diagnosis code with a principal diagnosis code of one of codes 707.00 through 707.09.

b. End-Stage Renal Disease Diagnosis Code

We received a suggestion from a commenter that diagnosis code 585.6 (End-stage renal disease) be added to the CC Exclusion List when reported with a principal diagnosis code of 403.90 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified) or diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease). Currently, diagnosis code 585.6 is designated as an MCC.

According to the commenter, diagnosis codes 585.6 and 403.91 are essentially the same diagnosis but coding guidelines require the reporting of two codes to identify the stage of chronic kidney disease when associated with hypertensive chronic kidney disease. The commenter suggested that there is no need for diagnosis code 585.6 to be designated as an MCC when reported with a principal diagnosis of hypertensive chronic kidney disease, stage V or end-stage renal disease. The commenter also pointed out that, while coding guidelines would preclude diagnosis codes 403.90 and 585.6 from being reported together, the MS–DRG GROUPER allows diagnosis code 585.6 to act as an MCC when reported as a secondary diagnosis with principal diagnosis code 403.90.

In response to the first issue, our clinical advisors disagree with the commenter. Diagnosis code 403.91 includes chronic kidney disease stage V or end-stage renal disease. These are two separate conditions (or stages) that are identified by two unique codes. Diagnosis code 585.5 identifies stage V chronic kidney disease and is classified as a CC. Diagnosis code 585.6 identifies end-stage renal disease, is classified as an MCC, and describes patients who require chronic dialysis. The patients diagnosed with stage V chronic kidney disease are a different population who require different resources than those patients who are diagnosed with end-stage renal disease. Therefore, we are not proposing to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis of code 403.91.

On the second issue raised by the commenter, our clinical advisors agree. Diagnosis code 403.90 identifies patients with chronic kidney disease, stages I through IV or unspecified, and diagnosis code 585.6 identifies end-stage renal disease. Our clinical advisors indicate that the reporting of diagnosis code 585.6 should not be designated as an MCC in this case. We agree with the commenter that diagnosis codes 403.90 and 585.6 should not be reported together as instructed by the Coding Guidelines. Only a code from the 585.1 through 585.4 range (stages I through IV, or unspecified) should be reported with diagnosis code 403.90. Diagnosis code 585.6 is the exclusive code that uniquely identifies end-stage renal disease and should only be reported with diagnosis code 403.91. Therefore, we are proposing to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis code of 403.90.

c. Hypertensive Chronic Kidney Disease With Chronic Kidney Disease Stage V or End-Stage Renal Disease Code

We received a comment recommending the addition of diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease) to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6 (End stage renal disease). The commenter stated that it would be unlikely that diagnosis code 403.91 would be reported as a secondary diagnosis code with diagnosis code 585.6 as the principal diagnosis code due to sequencing rules for end-stage renal disease with hypertension. Currently, diagnosis code 403.91 is designated as a CC.

Our clinical advisors agree with the commenter. Therefore, we are proposing to add diagnosis code 403.91 to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6.

We invite public comment on the above three proposals regarding the CC Exclusion List for FY 2012.

(2) Suggested Changes to Severity Levels for Encephalopathy

We received a request that we consider changing the following diagnosis codes from an MCC to a CC:

- 348.30 (Encephalopathy NOS)
- 348.32 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

For this FY 2012 IPPS/LTCH PPS proposed rule, we analyzed the claims data for the diagnosis codes mentioned above related to encephalopathy. We used the same approach we used in initially creating the MS–DRGs and classifying secondary diagnosis codes as non-CCs, CCs, or MCCs. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule (72 FR 47158 through 47161). We refer the readers to this discussion for complete information on our approach to developing the non-CC, CC, and MCC lists. Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

| Code | Diagnosis | Cnt1 | C1 | Cnt2 | C2 | Cnt3 | C3 |
|---|---|---|---|---|---|---|---|

Count (Cnt) is the number of patients in each subset. C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC. A value close to 1.0 in the C1 field would suggest that the diagnosis code produces the same expected value as a non-CC. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For additional details on this analysis, we refer readers to the FY 2008 IPPS final rule (72 FR 47158 through 47161).

The following chart shows the analysis for each of the encephalopathy diagnosis codes that are currently classified as MCCs.

| Code | Diagnosis Description | CC Level | Cnt 1 | Cnt 1 Impact | Cnt 2 | Cnt 2 Impact | Cnt 3 | Cnt 3 Impact |
|---|---|---|---|---|---|---|---|---|
| 34830 | Encephalopathy NOS | MCC | 10,082 | 2.1206 | 39,042 | 2.7774 | 60,381 | 3.3702 |
| 34831 | Metabolic encephalopathy | MCC | 6,389 | 2.0580 | 29,651 | 2.6952 | 49,343 | 3.4011 |
| 34839 | Encephalopathy NEC | MCC | 4,004 | 2.1118 | 15,003 | 2.7355 | 19,732 | 3.3708 |
| 34982 | Toxic encephalopathy | MCC | 4,333 | 2.3158 | 18,126 | 3.0023 | 26,009 | 3.5714 |
| 5722 | Hepatic encephalopathy | MCC | 1,375 | 1.5448 | 9,885 | 2.5054 | 12,421 | 3.4435 |

We ran the following data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC.

The chart above shows that the C1 findings ranged from a low of 1.5448 to a high of 2.3158. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that these codes are more like a CC than a MCC. However, the C2 findings ranged from a low of 2.5054 to a high of 3.0023. Values close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 findings support maintaining the encephalopathy codes as an MCC level. The data are clearly mixed between the C1 and C2 findings, and does not consistently support a change in the severity level. Our clinical advisers recommended that these encephalopathy codes remain at an MCC level because these patients with encephalopathy typically utilize significant resources and are at a higher severity level. Based on the clinical analysis and the lack of consistent claims data support for the severity level change, we believe that the encephalopathy codes should remain on the MCC list. Therefore, we are proposing to retain the following encephalopathy codes on the MCC list:

- 348.30 (Encephalopathy NOS)
- 348.32 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

We invite public comment on our proposal not to change the severity level classification for these codes.

(3) Suggested Changes to Severity Levels for Mechanical Complication and Infection Due to Device Related Codes

We received a request to change the severity classification from CCs to MCCs for the following diagnosis codes:

- 996.01 (Mechanical of cardiac device, implant and graft due to cardiac pacemaker (electrode)).
- 996.04 (Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator).
- 996.61 (Infection and inflammatory reaction due to internal prosthetic device, implant, and graft due to cardiac device, implant, and graft).

Currently, all three diagnosis codes are classified as a CC. For this proposed rule, we analyzed claims data using the methodology described previously in this section for these diagnosis codes. The following chart shows our findings:

BILLING CODE 4120–01–P

| Code | Diagnosis Description | CC Level | Cnt 1 | Cnt 1 Impact | Cnt 2 | Cnt 2 Impact | Cnt 3 | Cnt 3 Impact |
|---|---|---|---|---|---|---|---|---|
| 99601 | Malfunc cardiac pacemaker | CC | 1,296 | 1.6723 | 1,920 | 2.4332 | 1,333 | 3.1134 |
| 99604 | Mch cmp autm mplnt dfbrl | CC | 419 | 1.7041 | 1,032 | 2.5190 | 660 | 3.1508 |
| 99661 | React-cardiac dev/graft | CC | 149 | 1.9922 | 633 | 2.8134 | 1,253 | 3.5036 |

We reviewed the findings from these data. The C1 findings ranged from a low of 1.6723 to a high of 1.9922. As stated earlier, a value close to 2.0 in the C1 field suggests that the condition is more like a CC than a non-CC but not as

significant in resource usage as an MCC. The C1 findings clearly support the current classification of these three codes on the CC list and the C2 findings supports this classification. Our clinical advisors agree that the data findings and their own clinical evaluation of the severity level of these conditions support the classification of these three codes on the CC list. Therefore, we are proposing that these codes remain on the CC list. We invite public comment on this proposal.

Tables 6G and 6H, Additions to and Deletions from the CC Exclusion List, respectively, which are proposed to be effective for discharges occurring on or after October 1, 2011, are not being published in the Addendum to this proposed rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* Each of these principal diagnoses for which there is a CC exclusion is shown in Tables 6G and 6H, which are listed in section VI. of the Addendum to this proposed rule (and available via the Internet) with an asterisk, and the conditions that will not count as a CC, are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is also available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* If finalized in this rulemaking cycle, beginning with discharges on or after October 1, 2011, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the changes to the MCC and CC lists that occurred as a result of updates to the ICD–9–CM codes, as described in Tables 6A, 6C, and 6E, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, we are providing the following summaries of those MCC and CC changes for FY 2012.

BILLING CODE 4120–01–P

**SUMMARY OF ADDITIONS TO THE MS-DRG MCC LIST--TABLE 6I.1**

| Code | Description |
|---|---|
| 415.13 | Saddle embolus of pulmonary artery |
| 444.01 | Saddle embolus of abdominal aorta |
| 516.4 | Lymphangioleiomyomatosis |
| 516.61 | Neuroendocrine cell hyperplasia of infancy |
| 516.62 | Pulmonary interstitial glycogenosis |
| 516.63 | Surfactant mutations of the lung |
| 516.64 | Alveolar capillary dysplasia with vein misalignment |
| 516.69 | Other interstitial lung diseases of childhood |
| 747.31 | Pulmonary artery coarctation and atresia |
| 747.32 | Pulmonary arteriovenous malformation |
| 747.39 | Other anomalies of pulmonary artery and pulmonary circulation |
| 808.54 | Multiple open pelvic fractures without disruption of pelvic circle |

**SUMMARY OF DELETIONS FROM THE MS-DRG MCC LIST--TABLE 6I.2**

| Code | Description |
|---|---|
| 747.3 | Anomalies of pulmonary artery |

**SUMMARY OF ADDITIONS TO THE MS-DRG CC LIST--TABLE 6J.1**

| Code | Description |
|---|---|
| 286.52 | Acquired hemophilia |
| 286.53 | Antiphospholipid antibody with hemorrhagic disorder |
| 286.59 | Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors |
| 348.82 | Brain death |
| 358.30 | Lambert-Eaton syndrome, unspecified |
| 358.31 | Lambert-Eaton syndrome in neoplastic disease |
| 358.39 | Lambert-Eaton syndrome in other diseases classified elsewhere |
| 444.09 | Other arterial embolism and thrombosis of abdominal aorta |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified |
| 516.35 | Idiopathic lymphoid interstitial pneumonia |
| 516.36 | Cryptogenic organizing pneumonia |
| 516.37 | Desquamative interstitial pneumonia |
| 516.5 | Adult pulmonary Langerhans cell histiocytosis |
| 539.01 | Infection due to gastric band procedure |
| 539.09 | Other complications of gastric band procedure |
| 539.81 | Infection due to other bariatric procedure |
| 539.89 | Other complications of other bariatric procedure |
| 596.81 | Infection of cystostomy |
| 596.82 | Mechanical complication of cystostomy |
| 596.83 | Other complication of cystostomy |
| 808.44 | Multiple closed pelvic fractures without disruption of pelvic circle |
| 996.88 | Complications of transplanted organ, stem cell |
| 997.32 | Postprocedural aspiration pneumonia |
| 997.41 | Retained cholelithiasis following cholecystectomy |
| 997.49 | Other digestive system complications |
| 999.41 | Anaphylactic reaction due to administration of blood and blood products |
| 999.42 | Anaphylactic reaction due to vaccination |
| 999.49 | Anaphylactic reaction due to other serum |
| 999.51 | Other serum reaction due to administration of blood and blood products |
| 999.52 | Other serum reaction due to vaccination |
| 999.59 | Other serum reaction |

**SUMMARY OF DELETIONS FROM THE MS-DRG CC LIST--TABLE 6J.2**

| Code | Description |
|---|---|
| 286.5 | Hemorrhagic disorder due to intrinsic circulating anticoagulants |
| 444.0 | Embolism and thrombosis of abdominal aorta |
| 516.3 | Idiopathic fibrosing alveolitis |
| 997.4 | Digestive system complications, not elsewhere classified |
| 999.4 | Anaphylactic shock due to serum |
| 999.5 | Other serum reaction, not elsewhere classified |

BILLING CODE 4120–01–C

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current MS–DRG Definitions Manual, Version 28.0, is available on a CD for $225.00. Version 29.0 of this manual, which will include the final FY 2012 MS–DRG changes, will be available on a CD for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303, or by obtaining an order form at the Web site: *http://www.3MHIS.com.* Please specify the revision or revisions requested.

12. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 60.99, Other operations on prostate

All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[3]

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to change the procedures assigned among these MS–DRGs.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As noted above, there were no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS–DRGs to another of the three MS–DRGs based on average charges and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep

[3] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65 FR 47064); or in FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999) we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In the FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, FY 2010, and FY 2011, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), the FY 2009 final rule (73 FR 48513), the FY 2010 final rule (74 FR 43796); and the FY 2011 final rule (75 FR 50122).

the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There were no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to move any procedure codes among these MS–DRGs.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections III.G.12.a. and b., we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2012.

13. Changes to the ICD–9–CM Coding System, Including Discussion of the Replacement of the ICD–9–CM Coding System With the ICD–10–CM and ICD–10–PCS Systems in FY 2014

a. ICD–9–CM Coding System

As described in section II.B.1. of the preamble of this proposed rule, the ICD–9–CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD–9–CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD–9–CM is available from the Government Printing Office on CD–ROM for $19.00 by calling (202) 512–1800.) Complete information on ordering the CD–ROM is also available at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/05_CDROM.asp#TopOfPage.* The Official Version of the ICD–9–CM is no longer available in printed manual form from the Federal Government; it is only available on CD–ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases,* while CMS has lead responsibility for the ICD–9–CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures.*

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2012 at a public meeting held on September 15–16, 2010 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 19, 2010. Those coding changes are announced in Tables 6A through 6F, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet.

The Committee held its 2011 meeting on March 9–10, 2011. New codes for which there was a consensus of public support and for which complete tabular and indexing changes are made by May 2011 will be included in the October 1, 2011 update to ICD–9–CM. Code revisions that were discussed at the March 9–10, 2011 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to this proposed rule will be included in Tables 6A through 6F, which will be listed in section VI. of the Addendum to the final rule and available via the Internet, and will be marked with an asterisk (*).

Copies of the minutes of the procedure codes discussions at the Committee's September 15–16, 2010 meeting and March 9–10, 2011 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* The minutes of the diagnosis codes discussions at the September 15–16, 2010 meeting and March 9–10, 2011 meeting are found at: *http://www.cdc.gov/nchs/icd.htm.* These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by E-mail to: *dfp4@cdc.gov.*

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by E-mail to: *patricia.brooks2@cms.hhs.gov.*

The ICD–9–CM code changes that have been approved will become effective October 1, 2011. The new ICD–9–CM codes are listed, along with their MS–DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively), which are listed in section VI. of the Addendum to this proposed rule and available via the Internet. As we stated above, the code numbers and their titles were presented for public comment at the ICD–9–CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved.

In this proposed rule, we are soliciting comments on the proposed classification of these new codes, which are shown in Tables 6A and 6B listed in section VI. of the Addendum to this proposed rule and available via the Internet.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. New

procedure codes are shown in Table 6B, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes), which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Table 6D, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet contains invalid procedure codes. These invalid procedure codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, and also includes the MS–DRG assignments for these revised codes. Table 6F, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet includes revised procedure code titles for FY 2012.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October. As stated previously, ICD–9–CM codes discussed at the March 9–10, 2011 Committee meeting that received consensus and that are finalized by May 2011 will be included in Tables 6A through 6F, which will be listed in section VI. of the Addendum to the final rule and available via the Internet.

Section 503(a) of Public Law 108–173 included a requirement for updating ICD–9–CM codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the "Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date." This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–9–CM Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD–9–CM Coordination and Maintenance Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all changes to ICD–9–CM, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–9–CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2011 implementation of an ICD–9–CM code at the September 15–16, 2010 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2011.

Current addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/icd9ProviderDiagnosticCodes/01_overview.asp#TopofPage.* Information on ICD–9–CM diagnosis codes, along with the Official ICD–9–CM Coding Guidelines, can be found on the Web site at: *http://www.cdc.gov/nchs/icd9.htm.* Information on new, revised, and deleted ICD–9–CM codes is also provided to the AHA for publication in the *Coding Clinic for ICD–9–CM.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–9–CM coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

These same means of disseminating information on new, revised, and deleted ICD–9–CM codes will be used to notify providers, publishers, software vendors, contractors, and others of any changes to the ICD–9–CM codes that are implemented in April. The code titles

are adopted as part of the ICD–9–CM Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. For codes that are implemented in April, we will assign the new procedure code to the same MS–DRG in which its predecessor code was assigned so there will be no MS–DRG impact as far as MS–DRG assignment. Any midyear coding updates will be available through the Web sites indicated above and through the *Coding Clinic for ICD–9–CM.* Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these Web sites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD–10) coding system applicable to hospital inpatient services will be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362, January 16, 2009). The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

We responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, we indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. There was an announcement at the September 15–16, 2010 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes would be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets will be made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- There will be no updates to ICD–9–CM on October 1, 2013, as the system will no longer be a HIPAA standard. There will be only limited code updates to ICD–10 code sets on October 1, 2013, to capture new technology and new diseases.
- On October 1, 2014, regular updates to ICD–10 will begin.

The ICD–9–CM Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 on or after October 1, 2014, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–9–CM Coordination and Maintenance Committee Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03.* A summary of the September 15–16, 2010 Committee meeting, along with both written and audio transcripts of this meeting, are posted on the "Download" section of this Web page.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we discussed that we had received repeated requests from the hospital community to process all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1, 2011, hospitals could submit up to 25 diagnoses and 25 procedures; however, CMS' system limitations allowed for the processing of only the first 9 diagnoses and 6 procedures. We indicated in that final rule that, as part of our efforts to update Medicare systems prior to the implementation of ICD–10 on October 1, 2013, we were undergoing extensive system updates as part of the move to 5010, which includes the ability to accept ICD–10 codes. This complicated transition involved converting many internal systems prior to October 1, 2013, when ICD–10 will be implemented. We stated that, as one important step in this planned conversion process, we were planning to complete the expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We have not completed this expansion, and, as a result, we were able to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format starting on January 1, 2011. We continue to recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis, and other important uses.

d. ICD–10 MS–DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received comments on the creation of the ICD–10 version of the MS–DRGs, which will be implemented on October 1, 2013 (FY 2014) when we implement the reporting of ICD–10 codes (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting our current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–9–CM Coordination and Maintenance Committee. We undertook this early conversion project

to assist other payers and providers in understanding how to go about their own conversion projects. We posted ICD–10 MS–DRGs based on V26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for others to follow. All of this information can be found on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp.* We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems as well as the General Equivalence Mappings that assist in conversion through the ICD–9–CM Coordination and Maintenance Committee. Information on these committee meetings can be found at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.*

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRG Version 28.0 also includes the CC Exclusion List and the ICD–10 version of the hospital acquired conditions (HACs), which was not posted with Version 26.0. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* We will continue to work with the public to explain how we are approaching the conversion of MS–DRGs to ICD–10 and will post drafts of updates as they are developed for public review. The final version of the ICD–10 MS–DRGs to be implemented in FY 2014 will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD–9–CM Coordination and Maintenance Committee.

14. Other Issues

a. O.R./Non-O.R. Status of Procedures

(1) Brachytherapy Code

We received a request that we add ICD–9–CM procedure code 92.27 (Implantation or Insertion of Radioactive Elements) [Brachytherapy] into 41 MS–DRGs that are listed below:

- 129 (Major Head and Neck Procedures with CC/MCC or Major Device)
- 130 (Major Head and Neck Procedures without CC/MCC)
- 163 (Major Chest Procedures with MCC)
- 164 (Major Chest Procedures with CC)
- 165 (Major Chest Procedures without CC/MCC)
- 180 (Respiratory Neoplasms with MCC)
- 181 (Respiratory Neoplasms with CC)
- 182 (Respiratory Neoplasms without CC/MCC)
- 326 (Stomach, Esophageal and Duodenal Procedures with MCC)
- 327 (Stomach, Esophageal and Duodenal Procedures with CC)
- 328 (Stomach, Esophageal and Duodenal Procedures without CC/MCC)
- 329 (Major Small and Large Bowel Procedures with MCC)
- 330 (Major Small and Large Bowel Procedures with CC)
- 331 (Major Small and Large Bowel Procedures without CC/MCC)
- 332 (Rectal Resection with MCC)
- 333 (Rectal Resection with CC)
- 334 (Rectal Resection without CC/MCC)
- 344 (Minor Small and Large Bowel Procedures with MCC)
- 345 (Minor Small and Large Bowel Procedures with CC)
- 346 (Minor Small and Large Bowel Procedures without CC/MCC)
- 347 (Anal and Stomal Procedures with MCC)
- 348 (Anal and Stomal Procedures with CC)
- 349 (Anal and Stomal Procedures without CC/MCC)
- 405 (Pancreas, Liver and Shunt Procedures with MCC)
- 406 (Pancreas, Liver and Shunt Procedures with CC)
- 407 (Pancreas, Liver and Shunt Procedures without CC/MCC)
- 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator)
- 491 (Back and Neck Procedures Except Spinal Fusion without CC/MCC)
- 500 (Soft Tissue procedures with MCC)
- 501 (Soft Tissue procedures with CC)
- 502 (Soft Tissue procedures without CC/MCC)
- 584 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC)
- 585 (Breast Biopsy, Local Excision and Other Breast Procedures without CC/MCC)
- 597 (Malignant Breast Disorders with MCC)
- 598 (Malignant Breast Disorders with CC)
- 599 (Malignant Breast Disorders without CC/MCC)
- 653 (Major Bladder Procedures with MCC)
- 654 (Major Bladder Procedures with CC)
- 655 (Major Bladder Procedures without CC/MCC)
- 656 (Kidney and Ureter Procedures for Neoplasm with MCC)
- 657 (Kidney and Ureter Procedures for Neoplasm with CC)
- 658 (Kidney and Ureter Procedures for Neoplasm without CC/MCC)
- 662 (Minor Bladder Procedures with MCC)
- 663 (Minor Bladder Procedures with CC)
- 664 (Minor Bladder Procedures without CC/MCC)
- 668 (Transurethral Procedures with MCC)
- 669 (Transurethral Procedures with CC)
- 670 (Transurethral Procedures without CC/MCC)
- 671 (Urethral Procedures with CC/MCC)
- 672 (Urethral Procedures without CC/MCC)
- 707 (Major Male Pelvic Procedures with CC/MCC)
- 708 (Major Male Pelvic Procedures without CC/MCC)
- 736 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC)
- 737 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC)
- 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC)
- 739 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC)
- 740 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC)
- 741 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC)
- 746 (Vagina, Cervix and Vulva Procedures with CC/MCC)
- 747 (Vagina, Cervix and Vulva Procedures without CC/MCC)
- 748 (Female Reproductive System Reconstructive Procedures)
- 749 (Other Female Reproductive System O.R. Procedures with CC/MCC)
- 750 (Other Female Reproductive System O.R. Procedures without CC/MCC)

We examined MedPAR claims data on this request and only found 150 cases throughout these MS–DRGs. Our findings are presented in the table below.

BILLING CODE 4120–01–P

| MS-DRG with Code 92.27 | | | | MS-DRG without Code 92.27 | | |
|---|---|---|---|---|---|---|
| DRG | Number of Cases | Average Length of Stay | Average Costs | Number of Cases | Average Length of Stay | Average Costs |
| 129 | 6 | 6.67 | $15,793 | 1,326 | 5.35 | $14,400 |
| 130 | 2 | 1.00 | $7,587 | 904 | 2.78 | $7,860 |
| 163 | 17 | 8.18 | $24,166 | 11,871 | 13.90 | $31,860 |
| 164 | 52 | 5.94 | $17,505 | 16,487 | 7.13 | $16,865 |
| 165 | 41 | 2.95 | $10,638 | 9,260 | 4.27 | $11,754 |
| 180 | 0 | 0 | 0 | 19,304 | 7.37 | $11,396 |
| 181 | 0 | 0 | 0 | 22,205 | 5.30 | $8,014 |
| 182 | 0 | 0 | 0 | 2,365 | 3.59 | $5,580 |
| 326 | 0 | 0 | 0 | 10,321 | 15.48 | $35,437 |
| 327 | 1 | 4.00 | $9,302 | 9.671 | 8.67 | $17,889 |
| 328 | 0 | 0 | 0 | 8,461 | 3.49 | $9,161 |
| 329 | 1 | 24.00 | $37,654 | 41,107 | 15.10 | $33,003 |
| 330 | 2 | 9.00 | $20,043 | 53,584 | 8.91 | $16,736 |
| 331 | 0 | 0 | 0 | 22,105 | 5.13 | $10,654 |
| 332 | 1 | 48.00 | $61,169 | 1,439 | 13.40 | $29,727 |
| 333 | 1 | 10.00 | $11,446 | 4,494 | 7.86 | $16,008 |
| 334 | 1 | 16.00 | $27,312 | 2,855 | 4.76 | $10,518 |
| 344 | 0 | 0 | 0 | 756 | 11.30 | $21,590 |
| 345 | 0 | 0 | 0 | 2,906 | 6.67 | $11,190 |
| 346 | 0 | 0 | 0 | 2,331 | 4.52 | $7,757 |
| 347 | 0 | 0 | 0 | 1,430 | 8.80 | $16,644 |
| 348 | 0 | 0 | 0 | 3,975 | 5.40 | $9,326 |
| 349 | 0 | 0 | 0 | 3,512 | 2.75 | $5,311 |
| 405 | 1 | 8.00 | $8,444 | 3,940 | 15.45 | $35,970 |
| 406 | 2 | 10.50 | $23,231 | 4,749 | 7.83 | $17,333 |
| 407 | 0 | 0 | 0 | 1,799 | 8.04 | $12,148 |
| 490 | 0 | 0 | 0 | 19,840 | 4.24 | $11,940 |
| 491 | 0 | 0 | 0 | 38,574 | 2.05 | $6,794 |
| 500 | 0 | 0 | 0 | 1,935 | 10.86 | $20,600 |
| 501 | 5 | 7.00 | $12,896 | 4,961 | 5.77 | $10,256 |
| 502 | 5 | 7.40 | $13,876 | 5,009 | 2.78 | $6,844 |
| 584 | 0 | 0 | 0 | 790 | 5.32 | $11,126 |
| 585 | 0 | 0 | 0 | 1,318 | 2.12 | $7,283 |
| 597 | 0 | 0 | 0 | 532 | 7.41 | $10,990 |
| 598 | 0 | 0 | 0 | 1,369 | 5.32 | $7,624 |
| 599 | 0 | 0 | 0 | 165 | 3.26 | $4,368 |
| 653 | | | | 1,589 | 16.34 | $35,856 |
| 654 | | | | 3,502 | 9.13 | $19,367 |
| 655 | 0 | 0 | 0 | 1,121 | 5.53 | $413,162 |
| 656 | 1 | 20.00 | $77,737 | 3,110 | 10.00 | $24,022 |
| 657 | 0 | 0 | 0 | 7,885 | 5.63 | $13,345 |

BILLING CODE 4120–01–C

The numbers of cases in any of the MS–DRGs listed were minimal. Many of the MS–DRGs listed had no occurrences of procedure code 92.27. The highest number of cases found was 52, in MS–DRG 164 (Major Chest Procedures with CC). Based on these findings, we do not believe that making a MS–DRG change based on such a minimal number of cases can be justified. Therefore, we are proposing not to add procedure code 92.27 to any of the 41 MS–DRGs listed above. Further, we are not proposing any MS–DRG changes for procedure code 92.27. We welcome public comment on our proposal not to make changes to procedure code 92.27.

(2) Intraoperative Electron Radiation Therapy (IOERT)

| MS-DRG with Code 92.27 | | | | MS-DRG without Code 92.27 | | |
|---|---|---|---|---|---|---|
| DRG | Number of Cases | Average Length of Stay | Average Costs | Number of Cases | Average Length of Stay | Average Costs |
| 658 | 0 | 0 | 0 | 6,150 | 3.25 | $9,718 |
| 662 | 0 | 0 | 0 | 763 | 10.21 | $19,455 |
| 663 | 0 | 0 | 0 | 1,818 | 2.18 | $9,729 |
| 664 | 0 | 0 | 0 | 2,705 | 1.86 | $7,457 |
| 668 | 2 | 3.50 | $3,972 | 2,908 | 8.99 | $16,852 |
| 669 | 4 | 6.50 | $7,832 | 13,776 | 4.25 | $8,398 |
| 670 | 2 | 1.50 | $5,639 | 7,321 | 2.24 | $5,158 |
| 671 | 0 | 0 | 0 | 746 | 5.45 | $9,778 |
| 672 | 0 | 0 | 0 | 613 | 2.31 | $5,575 |
| 707 | 0 | 0 | 0 | 4,719 | 4.26 | $12,080 |
| 708 | 1 | 3.00 | $11,252 | 14,329 | 1.80 | $8,572 |
| 736 | 0 | 0 | 0 | 775 | 13.18 | $29,827 |
| 737 | 1 | 6.00 | $13,045 | 2,844 | 6.49 | $13,348 |
| 738 | 0 | 0 | 0 | 642 | 3.47 | $7,966 |
| 739 | 0 | 0 | 0 | 790 | 10.18 | $23,070 |
| 740 | 0 | 0 | 0 | 3,914 | 4.34 | $10,214 |
| 741 | 1 | 1.00 | $3,225 | 4,917 | 2.31 | $7,438 |
| 746 | 0 | 0 | 0 | 2,282 | 3.97 | $8,504 |
| 747 | 0 | 0 | 0 | 6,243 | 1.72 | $5,995 |
| 748 | 0 | 0 | 0 | 14,682 | 1.67 | $6,285 |
| 749 | 0 | 0 | 0 | 920 | 8.58 | $16,781 |
| 750 | 0 | 0 | 0 | 285 | 2.88 | $7,116 |

We received a public comment that was outside of the scope of the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for intraoperative electron radiation therapy (IOERT). This issue was discussed briefly in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128). However, we are addressing this issue in this FY 2012 proposed rule. IOERT is the direct application of radiation to a tumor and/or tumor bed while the patient is undergoing surgery for cancer. This technology may be used for cancers of the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. IOERT is a secondary procedure performed during the primary tumor removal surgery.

The commenter requested that CMS update the MS–DRG assignments for procedure code 92.41 (Intraoperative electron radiation therapy) to ensure that the cost of this technology is captured in each MS–DRG involving tumor removal in the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. Currently, this code is not assigned to a specific MS–DRG as the primary procedure performed, the tumor removal, would determine the appropriate MS–DRG assignment.

The commenter provided a recommended list of MS–DRGs to which IOERT should be assigned:

| MS-DRG | Description |
|---|---|
| 129 | Major Head and Neck Procedures with CC/MCC or Major Device |
| 130 | Major Head and Neck Procedures without CC/MCC |
| 133 | Other Ear, Nose, Mouth and Throat O,R, Procedures with CC/MCC |
| 134 | Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC |
| 163 | Major Chest Procedures with MCC |
| 164 | Major Chest Procedures with CC |
| 165 | Major Chest Procedures without CC/MCC |
| 166 | Other Respiratory System O.R. Procedures with MCC |
| 167 | Other Respiratory System O.R. Procedures with CC |
| 168 | Other Respiratory System O,R Procedures without CC/MCC |
| 326 | Stomach, Esophageal and Duodenal Procedures with MCC |
| 327 | Stomach, Esophageal and Duodenal Procedures with CC |
| 328 | Stomach, Esophageal and Duodenal Procedures without CC/MCC |
| 329 | Major Small and Large Bowel Procedures with MCC |
| 330 | Major Small and Large Bowel Procedures with CC |
| 331 | Major Small and Large Bowel Procedures without CC/MCC |
| 332 | Rectal Resection with MCC |
| 333 | Rectal Resection with CC |
| 334 | Rectal Resection without CC/MCC |
| 344 | Minor Small and Large Bowel Procedures with MCC |
| 345 | Minor Small and Large Bowel Procedures with CC |
| 346 | Minor Small and Large Bowel Procedures without CC/MCC |
| 347 | Anal and Stomal Procedures with MCC |
| 348 | Anal and Stomal Procedures with CC |
| 349 | Anal and Stomal Procedures without CC/MCC |
| 356 | Other Digestive System O.R. Procedures with MCC |
| 357 | Other Digestive System O.R. Procedures with CC |
| 358 | Other Digestive System O,R, Procedures without CC/MCC |
| 405 | Pancreas, Liver and Shunt Procedures with MCC |
| 406 | Pancreas, Liver and Shunt Procedures with CC |
| 407 | Pancreas, Liver and Shunt Procedures without CC/MCC |
| 490 | Back and Neck Procedures Except Spinal Fusion with CC/MCC |
| 491 | Back and Neck Procedures Except Spinal Fusion without CC/MCC |
| 500 | Soft Tissue Procedures with MCC |
| 501 | Soft Tissue Procedures with CC |
| 502 | Soft Tissue Procedures without CC/MCC |
| 579 | Other Skin, Subcutaneous Tissue and Breast Procedures with MCC |
| 580 | Other Skin, Subcutaneous Tissue and Breast Procedures with CC |
| 58 1 | Other Skin, Subcutaneous Tissue and Breast Procedures without CC/MCC |
| 584 | Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC |
| 585 | Breast Biopsy, Local Excision and Other Breast Procedures without |

| MS-DRG | Description |
|---|---|
| | CC/MCC |
| 653 | Major Bladder Procedures with MCC |
| 654 | Major Bladder Procedures with CC |
| 655 | Major Bladder Procedures without CC/MCC |
| 656 | Kidney and Ureter Procedures For Neoplasm with MCC |
| 657 | Kidney and Ureter Procedures For Neoplasm with CC |
| 658 | Kidney and Ureter Procedures for Neoplasm without MCC/CC |
| 662 | Minor Bladder Procedures with MCC |
| 663 | Minor Bladder Procedures with CC |
| 664 | Minor Bladder Procedures without CC/MCC |
| 668 | Transurethral Procedures with MCC |
| 669 | Transurethral Procedures with CC |
| 670 | Transurethral Procedures without CC/MCC |
| 671 | Urethral Procedures with CC/MCC |
| 672 | Urethral Procedures without CC/MCC |
| 707 | Major Male Pelvic Procedures with CC/MCC |
| 708 | Major Male Pelvic Procedures without CC/MCC |
| 715 | Other Male Reproductive System O.R. Procedures For Malignancy with CC/MCC |
| 716 | Other Male Reproductive System O.R. Procedures For Malignancy without CC/MCC |
| 736 | Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC |
| 737 | Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC |
| 738 | Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC |
| 739 | Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC |
| 740 | Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC |
| 741 | Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC |
| 746 | Vagina, Cervix and Vulva Procedures with CC/MCC |
| 747 | Vagina Cervix and Vulva Procedures without CC/MCC |
| 748 | Female Reproductive System Reconstructive Procedures |
| 749 | Other Female Reproductive System O.R. Procedures with CC/MCC |
| 750 | Other Female Reproductive System O.R. Procedures without CC/MCC |

BILLING CODE 4120–01–C

Based on our review of the FY 2010 MedPAR claims data, we found a total of 12 cases with procedure code 92.41 reported. There were three cases assigned to MS–DRG 502; two cases each assigned to two different MS–DRGs: MS–DRG 333 and MS–DRG 501; and one case assigned each to five MS–DRGs: MS–DRGs 130, 168, 327, 329, and 330.

The IOERT cases were assigned to an MS–DRG that included the tumor removal of that particular site, which was listed on the table above. Therefore, the cost of this technology is appropriately identified in the MS–DRG assignment for the removal of the tumor by specific site, and no change is warranted at this time. Therefore, we are not proposing any changes to the assignment for IOERT cases. We invite public comment on our proposal to not change the assignment for IOERT cases for FY 2012.

b. IPPS Recalled Device Policy Clarification

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we would reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit equal to 50 percent or more of the cost of the device when a manufacturer provided a credit for a recalled device.

A similar policy was adopted under the Outpatient Prospective Payment System (OPPS) in CY 2008 (the "partial credit" policy). This policy can be viewed in its entirety at 72 FR 66743 though 66748. In general terms, under the partial credit policy, CMS reduces the amount of payment for an implanted device made under the OPPS for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device when the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

It has come to our attention that there is a discrepancy between the IPPS policy and the OPPS partial credit policy for replacement devices. In particular, the OPPS partial credit policy specifies that the credit must be 50 percent or greater of the cost of the replacement device. However, the IPPS policy does not specify whether the credit should be 50 percent or greater of the replacement device or the original device. We believe that the OPPS partial credit policy and the IPPS policy should be consistent with each other on the issue of whether the 50 percent or more credit is with respect to the replacement device or the original device. Therefore, we are proposing to clarify the IPPS policy to state that the policy applies where "the hospital received a credit equal to 50 percent or more of the cost of the replacement device." We invite public comment on this proposal.

*H. Recalibration of MS–DRG Weights*

In developing the proposed FY 2012 system of weights, we used two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2010 MedPAR data used in this proposed rule include discharges occurring on October 1, 2009, through September 30, 2010, based on bills received by CMS through December 31, 2010, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2010 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,814,950 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR "GHO Paid" indicator field on the claim record is equal to "1" or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR "Indirect Medical Education (IME)" payment field, indicating that the claim was an "IME only" claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the FY 2009 Medicare cost report data files from HCRIS (that is, cost reports beginning on or after October 1, 2008, and before October 1, 2009), which represents the most recent full set of cost report data available. We used the December 31, 2010 update of the HCRIS cost report files for FY 2009 in setting the relative cost-based weights.

The methodology we used to calculate the DRG cost-based relative weights from the FY 2010 MedPAR claims data and FY 2009 Medicare cost report data is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2012 MS–DRG classifications discussed in sections II.B. and G. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2010 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.
- At least 96.2 percent of the providers in the MedPAR file had charges for 10 of the 15 cost centers. Claims for providers that did not have charges greater than zero for at least 10 of the 15 cost centers were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA

indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to "Y" for "Yes" for all claims that otherwise have an "N" (No) or a "U" (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a "Y" indicator is associated with the diagnosis on the claim), then it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an "N" indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HACs are likely to be higher as well. Thus, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to "Y" only for relative weight-setting purposes for all claims that otherwise have a "N" or an "U" in the POA field. This resetting "forced" the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 15 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 15 cost groups so that each MS–DRG had 15 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2009 cost report data.

The 15 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 15 national cost center CCRs.

BILLING CODE 4120–01–P

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| Routine Days | Private Room Charges | 011X and 014X | | Adults & Pediatrics (General Routine Care) | C_1_C5_25 | C_1_C6_25 | D4_HOS_C2_25 |
| | Semi-Private Room Charges | 010X, 012X, 013X and 016X-019X | | | | C_1_C7_25 | D4_HOS_C2_26 |
| | Ward Charges | 015X | | | | | |
| | | | | | | | |
| Intensive Days | Intensive Care Charges | 020X | | Intensive Care Unit | C_1_C5_26 | C_1_C6_26 | D4_HOS_C2_26 |
| | | | | | | C_1_C7_26 | |
| | Coronary Care Charges | 021X | | Coronary Care Unit | C_1_C5_27 | C_1_C6_27 | D4_HOS_C2_27 |
| | | | | | | C_1_C7_27 | |
| | | | | Burn Intensive Care Unit | C_1_C5_28 | C_1_C6_28 | D4_HOS_C2_28 |
| | | | | | | C_1_C7_28 | |
| | | | | Surgical Intensive Care Unit | C_1_C5_29 | C_1_C6_29 | D4_HOS_C2_29 |
| | | | | | | C_1_C7_29 | |
| | | | | Other Special Care Unit | C_1_C5_30 | C_1_C6_30 | D4_HOS_C2_30 |
| | | | | | | C_1_C7_30 | |
| | | | | | | | |
| Drugs | Pharmacy Charges | 025X, 026X and 063X | | Intravenous Therapy | C_1_C5_48 | C_1_C6_48 | D4_HOS_C2_48 |

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| | | | | | | C_1_C7_48 | |
| | | | | Drugs Charged To Patient | C_1_C5_56 | C_1_C6_56 | D4_HOS_C2_56 |
| | | | | | | C_1_C7_56 | |
| | | | | | | | |
| Supplies and Equipment | Medical/Surgical Supply Charges | 027X and 062X | | Medical Supplies Charged to Patients | C_1_C5_55 | C_1_C6_55 | D4_HOS_C2_55 |
| | | | | | | C_1_C7_55 | |
| | Durable Medical Equipment Charges | 0290, 0291, 0292 and 0294-0299 | | DME-Rented | C_1_C5_66 | C_1_C6_66 | D4_HOS_C2_66 |
| | | | | | | C_1_C7_66 | |
| | Used Durable Medical Charges | 0293 | | DME-Sold | C_1_C5_67 | C_1_C6_67 | D4_HOS_C2_67 |
| | | | | | | C_1_C7_67 | |
| | | | | | | | |
| Therapy Services | Physical Therapy Charges | 042X | | Physical Therapy | C_1_C5_50 | C_1_C6_50 | D4_HOS_C2_50 |
| | | | | | | C_1_C7_50 | |
| | Occupational Therapy Charges | 043X | | Occupational Therapy | C_1_C5_51 | C_1_C6_51 | D4_HOS_C2_51 |
| | | | | | | C_1_C7_51 | |
| | Speech Pathology Charges | 044X and 047X | | Speech Pathology | C_1_C5_52 | C_1_C6_52 | D4_HOS_C2_52 |
| | | | | | | C_1_C7_52 | |

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| Inhalation Therapy | Inhalation Therapy Charges | 041X and 046X | | Respiratory Therapy | C_1_C5_49 | C_1_C6_49 | D4_HOS_C2_49 |
| | | | | | | C_1_C7_49 | |
| | | | | | | | |
| Operating Room | Operating Room Charges | 036X, 071X and 072X | | Operating Room | C_1_C5_37 | C_1_C6_37 | D4_HOS_C2_37 |
| For all DRGs but Labor & Delivery | | | | | | C_1_C7_37 | |
| | | | | Recovery Room | C_1_C5_38 | C_1_C6_38 | D4_HOS_C2_38 |
| | | | | | | C_1_C7_38 | |
| | | | | | | | |
| Labor & Delivery | Operating Room Charges | 036X, 071X and 072X | | Delivery Room and Labor Room | C_1_C5_39 | C_1_C6_39 | D4_HOS_C2_39 |
| **ONLY FOR THE 6 Labor & Delivery DRGs** | | | | | | C_1_C7_39 | |
| **370, 371, 372, 373, 374, 375** | Clinic Charges | 051X | | Obstetrics Clinic | C_1_C5_63 | C_1_C6_63 | D4_HOS_C2_63 |
| | | | | | | C_1_C7_63 | |
| | | | | | | | |
| Anesthesia | Anesthesia Charges | 037X | | Anesthesi-ology | C_1_C5_40 | C_1_C6_40 | D4_HOS_C2_40 |
| | | | | | | C_1_C7_40 | |
| | | | | | | | |

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| Cardiology | Cardiology Charges | 048X and 073X | | Electro-cardiology | C_1_C5_53 | C_1_C6_53 | D4_HOS_C2_53 |
| | | | | | | C_1_C7_53 | |
| | | | | | | | |
| Laboratory | Laboratory Charges | 030X, 031X, 074X and 075X | | Laboratory | C_1_C5_44 | C_1_C6_44 | D4_HOS_C2_44 |
| | | | | | | C_1_C7_44 | |
| | | | | PBP Clinic Laboratory Services | C_1_C5_45 | C_1_C6_45 | D4_HOS_C2_45 |
| | | | | | | C_1_C7_45 | |
| | | | | Electro-encep halography | C_1_C5_54 | C_1_C6_54 | D4_HOS_C2_54 |
| | | | | | | C_1_C7_54 | |
| | | | | | | | |
| Radiology | Radiology Charges | 028X, 032X, 033X, 034X, 035X and 040X | | Radiology - Diagnostic | C_1_C5_41 | C_1_C6_41 | D4_HOS_C2_41 |
| | | | | | | C_1_C7_41 | |
| | | | | | | | |
| | MRI Charges | 061X | | Radiology - Therapeutic | C_1_C5_42 | C_1_C6_42 | D4_HOS_C2_42 |
| | | | | Radioisotope | C_1_C5_43 | C_1_C6_43 | D4_HOS_C2_43 |
| | | | | | | C_1_C7_43 | |
| | | | | | | | |

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| Emergency Room | Emergency Room Charges | 045x | | Emergency | C_1_C5_61 | C_1_C6_61 | D4_HOS_C2_61 |
| | | | | | | C_1_C7_61 | |
| Blood and Blood Products | Blood Charges | 038x | | Whole Blood & Packed Red Blood Cells | C_1_C5_46 | C_1_C6_46 | D4_HOS_C2_46 |
| | | | | | | C_1_C7_46 | |
| | Blood Storage / Processing | 039x | | Blood Storing, Processing, & Transfusing | C_1_C5_47 | C_1_C6_47 | D4_HOS_C2_47 |
| | | | | | | C_1_C7_47 | |
| Other Services | Lithotripsy Charge | 079X | | | | | |
| | | | | | | | |
| | Other Service Charge | 0002-0099, 022X, 023X, 024X,052X,053X | | | | | |
| | | 055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X | | | | | |
| | | | | ASC (Non Distinct Part) | C_1_C5_58 | C_1_C6_58 | D4_HOS_C2_58 |
| | | | | | | C_1_C7_58 | |
| | Outpatient Service Charges | 049X and 050X | | Other Ancillary | C_1_C5_59 | C_1_C6_59 | D4_HOS_C2_59 |
| | | | | | | C_1_C7_59 | |
| | | | | Clinic | C_1_C5_60 | C_1_C6_60 | D4_HOS_C2_60 |
| | | | | | | C_1_C7_60 | |
| | Ambulance Charges | 054X | | | | | |

| Cost Center Group Name (15 total) | MedPAR Charge Field | Revenue Codes contained in MedPAR Charge Field | | Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4) | Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) | Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) | Medicare Charges from HCRIS (Worksheet D-4, Column & line number) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | ESRD Revenue Setting Charges | 080X and 082X-088X | | Observation beds | C_1_C5_62 | C_1_C6_62 | D4_HOS_C2_62 |
| | | | | | | C_1_C7_62 | |
| | Clinic Visit Charges | 051X | | Observation beds | C_1_C5_6201 | C_1_C6_6201 | D4_HOS_C2_6201 |
| | (excluding Labor & Delivery DRGs) | | | | | C_1_C7_6201 | |
| | | | | Rural Health Clinic | C_1_C5_6350 | C_1_C6_6350 | D4_HOS_C2_6350 |
| | Professional Fees Charges | 096X, 097X, and 098X | | | | C_1_C7_6350 | |
| | | | | FQHC | C_1_C5_6360 | C_1_C6_6360 | D4_HOS_C2_6360 |
| | | | | | | C_1_C7_6360 | |
| | | | | Home Program Dialysis | C_1_C5_64 | C_1_C6_64 | D4_HOS_C2_64 |
| | | | | | | C_1_C7_64 | |
| | | | | Ambulance | C_1_C5_65 | C_1_C6_65 | D4_HOS_C2_65 |
| | | | | | | C_1_C7_65 | |
| | | | | Other Reimbursable | C_1_C5_68 | C_1_C6_68 | D4_HOS_C2_68 |
| | | | | | | C_1_C7_68 | |

BILLING CODE 4120–01–C

We developed the national average CCRs as follows:

Taking the FY 2009 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland as we are including their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–4 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–4. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 15 cost centers by the corresponding national average CCR, we summed the 15 "costs" across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The new cost-based relative weights were then normalized by an adjustment factor of 1.5798292955 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 15 proposed national average CCRs for FY 2012 are as follows:

| Group | CCR |
|---|---|
| Routine Days | 0.514 |
| Intensive Days | 0.448 |
| Drugs | 0.199 |
| Supplies & Equipment | 0.331 |
| Therapy Services | 0.381 |
| Laboratory | 0.145 |
| Operating Room | 0.251 |
| Cardiology | 0.154 |
| Radiology | 0.140 |
| Emergency Room | 0.239 |
| Blood and Blood Products | 0.408 |
| Other Services | 0.395 |
| Labor & Delivery | 0.470 |
| Inhalation Therapy | 0.192 |
| Anesthesia | 0.117 |

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In this FY 2012 IPPS/LTCH PPS proposed rule, we are proposing to use that same case threshold in recalibrating the MS–DRG weights for FY 2012. Using the FY 2010 MedPAR data set, there are 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients age 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients age 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have heard frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed below are for newborns. In FY 2012, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS–DRGs, we are

proposing to compute weights for the low-volume MS–DRGs by adjusting their FY 2011 weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown below:

| Low-Volume MS-DRG | MS-DRG Title | Crosswalk to MS-DRG |
|---|---|---|
| 768 | Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 789 | Neonates, Died or Transferred to Another Acute Care Facility | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 790 | Extreme Immaturity or Respiratory Distress Syndrome, Neonate | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 791 | Prematurity with Major Problems | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 792 | Prematurity without Major Problems | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 793 | Full-Term Neonate with Major Problems | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 794 | Neonate with Other Significant Problems | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 795 | Normal Newborn | FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |

*I. Proposed Add-On Payments for New Services and Technologies*

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." We note that beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations implementing these provisions specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. These

three criteria are explained below in the ensuing paragraphs in further detail.

Under the first criterion, as reflected in 42 CFR 412.87(b)(2), a specific medical service or technology will be considered "new" for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. Typically, there is a lag of 2 to 3 years from the point a new medical service or technology is first introduced on the market (generally on the date that the technology receives FDA approval/clearance) and when data reflecting the use of the medical service or technology are used to calculate the MS–DRG weights. For example, data from discharges occurring during FY 2010 are used to calculate the FY 2012 MS–DRG weights in this proposed rule. Section 412.87(b)(2) of the regulations therefore provides that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). After CMS has recalibrated the MS–DRGs, based on available data to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section."

The 2-year to 3-year period during which a medical service or technology can be considered new would ordinarily begin on the date on which the medical service or technology received FDA approval or clearance. (We note that, for purposes of this section of this proposed rule, we generally refer to both FDA approval and FDA clearance as FDA "approval.") However, in some cases, there may be few to no Medicare data available for the new service or technology following FDA approval. For example, the newness period could extend beyond the 2-year to 3-year period after FDA approval is received in cases where the product initially was generally unavailable to Medicare patients following FDA approval, such as in cases of a national noncoverage determination or a documented delay in bringing the product onto the market after that approval (for instance, component production or drug production has been postponed following FDA approval due to shelf life concerns or manufacturing issues). After the MS–DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the medical service or technology is no longer eligible for special add-on payment for new medical services or technologies (as specified under § 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2009 and entered the market at that time may be eligible to receive add-on payments as a new technology for discharges occurring before October 1, 2012 (the start of FY 2013). Because the FY 2013 MS–DRG weights would be calculated using FY 2011 MedPAR data, the costs of such a new technology would be fully reflected in the FY 2013 MS–DRG weights. Therefore, the new technology would no longer be eligible to receive add-on payments as a new technology for discharges occurring in FY 2013 and thereafter.

We do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351), we explained our policy regarding substantial similarity in detail and its relevance for assessing if the hospital charge data used in the development of the relative weights for the relevant DRGs reflect the costs of the technology. In that final rule, we stated that, for determining substantial similarity, we consider (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, and (2) whether a product is assigned to the same or a different DRG. We indicated that both of the above criteria should be met in order for a technology to be considered "substantially similar" to an existing technology. However, in that same final rule, we also noted that, due to the complexity of issues regarding the substantial similarity component of the newness criterion, it may be necessary to exercise flexibility when considering whether technologies are substantially similar to one another. Specifically, we stated that we may consider additional factors, depending on the circumstances specific to each application.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we noted that the discussion of substantial similarity in the FY 2006 IPPS final rule related to comparing two separate technologies made by different manufacturers. Nevertheless, we stated that the criteria discussed in the FY 2006 IPPS final rule also are relevant when comparing the similarity between a new use and existing uses of the same technology (or a very similar technology manufactured by the same manufacturer). In other words, we stated that it is necessary to establish that the new indication for which the technology has received FDA approval is not substantially similar to that of the prior indication. We explained that such a distinction is necessary to determine the appropriate start date of the newness period in evaluating whether the technology would qualify for add-on payments (that is, the date of the "new" FDA approval or that of the prior approval), or whether the technology could qualify for separate new technology add-on payments under each indication.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43814), we added a third factor of consideration to our analysis of whether a new technology is substantially similar to one or more existing technologies. Specifically, in making a determination of whether a technology is substantially similar to an existing technology, we adopted a policy to consider whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population (74 FR 24130), in addition to considering the already established factors described in the FY 2006 IPPS final rule (that is, (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and (2) whether a product is assigned to the same or a different DRG). As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, if all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology (that is, beyond the newness period), we would conclude that the technology is not new and, therefore, is ineligible for the new technology add-on payment.

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold

amounts. In the FY 2004 IPPS final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the MS–DRG plus 75 percent of 1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and converted back to charges) for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs, if the new medical service or technology occurs in more than one MS–DRG).

However, section 503(b)(1) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide that, beginning in FY 2005, CMS will apply "a threshold * * * that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved." (We refer readers to section IV.D. of the preamble to the FY 2005 IPPS final rule (69 FR 49084) for a discussion of the revision of the regulations to incorporate the change made by section 503(b)(1) of Pub. L. 108–173.) Table 10 that was included in the IPPS/LTCH PPS final rule published in the **Federal Register** on August 16, 2010, contained the final thresholds that were used to evaluate applications for new technology add-on payments for this proposed rule for FY 2012 (75 FR 50605 through 50613).

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR Parts 160 and 164 applies to claims information that providers submit with applications for new technology add-on payments. Specifically, we explained that health plans, including Medicare, and providers that conduct certain transactions electronically, including hospitals that would receive new technology add-on payments, are required to comply with the HIPAA Privacy Rule. We further explained how such entities could meet the applicable HIPAA requirements by discussing how the HIPAA Privacy Rule permitted providers to share with health plans information needed to ensure correct payment, if they had obtained consent from the patient to use that patient's data for treatment, payment, or health care operations. We also explained that, because the information to be provided within applications for new technology add-on payment would be needed to ensure correct payment, no additional consent would be required. The HHS Office for Civil Rights has since amended the HIPAA Privacy Rule, but the results remain. The HIPAA Privacy Rule does not require a covered entity to obtain consent from patients to use or disclose protected health information for the covered entity's treatment, payment, or health care operations purposes, and expressly permits such entities to use or to disclose protected health information for these purposes and for the treatment purposes of another health care provider and the payment purposes of another covered entity or health care provider. (We refer readers to 45 CFR 164.502(a)(1)(ii) and 164.506(c)(1) and (c)(3) and the Standards for Privacy of Individually Identifiable Health Information published in the **Federal Register** (67 FR 53208 through 53214) on August 14, 2002, for a full discussion of consent in the context of the HIPAA Privacy Rule.)

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a complete discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost to charge ratios ("CCRs") as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology.

Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual MS–DRG classifications and relative weights be made in a manner that ensures that aggregate payments to hospitals are not more or less than they were in the prior fiscal year (i.e., they are "budget neutral"). Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year, while at the same time estimating the payment effect of changes to the MS–DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts. However, section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criteria, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other

entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Office of Clinical Standards and Quality (OCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, OCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

CMS plans to continue its Open Door forums with stakeholders who are interested in CTI's initiatives. In addition, to improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an "Innovator's Guide" to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in August 2008 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2013 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2013, the Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2012 prior to publication of the FY 2012 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 29, 2010 (75 FR 73091 through 73094), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 2, 2011. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2012 new medical service and technology add-on payment applications before the publication of the FY 2012 proposed rule.

Approximately 50 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Each of the three FY 2012 applicants presented information on its technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications, in our evaluation of the new technology add-on applications for FY 2012 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received three written comments regarding applications for FY 2012 new technology add-on payments. We summarize these comments or, if applicable, indicate that there were no comments received, at the end of each discussion of the individual applications in this proposed rule.

*Comment:* A number of attendees at the new technology town hall meeting provided comments that were unrelated to "substantial clinical improvement."

*Response:* As explained above and in the **Federal Register** notice announcing the meeting (75 FR 73091), the purpose of the new technology town hall meeting was specifically to discuss substantial clinical improvement of pending new technology applications for FY 2012. Therefore, we are not summarizing those comments in this proposed rule. Commenters are welcome to resubmit these comments in

response to proposals in this proposed rule.

*Comment:* One commenter, a major device association, requested that CMS provide more flexibility for the substantial clinical improvement criteria by allowing new technologies to demonstrate a substantial likelihood that clinical improvement will result. The commenter believed that this request was not unreasonable, given the fact that conclusive evidence would not necessarily be available in the short period of time for which an add-on payment would be available. The commenter also suggested that CMS consider a broader range of evidence in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology.

*Response:* As stated in the 2001 new technology add-on payment final rule (66 FR 46913), we believe that the "substantial clinical improvement" criterion is intended "to limit these special payments for those technologies that afford clear improvements over the use of previously available technologies." We believe that special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial clinical improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. If such an improvement is not demonstrated, we continue to believe the incentives of the MS–DRG system provide a useful balance to the introduction of new technologies. In that regard, we point out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We believe it is in the best interest of Medicare beneficiaries for CMS to proceed carefully with respect to the incentives created to quickly adopt new technologies.

With respect to the comment that CMS should consider a broader range of evidence in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology, we accept different types of data (for example, peer-reviewed articles, study results, or letters from major associations, among others) that demonstrate and support the substantial clinical improvement associated with the new technology. In addition to clinical data, we will consider any evidence that would support the substantial clinical improvement associated with a new technology. Therefore, we believe we already consider an appropriate range of evidence as the commenter has requested.

*Comment:* One commenter stated that, while it appreciated that new technology add-on payments are intended to encourage innovation, CMS' application of the substantial clinical improvement criterion fails to account for how many technological advances may occur in practice. The commenter expressed confidence that many recent design improvements in medical devices represent significant advances in clinical utility of older/established technologies, and indicated CMS may fail to recognize these improvements in the current context of applying add-on payments.

*Response:* As discussed above, a service or technology is not "new" for purposes of the new technology add-on payment if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. To determine substantial similarity, we consider (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, (2) whether a product is assigned to the same or a different DRG and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), if all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology (that is, beyond the newness period), we would conclude that the technology is not new and, therefore, is ineligible for the new technology add-on payment. A complete discussion of the substantial similarity criteria and policy can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814)

*Comment:* One commenter believed that CMS has narrowly interpreted the statutory criteria for granting new technology add-on payments, which has created a situation in which it has become increasingly difficult for new technologies to qualify for this add-on payment. The commenter asserted that the criteria are so steep and the process so opaque that many companies, especially small companies, cannot afford to undertake the process at all. The commenter recommended that CMS continue to engage stakeholders to improve the new technology add-on payment process. The commenter also recommended that CMS consider creating additional guidance to further clarify the requirements as to what qualifies as a new technology. The commenter believed that additional guidance could provide greater certainty and predictability for many companies developing novel technologies.

*Response:* We believe it is important to maintain an open dialogue on the IPPS new technology add-on payment process, as well as the broader issue of how new technology is introduced into all of the Medicare payment systems. As announced in a notice published in the **Federal Register** (75 FR 73091 through 73094), on February 2, 2011, prior to the new technology town hall meeting, we held an informational workshop for the general public that gave an overview on the processes of the new technology provisions in both the inpatient hospital and outpatient hospital settings, in addition to the procedures involved with ICD–9–CM coding and MS–DRG reassignment under the IPPS. We believe that our annual new technology town hall meeting and rulemaking process (including the posting of the applicants' tracking forms on the CMS Web site) allow for an ongoing dialogue between CMS and the public on the new technology add-on payment process. Furthermore, we are willing to meet with potential applicants prior to and after an application has been submitted in order to ensure an application meets the submission requirements and to provide technical feedback on an applicant's application.

In reference to the commenter's general statement that CMS' interpretation of the statutory criteria has been narrowly cited, we are interested in and welcome comment on any specific criteria or data quality standards that commenters believe we should adopt to improve the new technology add-on application process, or any concerns or challenges that commenters believe we may encounter in undertaking this effort. Again, as we stated at the new technology town hall meeting, we are interested in working with stakeholders to improve the inpatient new technology add-on payment process. We are interested in ensuring that the latest medical technology that improves care for the Medicare patient population continues to be available to our beneficiaries. In addition, we invite potential applicants to contact CMS with any specific questions or concerns they may have prior to the submission of their

application for new technology add-on payment.

3. FY 2012 Status of Technologies Approved for FY 2011 Add-On Payments

a. Spiration® IBV® Valve System

Spiration, Inc. submitted an application for new technology add-on payments for the Spiration® IBV® Valve System (Spiration® IBV®). The Spiration® IBV® is a device that is used to place, via bronchoscopy, small, one-way valves into selected small airways in the lung in order to limit airflow into selected portions of lung tissue that have prolonged air leaks following surgery while still allowing mucus, fluids, and air to exit, thereby reducing the amount of air that enters the pleural space. The device is intended to control prolonged air leaks following three specific surgical procedures: Lobectomy; segmentectomy; or lung volume reduction surgery (LVRS). According to the applicant, an air leak that is present on postoperative day 7 is considered "prolonged" unless present only during forced exhalation or cough. In order to help prevent valve migration, there are five anchors with tips that secure the valve to the airway. The implanted valves are intended to be removed no later than 6 weeks after implantation.

With regard to the newness criterion, the Spiration® IBV® received a HDE approval from the FDA on October 24, 2008. We were unaware of any previously FDA-approved predicate devices, or otherwise similar devices, that could be considered substantially similar to the Spiration® IBV®. However, the applicant asserted that the FDA had precluded the device from being used in the treatment of any patients until the Institutional Review Board (IRB) granted approvals regarding its study sites. Therefore, the Spiration® IBV® met the newness criterion once it obtained at least one IRB approval because the device would then be available on the market to treat Medicare beneficiaries. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43819), the applicant stated that the first IRB approval for the Spiration® IBV® was March 12, 2009. In that final rule, based on the information above from the applicant, we determined that the Spiration® IBV® meets the newness criterion and the newness period for the Spiration® IBV® begins on March 12, 2009.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the Spiration® IBV® and consideration of the public comments we received in response to the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the Spiration® IBV® for new technology add-on payments for FY 2010 with a maximum add-on payment of $3,437.50.

In the FY 2011 IPPS/LTCH PPS proposed rule, we did not propose any changes to the new technology add-on payments for the Spiration® IBV®. We did not receive any public comments on whether to continue or discontinue the new technology add-on payment for the Spiration® IBV® for FY 2011. Therefore, for FY 2011, we continued new technology add-on payments for cases involving the Spiration® IBV® in FY 2011, with a maximum add-on payment of $3,437.50.

The new technology add-on payment regulations provide that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology" (42 CFR 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). With regard to the newness criterion for the Spiration® IBV®, as stated above, we consider the beginning of the newness period for the device to have commenced on the date of the first IRB approval for the Spiration® IBV®, which was March 12, 2009. For FY 2012, as of March 12, 2012, the Spiration® IBV® will have been on the market for 3 years, and is therefore no longer considered "new" as of March 12, 2012. Because the 3-year anniversary date of the Spiration® IBV®'s entry onto the market will occur in the first half of the fiscal year, we are proposing to discontinue its new technology add-on payment for FY 2012.

b. CardioWest™ Temporary Total Artificial Heart System (CardioWest™ TAH-t)

SynCardia Systems, Inc. submitted an application for approval of the CardioWest™ Temporary Total Artificial Heart System (TAH-t) in FY 2009. The TAH-t is a technology that is used as a bridge to heart transplant device for heart transplant-eligible patients with end-stage biventricular failure. The TAH-t pumps up to 9.5 liters of blood per minute. This high level of perfusion helps improve hemodynamic function in patients, thus making them better heart transplant candidates.

The TAH-t was approved by the FDA on October 15, 2004, for use as a bridge to transplant device in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The TAH-t is intended to be used in hospital inpatients. One of the FDA's post-approval requirements is that the manufacturer agrees to provide a post-approval study demonstrating that success of the device at one center can be reproduced at other centers. The study was to include at least 50 patients who would be followed up to 1 year, including (but not limited to) the following endpoints: Survival to transplant; adverse events; and device malfunction.

In the past, Medicare did not cover artificial heart devices, including the TAH-t. However, on May 1, 2008, CMS issued a final national coverage determination (NCD) expanding Medicare coverage of artificial hearts when they are implanted as part of a study that is approved by the FDA and is determined by CMS to meet CMS' Coverage with Evidence Development (CED) clinical research criteria. (The final NCD is available on the CMS Web site at: *http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=211*.)

We indicated in the FY 2009 IPPS final rule (73 FR 48555) that, because Medicare's previous coverage policy with respect to this device had precluded payment from Medicare, we did not expect the costs associated with this technology to be currently reflected in the data used to determine the relative weights of MS–DRGs. As we have indicated in the past, and as we discussed in the FY 2009 IPPS final rule, although we generally believe that the newness period would begin on the date that FDA approval was granted, in cases where the applicant can demonstrate a documented delay in market availability subsequent to FDA approval, we would consider delaying the start of the newness period. This technology's situation represented such a case. We also noted that section 1886(d)(5)(K)(ii)(II) of the Act requires that we provide for the collection of cost data for a new medical service or technology for a period of at least 2 years and no more than 3 years "beginning on the date on which an inpatient hospital code is issued with

respect to the service or technology." Furthermore, the statute specifies that the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under the IPPS and includes ICD–9–CM codes and any subsequent revisions. Although the TAH-t has been described by the ICD–9–CM code(s) since the time of its FDA approval, because the TAH-t had not been covered under the Medicare program (and, therefore, no Medicare payment had been made for this technology), this code could not be "used with respect to inpatient hospital services for which payment" is made under the IPPS, and thus we assumed that none of the costs associated with this technology would be reflected in the Medicare claims data used to recalibrate the MS–DRG relative weights for FY 2009. For this reason, as discussed in the FY 2009 IPPS final rule, despite the FDA approval date of the technology, we determined that TAH-t would still be eligible to be considered "new" for purposes of the new technology add-on payment because the TAH-t met the newness criterion on the date that Medicare coverage began, consistent with issuance of the final NCD, effective on May 1, 2008.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the TAH-t and consideration of the public comments we received in response to the FY 2009 IPPS proposed rule, we approved the TAH-t for new technology add-on payments for FY 2009 (73 FR 48557). We also continued to make new technology add-on payments for the TAH-t in FY 2010 and FY 2011.

We describe the new technology add-on payment requirements with regard to newness above. With regard to the newness criterion for the TAH-t, as stated above, we consider the beginning of the newness period for the device to have commenced from the Medicare NCD date of May 1, 2008; it is no longer considered new as of May 11, 2011. Because the 3-year anniversary date of the TAH-t will occur prior to the start of FY 2012, we are proposing to discontinue the new technology add-on payment for the TAH-t in FY 2012.

c. Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. The technology can be identified by ICD–9–CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which became effective on October 1, 2009.

The AutoLITT™ received a 510K FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain (GBM) tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. The applicant explained that it was necessary to reduce the thermal damage lines from three to one and complete International Electrotechnical Commission/ Underwriter Laboratory testing, which led to the introduction of the technology to the market in December 2009, although the technology was approved by FDA in May 2009. The applicant also stated through supplementary information to its application that the first sale of the product took place on March 19, 2010. However, because the product was already available for use in December 2009, it appears that the newness date would begin in December 2009. In the FY 2011 IPPS/LTCH PPS proposed rule, we welcomed public comments on this issue.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/RY 2011 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of Glioblastoma Multiforme. Therefore, we limited the new technology add-on payment to cases involving the AutoLITT™ in MS–DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS–DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a primary diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS–DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS–DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS–DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

The average cost of the AutoLITT™ is reported as $10,600 per case. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the AutoLITT™ is $5,300.

We describe the new technology add-on payment requirements with regard to newness above. With regard to the newness criterion for the AutoLITT™, as stated above, we consider the beginning of the newness period for the device to commence from the market release date of December 2009. Therefore, the device will be considered "new" until December 2012. Because the 3-year anniversary date for the AutoLITT™ will occur after FY 2012, we are proposing to continue to make new technology add-on payments for the AutoLITT™ in FY 2012.

4. FY 2012 Applications for New Technology Add-On Payments

a. AxiaLIF® 2L+™ System

TranS1 submitted an application for new technology add-on payments for the AxiaLIF® 2L+™ System for FY 2012. The AxiaLIF® 2L+™ System is an implantable spinal fixation system, delivered through a pre-sacral approach, facilitating spinal fusion through axial stabilization of the anterior lumbar spine at Lumbar vertebrae 4 through Sacral vertebrae 1 (L4–S1).

The AxiaLIF® 2L+™ System received 510K FDA clearance (K092124) on January 21, 2010, and the applicant asserts that the device was available on the market immediately afterward through a limited market release program. The AxiaLIF® 2L+™ System is indicated for use to provide anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. It is also indicated for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of L4–S1 interbody fusion. The AxiaLIF® 2L+™ System may be used in patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® 2L+™ System is coded using ICD–9–CM procedure code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

With regard to the newness criterion, we are concerned that the AxiaLIF® 2L+™ System may be substantially similar to the other devices manufactured by the applicant, AxiaLIF® System and AxiaLIF® II™ System, the latter of which is listed as the predicate device on the AxiaLIF® 2L+™ System's application for FDA approval. Specifically, in making a determination of substantial similarity, we consider the following: (1) Whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or different DRG; and (3) whether the new use of a technology involves the treatment of the same or similar type of disease and the same or similar patient population.

We are particularly concerned that the AxiaLIF® 2L+™ System uses the same or similar mechanism of action as the AxiaLIF® II™ System to achieve a therapeutic outcome. According to the applicant's 510K summary submitted to the FDA (K073514), the AxiaLIF® System is a multicomponent system including titanium alloy implantable devices and instrumentation for creating a pre-sacral axial track to the L5–S1 disk space. Similarly, the AxiaLIF® II™ System is described in the applicant's 510K summary submitted to the FDA (K073643) as a system of medical grade titanium alloy for the anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. The applicant states that the AxiaLIF® 2L+™ System was created from the AxiaLIF® II™ System platform. The applicant submitted the following to distinguish the AxiaLIF® 2L+™ System from the AxiaLIF® II™ System:

- There have been internal thread changes for the 2L+ implant to accompany the Spanning Distraction Rod, which is designed to create and hold distraction in the L5–S1 disc space and allow for a higher degree of control over the Rod advancement and distraction;
- The design enhancements in the 2L+ System remove the dependence of distraction on size and placement of the S1 Rod, thus allowing precise implant placement in the vertebral bodies;
- In the 2L+ Implant, the L4 section of the L4–L5 Rod incorporates a conical design to increase fixation. The outer diameter (O.D.) of the L5 section is increased to be identical to the O.D. of the S1 implant to provide more surface area bone contact;
- The 2L+ Instrumentation incorporates Dilator Trials as an opportunity to enhance and simplify the intraoperative measuring technique by providing a direct visual means of measurement; and
- The 2L+ Fixation Rod fills the cannulation to prevent graft from moving into the rod from the disc space. The Fixation Rod also fixates the S1 Anchor and L4–L5 Rod together such that these components cannot passively separate.

Based on indications for use listed by the FDA for the AxiaLIF® System (K073514), the AxiaLIF® II™ System (K073643), and the AxiaLIF® 2L+™ System (as described above), we also are concerned that all of these devices involve the treatment of the same or similar type of disease and the same or similar patient population. With respect to whether a product is assigned to the same or different DRG, we note that currently the AxiaLIF® System and the AxiaLIF® 2L+™ System both generally map to MS–DRGs 459 (Spinal Fusion Except Cervical with MCC) and 460 (Spinal Fusion Except Cervical without MCC). Though the AxiaLIF® II™ System is no longer on the market, it would also map to the same DRGs.

If the AxiaLIF® 2L+™ System is found to be substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System, the AxiaLIF® 2L+™ System would no longer qualify for the new technology add-on payment. Specifically, the appropriate start date for the AxiaLIF® 2L+™ System would be the start date of the device that is found to be substantially similar to the AxiaLIF® 2L+™ System. As noted above, the AxiaLIF® II™ System received FDA approval on April 28, 2008. The 3-year newness period for the AxiaLIF® II™ System ends prior to the start of FY 2012 (July 28, 2011). Given the length of time since the AxiaLIF® II™ System's entry into the market, cost-related data for the AxiaLIF® II™ System is already reflected in the most recent MS–DRG relative weights. Additionally, the AxiaLIF® System received multiple FDA approvals, the most recent of which was on January 11, 2008. The 3-year newness period for the AxiaLIF® System also ends prior to the start of FY 2012 (January 11, 2011). Given the length of time since the AxiaLIF® System's entry into the market, cost-related data for the AxiaLIF® System is already reflected in the most recent MS–DRG relative weights. However, if the AxiaLIF® 2L+™ System is not substantially similar to any of the predicate devices mentioned above, then the newness period for the AxiaLIF® 2L+™ System would begin on January 21, 2010 (the AxiaLIF® 2L+™ System's FDA approval date) and would be within the year newness period for FY 2012. We invite public comment regarding whether or not the AxiaLIF® 2L+™ System meets the newness criteria, and, in particular, whether it is substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System.

In an effort to demonstrate that the AxiaLIF® 2L+™ System meets the cost criterion, the applicant used data from the FY 2009 MedPAR file. The applicant explained through supplemental information to its application that most cases of the AxiaLIF® 2L+™ System would map to MS–DRGs 459 (Spinal Fusion Except Cervical with MCC) and 460 (Spinal Fusion Except Cervical without MCC). The applicant searched the FY 2009 MedPAR file for cases with an ICD–9–CM procedure code of 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique). The applicant found 2,533 cases in MS–DRG 459 (5 percent of all cases) and 48,135 cases in MS–DRG 460 (95 percent of all cases). The average standardized charge per case was $117,847 for MS–DRG 459 and $84,153 for MS–DRG 460, equating to a case-weighted average standardized charge per case of $77,195.

This case-weighted standardized charge per case contains charges related to other implantable devices. Therefore, it is necessary to remove charges of other implantable devices from the case-weighted standardized charge per case (before substituting charges for the AxiaLIF® 2L+™ System). The applicant used the following methodology to

determine the average amount of charges related to other implantable devices within the case-weighted average standardized charge per case. The applicant estimated a standardized medical/surgical supplies charge of $47,860. After searching all claims in the CY 2008 100 percent inpatient limited data set standardized file, the applicant determined that, on average, implantable devices (revenue center 0278) accounted for 75 percent of the of medical/surgical supplies charges, equating to $36,104 for the cases the applicant found in MS–DRGs 459 and 460. The applicant then subtracted this amount from the case-weighted average standardized charge per case, which resulted in a case-weighted average standardized charge per case, excluding an implantable device, of $41,090 ($77,195 − $36,104).

The applicant then estimated the charges for the AxiaLIF® 2L+™ System by inflating the expected purchase price of the AxiaLIF® 2L+™ System by 2.77 times the purchase price of defibrillators, resulting in a standardized charge of $51,482 for the AxiaLIF® 2L+™ System. The applicant stated that using a markup based on defibrillators was appropriate because, like the AxiaLIF® 2L+™ System, defibrillators are also a high-cost implantable device. The applicant then added the average standardized charge for the AxiaLIF® 2L+™ System to the average standardized charge per case excluding an implantable device, which resulted in a total case-weighted average standardized charge per case of $92,557 ($41,075 + $51,482). The applicant calculated a case-weighted threshold of $78,354 for MS–DRGs 459 and 460. Because the total average standardized charge per case ($92,557), as calculated by the applicant, exceeds the case-weighted threshold ($78,354), the applicant maintains that it meets the cost criteria.

We have concerns with the applicant's methodology. Specifically, in determining the projected standardized charge for the AxiaLIF® 2L+™ System, the applicant relies on a charge markup for defibrillators because it is also a high-cost implantable device for which a hospital purchase price is known. We are concerned about whether more direct data or different proxies are available, including a charge markup for the AxiaLIF® System or AxiaLIF® II™ System. In reviewing the applicant's charge markup, we also are concerned about the source data for determining the 2.77 charge markup ratio for defibrillators. We invite public comment on whether the AxiaLIF® 2L+™ System meets the cost criterion for a new technology add-on payment for FY 2012.

With respect to the substantial clinical improvement criterion, the applicant asserts that it meets this criterion in its application. The applicant stated that substantial clinical improvement is demonstrated by the AxiaLIF® 2L+™ System's facilitation of spinal fusion surgery without a laparotomy. By avoiding a laparotomy, the AxiaLIF® 2L+™ System reduces blood loss, postoperative pain, narcotic use, denervation, morbidity, the probability of complications, and the risk of trauma to the tissue area surrounding the lumbar. The applicant further stated that the AxiaLIF® 2L+™ System reduces morbidity and has reduced risk of injuring vital organs and important intrinsic stabilizing structures, with a lower complication profile than traditional open fusion techniques. The applicant noted that long-term results can include better support of lordosis and prevention of adjacent level disease. We are concerned that this does not demonstrate a substantial clinical improvement from the AxiaLIF® II™ System, which also facilitated spinal fusion surgery without a laparotomy.

The applicant has not conducted clinical trials, but the 300 cases of AxiaLIF® 2L+™ System's use (through the Limited Market Release) yielded a complication rate of 0.7 percent. The applicant also asserts that the pre-sacral approach results in a lower average length of stay than a non-sacral approach.

The applicant has referred us to several sources of literature presenting data related to the pre-sacral approach for the applicant's AxiaLIF® device. We are concerned that the applicant has generally repeated the statements made regarding the clinical improvement of its AxiaLIF® device and has not provided information that indicates that the AxiaLIF® 2L+™ System offers a substantial clinical benefit over the earlier AxiaLIF® or AxiaLIF® II™ devices. Moreover, the applicant has not provided any clinical outcomes data for the AxiaLIF® 2L+™ System to substantiate its assertions regarding substantial clinical improvement for the AxiaLIF® 2L+™ System. While the applicant maintains that data from the AxiaLIF® device are relevant and can be used to substantiate its assertions for the AxiaLIF® 2L+™ System, we are concerned that data directly associated with the use of the AxialLIF® 2L+™ System are not available. For example, it is not clear the degree to which the population that requires treatment with the AxiaLIF® 2L+™ System differs from the population that requires treatment with the AxiaLIF® device or the AxiaLIF® II™ System, and it is also not clear the degree to which the differences between the devices discussed above may affect clinical outcomes.

The applicant also believes that an inline placement of the fixation implant may provide an advantage due to closeness of the implant to functional axis of the spine and through alignment with the direction of the compressive forces on the vertebral bodies. The applicant maintains that evaluation and testing have proven the AxiaLIF® 2L+™ System to be a biomechanically sturdy L4–S1 axial construct that significantly reduces the range of motion at the desired point and achieves decompression by increasing the L4–S1 disc spaces. We note that the only clinical change from the AxiaLIF® device and the AxiaLIF® 2L+™ System is that the latter reaches the L4. There is no stated clinical change between the AxiaLIF® II™ and the AxiaLIF® 2L+™ System. We invite public comment on whether the AxiaLIF® 2L+™ System meets the substantial clinical improvement criterion for the new technology add-on payment for FY 2012.

b. Champion™ HF Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2012 for the Champion™ HF Monitoring System, an Implantable Hemodynamic Monitor System (IHMS). The IHMS is comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The IHMS measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site. The IHMS utilizes radiofrequency energy to power the sensor and to measure pulmonary artery pressure. The data are accessed by clinicians via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy while the patient is at home. Changes in pulmonary artery pressure can be used along with heart failure signs and symptoms to adjust medications. There are currently no FDA approved devices performing this IHMS function. The IHMS consists of three components: (1) A wireless implantable hemodynamic sensor/monitor which is implanted in the distal pulmonary artery (sensor); (2) an external patient measurement system; and (3) a patient data management system.

CardioMEMS, Inc. believes that a large majority of patients receiving the sensor will be admitted to an inpatient hospital with a diagnosis of "acute or chronic heart failure" (ICD–9–CM code 428.43 (Acute or chronic combine systolic and diastolic heart failure)) and the sensor will be implanted during this hospital stay. For safety considerations, a small portion of these patients may be discharged and the sensor implanted at a future date in the hospital outpatient setting. In addition, there will likely be a group of patients in chronic heart failure who are not currently hospitalized, but who have been hospitalized in the past few months for whom the treating physician believes that regular pulmonary artery pressure readings are necessary to optimize patient management. Depending on the patient's status, these patients may have the sensor implanted in the hospital inpatient or outpatient setting.

With respect to the newness criterion, we note that this device is not currently approved by the FDA, but the manufacturer anticipates that FDA approval will be granted in the second quarter of 2011. No ICD–9–CM procedure code exists at this time that uniquely identifies the System. As noted in Table 6B, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, we have approved the use of new procedure code 38.26 (Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring), which will identify use of the System. The new ICD–9–CM procedure code 38.26 will be assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures).

In an effort to demonstrate that the System meets the cost criteria, the applicant used data from a clinical trial. Specifically, the manufacturer used data from the *C*ardioMEMS *H*eart Sensor *A*llows Monitoring of *P*ressure to *I*mprove Outcomes in NYHA Class III heart failure patients (CHAMPION) trial [4] which enrolled 550 patients in 30 hospitals within the United States. We note that there were 575 patients initially enrolled in the trial. Of these 575 patients, 25 underwent a right heart catheterization and did not receive an implant primarily because of anatomical/physiological conditions identified during the catheterization. The manufacturer collected 310 hospital claims from the 550 patients enrolled in the CHAMPION trial. The applicant eliminated claims with incomplete data or statistical outliers, and was left with 137 claims for its cost analysis. CardioMEMS funded the clinical trial and, therefore, did not submit these 137 claims. The applicant believes that cases eligible for the System would map to MS–DRG 264. Using the 137 claims from the CHAMPION trial, the manufacturer determined an average standardized charge per case without the new technology to equal $12,817. The applicant indicated that the case-weighted average standardized charge per case does not include charges related to the System, so it is then necessary to add the charges related to the device to the average standardized charge per case to evaluate the cost threshold criterion. To convert the costs of the technology to charges, CardioMEMS used an average cost-to-charge ratio (CCR) of 0.311 based on FY 2008 hospital cost reports from the 30 hospitals who participated in the CHAMPION trial. Based on this CCR, the manufacturer determined an average charge for the System to equal $45,016. Using this methodology, the total average standardized charge per case including the new technology equals $57,833 ($45,016 + $12,817). This amount exceeds the cost threshold of $46,546 for MS–DRG 264 (Table 10 of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50607)). Because the total average standardized charge per case ($57,833) exceeds the threshold ($46,546), the applicant maintains that it meets the cost criteria.

In addition to the methodology described above, the manufacturer searched for claims for patients in the CHAMPION trial that were aged 65 years or older at the time of device implantation as a proxy for Medicare patients. Out of the original 137 hospital claims, 56 (41 percent) were for patients aged 65 years or older. From these 56 claims (across 23 hospitals from the CHAMPION study), the applicant calculated an average standardized charge of $13,031, which did not include charges for the device. The applicant added the charges related to the device ($45,016, calculated as described above) to the average standardized charge per case to evaluate the cost threshold criterion. Using this methodology, the total average standardized charge per case including the new technology equals $58,047 ($45,016 + $13,031). This amount also exceeds the FY 2012 cost threshold of $46,546 for MS–DRG 264. Because the total average standardized charge per case ($58,047) exceeds the threshold ($46,546), the applicant maintains that it meets the cost criteria. We invite public comment on whether or not the Champion™ HF Monitoring System meets the cost criterion.

With regard to substantial clinical improvement, the applicant cited clinical data from the CHAMPION trial. The trial is a prospective, multicenter, randomized, single-blinded clinical trial conducted in the United States, designed to evaluate the safety and efficacy of the System in reducing heart failure-related hospitalizations in a subset of subjects suffering from heart failure. The applicant shared several major findings from the CHAMPION trial [5] as described below. First, at 6 months, the treatment group exhibited a 30 percent relative risk reduction in the rate of heart failure-related hospitalization (0.31 vs. 0.44, $p < 0.0001$). There were 83 heart failure-related hospitalizations in 270 treatment patients compared to 120 heart failure-related hospitalizations in the 280 control subjects. The "number needed to treat" (NNT) to reduce one heart failure-related hospitalization was eight patients. Second, during the 6-month follow-up period, the proportion of subjects hospitalized for one or more heart failure-related hospitalizations was significantly lower in the treatment group (54 out of 270 patients) than in the control group (80 out of 280 patients) (20 percent vs. 28.6 percent; $p = 0.0222$). Third, at 6 months, treatment patients had more days alive outside of the hospital (174.4 vs. 172.1, $p = 0.0222$) and fewer average days in the hospital (2.2 vs. 3.8, $p = 0.0194$) compared to control patients. Treatment patients spent 472 fewer days in the hospital than the control patients. Finally, the treatment group was assessed with the Minnesota Living with Heart Failure Questionnaire, which reported a greater improvement in quality of life (QOL) than the control group ($-10.6$ vs. $-7.4$, $p = 0.0373$). The applicant concluded that the CHAMPION trial demonstrated that, with knowledge of class III heart failure patients' pulmonary artery pressures, physicians could improve medical management leading to fewer heart failure-related hospitalizations. The applicant further stated that the device

[4] *Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial.* Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; for the CHAMPION Trial Study Group. Lancet. 2011 Feb 19;377(9766):658–666.

[5] *Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial.* Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; for the CHAMPION Trial Study Group. Lancet. 2011 Feb 19;377(9766):658–666

had very few device-related and system-related complications over the course of the clinical trial, and that primary and secondary study endpoints were successfully achieved. There was one report of an "Unanticipated Serious Adverse Device Event" involving a "tingling sensation" in a control patient, which was adjudicated by the Clinical Events Committee as not device/system-related. There were two reports of Serious Adverse Device Events due to hemoptysis and a blood clot, both of which resolved without permanent sequelae. The Clinical Events Committee adjudicated both events as device/system-related. The applicant maintained that during the first 6 months, there were 336 Serious Adverse Events (hospitalizations or deaths due to heart failure or other common comorbidities seen in this population) in 121 patients in the treatment group (44.8 percent) versus 385 Serious Adverse Events in 155 patients in the control group (55.4 percent).

In addition, the manufacturer stated that the CHAMPION trial suggests the safety and effectiveness of the device was maintained during longer term follow-up. (The primary efficacy endpoint of the CHAMPION trial was 6 months. However, patients remained in their assigned groups until the last patient reached 6 months, which is referred to as "the entire follow-up." The mean time of this entire follow up was up to 15 months.) Therefore, the manufacturer believes that the System meets the substantial clinical improvement criterion. We invite public comment on whether or not the Champion™ HF Monitoring System technology represents a substantial clinical improvement in the Medicare population.

c. PerfectCLEAN With Micrillon®

UMF Corporation (the manufacturer) submitted an application for a technology called the PerfectCLEAN with Micrillon® (PerfectCLEAN). PerfectCLEAN is a cleaning textile product (or cleaning mat/wipe) with chlorine embedded or bound to the extruded fiber. The manufacturer asserts that PerfectCLEAN is intended to be used to trap and eliminate pathogens such as Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile (C diff.) and the H1N1 flu virus from surfaces within the hospital (as well as other health care facilities and locations). The applicant asserts that it can trap and remove more than 99.99 percent of bacteria on hard surfaces.

The manufacturer stated that the PerfectCLEAN is an Environmental Protection Agency (EPA) approved antimicrobial/disinfectant that will be available on the market in the first quarter of 2011. The applicant maintains that PerfectCLEAN is subject to review and approval by the EPA per the EPA's Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Treated Article Exemption and, therefore, is not subject to review by the FDA. The applicant states that it was determined in a pre-registry meeting with the EPA that the underlying chemistries used to create the chlorine binding effects of Micrillon® chemistry are EPA and FDA approved even though no FDA claims are being sought.

With respect to whether the PerfectCLEAN is eligible for new technology add-on payments, we note that our regulations at § 412.87(c) state, "CMS will only consider, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA approval or clearance by July 1 prior to the particular fiscal year." FDA "approval," refers to the premarket approval application (PMA) process for most Class III devices, and FDA "clearance" refers to the 510(k) premarket notification submission process for most Class II devices and some Class I and Class III devices (section 515 of the Food, Drug and Cosmetic Act (FDCA) for PMA) and sections 510(k) and 513(i) of the FDCA (for premarket notification submission process)). Therefore, we believe our regulations, by requiring applicants to receive an FDA approval or clearance in order to be eligible for new technology add-on payments, limit the universe of items and services eligible to receive these payments to those that require FDA approval or clearance. The applicant has informed CMS that it is in the process of registering and listing its product with the FDA under section 510(b) through (d) and (j) and anticipates this process to be completed prior to the July 1 regulatory deadline. The registration process that the applicant is currently pursing will result in neither FDA approval nor clearance, and we are therefore concerned that the PerfectCLEAN is not eligible for new technology add-on payments under our existing regulations., which require "FDA approval or clearance by July 1 prior to the particular fiscal year" (42 CFR § 412.87(c)). We welcome public comments on whether the PerfectCLEAN is eligible for new technology add-on payments under the current regulations.

With regard to the cost criterion, the applicant used data from the FY 2011 After Outliers Removed (AOR) file (posted on the CMS Web site) for its cost analysis, which is based on the FY 2009 MedPAR file. The applicant considered MS–DRGs that relate to surgeries, skin abrasions, open sores, wounds, and similar inflamed tissue conditions where infection sites are thought to be more likely to occur for inpatient care situations. This resulted in the applicant determining that the technology would be most frequently used in 622 different MS–DRGs. The applicant noted that the charges from the FY 2011 AOR file were not inflated from FY 2009 to FY 2011; therefore the applicant applied a 2-year inflation factor of 12 percent (to update the charges from FY 2009 to FY 2011). The applicant based the 2-year inflation factor of 12 percent on a 3-year average of the 2 year rate-of-change in charges (the 2-year rate-of-change for FY 2009 of 11.841 percent (73 FR 48764); the 2-year rate-of-change for FY 2010 of 14.184 percent (74 FR 44010); and the 2-year rate-of-change for FY 2011 of 9.8843 percent (75 FR 50429)) that CMS uses in its outlier threshold calculation as published in section II. of the Addendum to the annual IPPS final rule. The applicant computed a case-weighted standardized charge per case of $40,442 for all 622 MS–DRGs, which did not include any charges related to the PerfectCLEAN. Therefore, it added the charges related to the technology to the case-weighted average standardized charge per case in evaluating the cost threshold criterion. The manufacturer estimates a charge per patient of $100 per day for the PerfectCLEAN. The applicant includes in this amount charges for payroll, treated textiles, packaging and protective gloves, laundering, storage, and distribution. The applicant multiplied the average length of stay for each MS–DRG (as found in Table 5 of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50547 through 50566)) by the charge per patient per day to determine the total charges per stay by MS–DRG related to the PerfectCLEAN. The applicant added additional charges per stay for the PerfectCLEAN to the case-weighted standardized charge per case and determined a total case-weighted average standardized charge per case of $41,105. Based on the 622 MS–DRGs to which the technology mapped, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $41,105 exceeds the case weighted threshold of $40,834, the

applicant maintains that it meets the cost criteria.

We have several concerns regarding the applicant's cost analysis. First, although the technology can potentially be used in every single Medicare case, the application targets specific MS–DRGs. The applicant did not provide a detailed clinical justification regarding their selection of MS–DRGs, or a detailed justification for why the technology could not be used in other MS–DRGs. We believe it would be more appropriate to target all cases in every MS–DRG when conducting the cost analysis for this type of non-procedure or condition specific item. Using the FY 2011 AOR file, we conducted our own analysis with the same methodology above (and inflated the charges and included the total charges per stay related to the PerfectCLEAN) across all MS–DRGs. Based on our analysis, we determined a total case-weighted average standardized charge per case of $29,535. Using the applicant's methodology, we also determined a case-weighted threshold of $37,384 across all MS–DRGs. Because the total case-weighted average standardized charge per case of $29,535 is less than the case-weighted threshold of $37,384, we believe the PerfectCLEAN may not meet the cost criteria.

Second, the applicant included in the average charge per day more general charges unrelated to the specific new technology, such as payroll, packaging and protective gloves, laundering, storage and distribution. We do not believe it is appropriate to include charges for expenses already accounted for in MS–DRG based payments, such as laundering, storage, and distribution, and supplies already used by hospital staff such as packaging and protective gloves. We also note that the applicant states in its substantial clinical improvement discussion that the PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for HAIs from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. If the PerfectCLEAN is a substitute for other cleaning mechanisms such as wiping down a hospital room with a spray and can produce significant savings across many cost centers, then it would be appropriate to deduct some charges from the average charge per day in order to accurately reflect the cost to hospitals of this technology. For these reasons, we remain concerned about the accuracy of the computation of a charge per patient of $100 per day and whether the PerfectCLEAN meets the cost criterion.

Thirdly, the applicant based the 12-percent, 2-year rate-of-change in charges on a 3-year average (FY 2009 through FY 2011) of the 2-year rate-of-change in charges as published in section II. of the Addendum to the annual IPPS final rule. We do not believe it is appropriate to use a 3-year average of the 2-year rate-of-change in charges as the 2-year rate-of-change in charges already uses the most recent data available to measure this change and, therefore, does not need to be averaged with prior years. Specifically, as described in section II. of the Addendum to this proposed rule, to calculate the proposed FY 2012 2-year rate-of-change in charges, we compared the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. If we substitute the FY 2012 proposed 2-year rate-of-change in charges of 9.07 percent for the 12-percent 3-year average of the 2-year rate-of-change in charges that the applicant used in its cost analysis, the total case-weighted average standardized charge per case would be $40,047 across the 622 MS–DRGs to which the applicant believes the technology would map. As mentioned above, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $40,047 is less than the case-weighted threshold of $40,834, it appears the applicant would not meet the cost criteria. We invite public comment on whether the PerfectCLEAN meets the cost criterion.

The applicant maintains that it meets the substantial clinical improvement criteria for the following reasons: The applicant believes the PerfectCLEAN significantly improves clinical outcomes for a patient population as compared to currently available treatments, decreases rate of subsequent diagnostic or therapeutic interventions, and decreases the number of future hospitalizations or physician visits. The applicant cited independent laboratory studies that set forth the level of removal and elimination of pathogens achieved by the PerfectCLEAN. The applicant stated that the PerfectCLEAN includes "more precise and focused patient room procedures that when properly applied utilize the textile and micro-denier efficacies" listed in the product's independent test reports. The applicant states that this results "in a safer patient environment where the likelihood of cross contamination is reasonable." The applicant included test report data for the product, which demonstrated a 99.99 percent effectiveness of removing pathogens such as MRSA and C diff. The applicant cited industry and clinical support to demonstrate that improved patient environment can save lives. The applicant also stated that PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for hospital acquired infections from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. The applicant stated that this new innovative system delivers reliable and repeatable results not currently achieved using currently available protocols and products. The applicant provided the following example: a traditional method of disinfection is to apply liquid disinfectants, which the applicant stated typically requires a 10-minute dwell time (which in most cases is not completed by the hospital) and then wiping or mopping up the nonevaporated liquids. Compared to this method, the applicant asserts that the PerfectCLEAN first removes the micro-organisms from those surfaces using specially designed microscopic fibers. The applicant asserts that these pathogens are trapped in a formulation of a chlorine binding technology which eliminates the pathogens.

The applicant further asserts that the PerfectCLEAN maintains its disinfecting capability longer than other methods because the chlorine-binding technology is introduced at the pellet stage of fiber extrusion so that it is present throughout the fiber, as opposed to a finish or coating process that wears off as textiles are used and laundered. Additionally, the applicant asserts that the technology's non-leaching chlorination system recharges in the wash process by attracting and binding free molecules of chlorine. The applicant further asserts that in this way the PerfectCLEAN recharges back to its original strength and efficacy which allows it to work more rapidly than other techniques. The applicant asserts that this reduces cross-contamination by those persons handling soiled textiles after the people contact surfaces which have been cleaned of harmful micro-organisms. The applicant added that the training in use of color coated textiles (different color mats) affords superior monitoring and compliance supervision of the hygiene specialists charged with

responsibility to reduce cross-contamination. We invite public comment on whether the PerfectCLEAN meets the substantial clinical improvement criterion.

## III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

### *A. Background*

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2012 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2012 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2012 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply beginning October 1, 2011 (the FY 2012 wage index) appears under section III.C. of this preamble.

### *B. Core-Based Statistical Areas for the Hospital Wage Index*

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB and announced in December 2003 (69 FR 49027). For a discussion of OMB's revised delineations of CBSAs and our implementation of the CBSA definitions, we refer readers to the preamble of the FY 2005 IPPS final rule (69 FR 49026 through 49032).

As with the FY 2011 final rule, in this FY 2012 proposed rule, we are proposing to provide that hospitals receive 100 percent of their wage index based upon the CBSA configurations. Specifically, for each hospital, we are proposing to determine a wage index for FY 2012 employing wage index data from hospital cost reports for cost reporting periods beginning during FY 2008 and using the CBSA labor market definitions. We consider CBSAs that are Metropolitan Statistical Areas (MSAs) to be urban, and CBSAs that are Micropolitan Statistical Areas as well as areas outside of CBSAs to be rural. In addition, it has been our longstanding policy that where an MSA has been divided into Metropolitan Divisions, we consider the Metropolitan Division to comprise the labor market areas for purposes of calculating the wage index (69 FR 49029) (regulations at § 412.64(b)(1)(ii)(A)).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. CMS adopted those changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50162), beginning October 1, 2010, and they are reflected in this FY 2012 proposed rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB*—go to "Agency Information" and click on "Bulletins".

### *C. Proposed Occupational Mix Adjustment to the FY 2012 Wage Index*

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

#### 1. Development of Data for the Proposed FY 2012 Occupational Mix Adjustment Based on the 2007–2008 Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

For the FY 2010 hospital wage index, we used occupational mix data collected on a revised 2007–2008 Medicare Wage Index Occupational Mix Survey (the 2007–2008 survey) to compute the occupational mix adjustment for FY 2010. (We refer readers to the FY 2010 IPPS final rule (74 FR 43827) for a detailed discussion of the 2007–2008 survey.) Again, for the FY 2011 hospital wage index, we used data from the 2007–2008 survey (including revised data for 45 hospitals) to compute the FY 2011 adjustment.

For the FY 2012 hospital wage index, we are proposing to again use occupational mix data collected on the 2007–2008 Medicare Wage Index Occupational Mix Survey to compute the occupational mix adjustment for FY 2012. We are including data for 3,165 hospitals that also have wage data included in the proposed FY 2012 wage index.

2. New 2010 Occupational Mix Survey for the FY 2013 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We used occupational mix data collected on the 2007–2008 survey to compute the occupational mix adjustment for FY 2010 and the FY 2011 wage index and are proposing to use the 2007–2008 occupational mix survey data in this proposed rule for the FY 2012 wage index. Therefore, a new measurement of occupational mix will be required for FY 2013.

The new 2010 survey (Form CMS–10079 (2010)) provides for the collection of hospital-specific wages and hours data for calendar year 2010 (that is, payroll periods ending between January 1, 2010 and December 31, 2010) and will be applied beginning with the FY 2013 wage index. The 2010 survey was adopted in the **Federal Register** on January 15, 2010 (75 FR 2548) and approved by OMB on February 26, 2010 (OMB control number 0938–0907). The survey is available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage* and through the fiscal intermediaries/MACs. Hospitals are required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data will be released in early October 2011, along with the FY 2009 Worksheet S–3 wage data, for the FY 2013 wage index review and correction process.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2012

For FY 2012 (as we did for FY 2011), we are proposing to calculate the occupational mix adjustment factor using the following steps:

*Step 1*—For each hospital, determine the percentage of the total nursing category attributable to a nursing subcategory by dividing the nursing subcategory hours by the total nursing category's hours. Repeat this computation for each of the four nursing subcategories: (1) Registered nurses; (2) licensed practical nurses; (3) nursing aides, orderlies, and attendants; and (4) medical assistants.

*Step 2*—Determine a national average hourly rate for each nursing subcategory by dividing a subcategory's total salaries for all hospitals in the occupational mix survey database by the subcategory's total hours for all hospitals in the occupational mix survey database.

*Step 3*—For each hospital, determine an adjusted average hourly rate for each nursing subcategory by multiplying the percentage of the total nursing category (from Step 1) by the national average hourly rate for that nursing subcategory (from Step 2). Repeat this calculation for each of the four nursing subcategories.

*Step 4*—For each hospital, determine the adjusted average hourly rate for the total nursing category by summing the adjusted average hourly rate (from Step 3) for each of the nursing subcategories.

*Step 5*—Determine the national average hourly rate for the total nursing category by dividing total nursing category salaries for all hospitals in the occupational mix survey database by total nursing category hours for all hospitals in the occupational mix survey database.

*Step 6*—For each hospital, compute the occupational mix adjustment factor for the total nursing category by dividing the national average hourly rate for the total nursing category (from Step 5) by the hospital's adjusted average hourly rate for the total nursing category (from Step 4).

If the hospital's adjusted average hourly rate is less than the national average hourly rate (indicating the hospital employs a less costly mix of nursing employees), the occupational mix adjustment factor is greater than 1.0000. If the hospital's adjusted average hourly rate is greater than the national average hourly rate, the occupational mix adjustment factor is less than 1.0000.

*Step 7*—For each hospital, calculate the occupational mix adjusted salaries and wage-related costs for the total nursing category by multiplying the hospital's total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section III.F. of this preamble) by the percentage of the hospital's total workers attributable to the total nursing category (using the occupational mix survey data, this percentage is determined by dividing the hospital's total nursing category salaries by the hospital's total salaries for "nursing and all other") and by the total nursing category's occupational mix adjustment factor (from Step 6 above).

The remaining portion of the hospital's total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted by the occupational mix. A hospital's all other portion is determined by subtracting the hospital's nursing category percentage from 100 percent.

*Step 8*—For each hospital, calculate the total occupational mix adjusted salaries and wage-related costs for a hospital by summing the occupational mix adjusted salaries and wage-related costs for the total nursing category (from Step 7) and the portion of the hospital's salaries and wage-related costs for all other employees (from Step 7).

To compute a hospital's occupational mix adjusted average hourly wage, divide the hospital's total occupational mix adjusted salaries and wage-related costs by the hospital's total hours (from Step 4 of the unadjusted wage index calculation in section III.F. of this preamble).

*Step 9*—To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

*Step 10*—To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the Nation, then sum the total hours for all hospitals in the Nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The proposed FY 2012 occupational mix adjusted national average hourly wage is $36.1406.

*Step 11*—To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 9) by the national occupational mix adjusted average hourly wage (Step 10).

*Step 12*—To compute the Puerto Rico specific occupational mix adjusted wage index, follow Steps 1 through 11 above. The proposed FY 2012 occupational mix adjusted Puerto Rico-specific average hourly wage is $15.4107.

The table below is an illustrative example of the occupational mix adjustment.

BILLING CODE 4120–01–P

## Example of Occupational Mix Adjustment

| Hospital A | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Step 1 | Step 2 | Step 3 | Step 5 | Step 6 | in Step 7 |
| | **Provider Occupational Mix Hours** | **Provider Occupational Mix Salaries** | **Provider % by Subcategory** | **National AHWs by Subcategory** | **Provider Adjusted AHW** | **National Adjusted Nurse AHW** | **Nurse Occupa-tional Mix Adjust-ment Factor** | **Provider % by Total** |
| **Registered Nurses** | 1,642,129 | 18,125,763 | **79.84%** | $40.00 | **$31.94** | | | |
| **Licensed Practical Nurses and Surgical Technologists** | 67,860 | 404,822 | **3.30%** | $20.00 | **$0.66** | | | |
| **Nursing Aides, Orderlies, & Attendants** | 259,177 | 1,762,579 | **12.60%** | $13.00 | **$1.64** | | | |
| **Medical Assistants** | 87,622 | 577,045 | **4.26%** | $12.00 | **$0.51** | | | |
| **Total Nurse Hours and Salaries** | **2,056,788** | **20,870,209** | | | **$34.75** | **$27.00** | **0.7771** | **52.40%** |
| | | | | | | | | |
| **ALL OTHER** | 5,000,000 | $18,957,010 | | | Step 4 | | | **47.60%** |
| **TOTAL** | **7,056,788** | **$39,827,219** | | | | | | |
| | | | | | | | | |
| **Wage Data from Cost Report** | | | | | | | | |
| **Wages (From S-3, Parts II and III)** | $83,312,942.55 | | | | | | | |
| **Hours (From S-3, Parts II and III)** | 3,836,299.60 | | | | | | | |
| **Hospital A Unadjusted AHW** | **$21.72** | | | | | | | |
| | | | | | | | | |
| **Nurse Occupational Mix Wages** | **$33,925,838** | Step 7 | | | | | | |
| **All Other Unadjusted Occupational Mix Wages** | **$39,655,400** | Step 7 | | | | | | |
| **Total Occupational Mix Wages** | **$73,581,237** | Step 8 | | | | | | |
| | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Hospital A Final Occupational Mix Adjusted AHW** | **$19.18** | Step 8 | | | | | | |
| **Hospital B** | | | | | | | | |
| | | | Step 1 | Step 2 | Step 3 | Step 5 | Step 6 | in Step 7 |
| | **Provider Occupational Mix Hours** | **Provider Occupational Mix Salaries** | **Provider % by Subcategory** | **National AHWs by Subcategory** | **Provider Adjusted AHW** | **National Adjusted Nurse AHW** | **Nurse Occupa-tional Mix Adjustment Factor** | **Provider % by Total** |
| **Registered Nurses** | 1,142,129 | 18,125,763 | **72.43%** | $30.00 | **$21.73** | | | |
| **Licensed Practical Nurses and Surgical Technologists** | 67,860 | 404,822 | **4.30%** | $20.00 | **$0.86** | | | |
| **Nursing Aides, Orderlies, & Attendants** | 279,177 | 1,762,579 | **17.71%** | $13.00 | **$2.30** | | | |
| **Medical Assistants** | 87,622 | 577,045 | **5.56%** | $12.00 | **$0.67** | | | |
| **Total Nurse Hours and Salaries** | **1,576,788** | **20,870,209** | | | **$25.56** | **$27.00** | **1.0564** | **52.40%** |
| | | | | | | | | |
| **ALL OTHER** | 5,000,000 | 18,957,010 | | | Step 4 | | | **47.60%** |
| **TOTAL** | **6,576,788** | **$39,827,219** | | | | | | |
| | | | | | | | | |
| **Wage Data from Cost Report** | | | | | | | | |
| **Wages (From S-3, Parts II and III)** | $25,979,714 | | | | | | | |
| **Hours (From S-3, Parts II and III)** | 1,097,585 | | | | | | | |
| **Hospital B Unadjusted AHW** | **$23.67** | | | | | | | |
| | | | | | | | | |
| **Nurse Occupational Mix Wages** | **$14,381,144** | Step 7 | | | | | | |
| **All Other Unadjusted Occupational Mix Wages** | **$12,365,857** | Step 7 | | | | | | |
| **Total Occupational Mix Wages** | **$26,747,001** | Step 8 | | | | | | |
| | | | | | | | | |
| **Hospital B Final Occupational Mix Adjusted AHW** | **$24.37** | Step 8 | | | | | | |
| | | | | | | | | |
| **Note:** The numbers in this example are hypothetical, including all National AHW amounts. | | | | | | | | |

BILLING CODE 4120–01–C

Because the occupational mix adjustment is required by statute, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2012 wage index. For the FY 2007–2008 survey, the response rate was 90.8 percent.

In computing the proposed FY 2012 wage index, if a hospital did not respond to the occupational mix survey, or if we determined that a hospital's submitted data were too erroneous to include in the wage index, we assigned the hospital the average occupational mix adjustment for its labor market area. This method has the least impact on the wage index for other hospitals in the area. For areas where no hospital submitted data for purposes of calculating the occupational mix adjustment, we applied the national occupational mix factor of 1.0000 in calculating the area's proposed FY 2012 occupational mix adjusted wage index. In addition, if a hospital submitted a survey, but that survey data could not be used because we determined the survey data to be aberrant, we also assigned the hospital the average occupational mix adjustment for its labor market area. For example, if a hospital's individual nurse category average hourly wages were out of range (that is, unusually high or low), and the hospital did not provide sufficient documentation to explain the aberrancy, or the hospital did not submit any registered nurse salaries or hours data, we assigned the hospital the average occupational mix adjustment for the labor market area in which it is located.

In calculating the average occupational mix adjustment factor for a labor market area, we replicated Steps 1 through 6 of the calculation for the occupational mix adjustment. However, instead of performing these steps at the hospital level, we aggregated the data at the labor market area level. In following these steps, for example, for CBSAs that contain providers that did not submit occupational mix survey data, the occupational mix adjustment factor ranged from a low of 0.9246 (CBSA 17780, College Station-Bryan, TX), to a high of 1.0761 (CBSA 19, Rural Louisiana). Also, in computing a hospital's occupational mix adjusted salaries and wage-related costs for nursing employees (Step 7 of the calculation), in the absence of occupational mix survey data, we multiplied the hospital's total salaries and wage-related costs by the percentage of the area's total workers attributable to the area's total nursing category. For FY 2012, there are five CBSAs (that include six hospitals) for which we did not have occupational mix data for any of its hospitals. The CBSAs are:

- CBSA 36140, Ocean City, NJ (1 hospital)
- CBSA 22140, Farmington, NM (1 hospital)
- CBSA 41900, San German-Cabo Rojo, PR (2 hospitals)
- CBSA 49500, Yauco, PR (1 hospital)
- CBSA 21940, Fajardo, PR (1 hospital)

Since the FY 2007 IPPS final rule, we have periodically discussed applying a hospital-specific penalty to hospitals that fail to submit occupational mix survey data (71 FR 48013 through 48014; 72 FR 47314 through 47315; 73 FR 48580; 74 FR 43832, and 75 FR 50167). During the FY 2008 rulemaking cycle, some commenters suggested a penalty equal to a 1- to 2-percent reduction in the hospital's wage index value or a set percentage of the standardized amount. During the FY 2009 and FY 2010 rulemaking cycles, several commenters reiterated their view that full participation in the occupational mix survey is critical, and that CMS should develop a methodology that encourages hospitals to report occupational mix survey data but does not unfairly penalize neighboring hospitals. We indicated in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule that, while we were not proposing a penalty at that time, we would consider the public comments we previously received, as well as any public comments on the proposed rule, as we developed the FY 2011 wage index.

In the FY 2011 IPPS/LTCH PPS proposed and final rules (75 FR 23943 and 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement will be effective beginning with the new 2010 occupational mix survey (the 2010 survey is discussed in section III.C.2. of this preamble). We will instruct fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We note that we reserve the right to apply a different approach in future years, including potentially penalizing nonresponsive hospitals.

*D. Worksheet S–3 Wage Data for the Proposed FY 2012 Wage Index*

The proposed FY 2012 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2008 (the FY 2011 wage index was based on data from cost reporting periods beginning during FY 2007).

1. Included Categories of Costs

The proposed FY 2012 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty)
- Home office costs and hours
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315))
- Wage-related costs, including pensions and other deferred compensation costs.

2. Proposal for Changes to the Reporting Requirements for Pension Costs for the Medicare Wage Index

a. Background

The instructions for determining and reporting defined benefit pension costs on the cost report for Medicare cost-finding purposes are located in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I). For Medicare wage index purposes, the instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of the PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension costs to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of

the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) are also typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a "funding target" and "target normal cost" measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA "funding target" and "target normal cost" values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new "funding target" and "target normal cost" basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, these instructions also serve as interim guidance for Medicare cost-finding purposes.

In this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis to be used by all types of plans. Therefore, we are proposing to no longer rely on actuarial computation to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our proposal would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we are proposing separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed in section IV.M. of this preamble) and for purposes of updating the wage index (discussed below in section III.D.2.b. of this preamble). We believe it is necessary to have two distinct proposals in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct proposals would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of our proposal for reporting pension costs under the wage index. A full discussion of our proposal for Medicare cost-finding is discussed in section IV.M. of this preamble.

The proposal below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review."

b. Proposal for Allowable Pension Cost for the Medicare Wage Index

As mentioned above, the function of the Medicare wage index is to measure relative hospital labor costs across all areas. Therefore, while we believe pension costs must be funded in order to be reportable (we refer readers to the August 12, 2010 **Federal Register** (74 FR 47369) for an explanation of this longstanding policy), it also is important for pension costs to be relatively stable from year to year so that there is less volatility in the wage index. Thus, we are proposing to include, in the wage index, pension costs equal to the average actual cash contributions deposited to a hospital's defined benefit pension plan by the hospital and/or the hospital system over a 3-year period. The use of cash contributions as a measure of the costs incurred is necessary to ensure uniformity among all hospitals, regardless of their tax status or ERISA coverage. The 3-year average is intended to reduce the volatility that often occurs due to timing of contributions. Most pension plan sponsors have flexibility to determine the pension funding for a particular period and their decisions may be based on cash-flow considerations or other factors unrelated to the normal operation of the plan. Furthermore, the funding of current period pension costs may be delayed by almost a full year after the close of the period to which it applies. By using a 3-year average, we hope to enhance the stability of the wage index.

To ensure that the average annual pension cost reflected in the wage index is consistent with the reporting period applicable to all other costs included in the index, we are proposing that the 3-year average be centered on the base cost reporting year for the wage index. For example, the FY 2013 wage index will be based on Medicare cost reporting periods beginning during FY 2009 and would reflect the average pension contributions made in hospitals' cost reporting periods beginning during FYs 2008, 2009, and 2010. Thus, this proposal would require pension plan contribution data for the cost reporting periods immediately preceding and immediately following the base cost reporting period for the wage index.

We do not anticipate that the use of contributions made in the cost reporting period immediately following the reporting year will create an administrative burden because, even under the existing rule, contributions to fund current period costs are often deferred until the following period. In addition, trust account statements and general ledger reports to support the contributions should be readily available. We are proposing to apply the above methodology for reporting pension costs for the wage index beginning with the FY 2013 IPPS update. We invite public comment on

this policy proposal and are especially interested in receiving comments related to the proposed 3-year averaging period.

3. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2011, the proposed wage index for FY 2012 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2012 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

4. Use of Wage Index Data by Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index are also currently used to calculate wage indices applicable to other providers, such as SNFs, home health agencies (HHAs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

*E. Verification of Worksheet S–3 Wage Data*

The wage data for the proposed FY 2012 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2007, and before October 1, 2008. For wage index purposes, we refer to cost reports during this period as the "FY 2008 cost report," the "FY 2008 wage data," or the "FY 2008 data." Instructions for completing Worksheet S–3, Parts II and III are in the Provider Reimbursement Manual (PRM), Part II, sections 3605.2 and 3605.3. The data file used to construct the proposed wage index includes FY 2008 data submitted to us as of March 3, 2011. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2012 wage index, we identified and excluded 23 providers with data that was too aberrant to include in the proposed wage index, although if data elements for some of these providers are corrected, we intended to include some of these providers in the FY 2012 final wage index. We instructed fiscal intermediaries/MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 13, 2011. We intend that all unresolved data elements will be resolved by the date the final rule is issued. The revised data will be reflected in the FY 2012 IPPS final rule.

In constructing the proposed FY 2012 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2008, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397). For this proposed rule, we removed 19 hospitals that converted to CAH status between February 16, 2010, the cut-off date for CAH exclusion from the FY 2011 wage index, and February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2012 wage index is calculated based on 3,484 hospitals.

In the FY 2008 final rule with comment period (72 FR 47317) and the FY 2009 IPPS final rule (73 FR 48582), we discussed our policy for allocating a multicampus hospital's wages and hours data, by full-time equivalent (FTE) staff, among the different labor market areas where its campuses are located. During the FY 2011 wage index desk review process, we requested fiscal intermediaries/MACs to contact multicampus hospitals that had campuses in different labor market areas to collect the data for the allocation. The FY 2011 wage index included separate wage data for campuses of three multicampus hospitals.

For FY 2012, as we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50168), we are proposing to no longer allow hospitals to use discharge data for the allocation of a multicampus hospital's wage data among the different labor market areas where its campuses are located. The Medicare cost report was updated in May 2008 to provide for the reporting of FTE data by campus for multicampus hospitals (Form CMS–2552–96, Worksheet S–2, lines 61 and 62). The data from cost reporting periods that begin in FY 2008 are now available for calculating the wage index for FY 2012. Therefore, a multicampus hospital will not have the option to use either FTE or discharge data for allocating wage data among its campuses by providing the information from the applicable cost reporting period to CMS through its fiscal intermediary/MAC. The table containing the proposed FY 2012 wage index, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, includes separate wage data for campuses of three multicampus hospitals.

*F. Method for Computing the Proposed FY 2012 Unadjusted Wage Index*

1. Steps for Computation

The method used to compute the proposed FY 2012 wage index without an occupational mix adjustment follows:

*Step 1*—As noted above, we are proposing to base the proposed FY 2012 wage index on wage data reported on the FY 2008 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2007, and before October 1, 2008. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2007 and reported a cost reporting period covering all of FY 2008. These data are included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2008 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2008 (for example, a hospital had two short cost reporting

periods beginning on or after October 1, 2007, and before October 1, 2008), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

*Step 2*—Salaries—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we include Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II for overhead services in the wage index. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation for FY 2011 is to compute a "revised" Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 22.01, 26.01, and 27.01.) In calculating a hospital's average salaries plus wage-related costs, we subtract from Line 1 (total salaries) the GME and CRNA costs reported on Lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and exclude salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we add to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

*Step 3*—Hours—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2.

*Step 4*—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S–3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S–3). We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S–3, Part III. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determine the ratio of overhead hours (Part III, Line 13 minus the sum of Lines 22.01, 26.01, and 27.01) to revised hours excluding the sum of Lines 22.01, 26.01, and 27.01 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, 8, 8.01, 22.01, 26.01, and 27.01). (We note that for the FY 2008 and subsequent wage index calculations, we are excluding the sum of Lines 22.01, 26.01, and 27.01 from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 22.01, 26.01, and 27.01 require that associated wage-related costs be combined with wages on the respective contract labor lines.); (2) we compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiply the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

*Step 5*—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2005, through April 15, 2007, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage for FY 2012. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

## MIDPOINT OF COST REPORTING PERIOD

| After | Before | Adjustment Factor |
|---|---|---|
| 10/14/2007 | 11/15/2007 | 1.03990 |
| 11/14/2007 | 12/15/2007 | 1.03699 |
| 12/14/2007 | 01/15/2008 | 1.03402 |
| 01/14/2008 | 02/15/2008 | 1.03113 |
| 02/14/2008 | 03/15/2008 | 1.02831 |
| 03/14/2008 | 04/15/2008 | 1.02555 |
| 04/14/2008 | 05/15/2008 | 1.02286 |
| 05/14/2008 | 06/15/2008 | 1.02024 |
| 06/14/2008 | 07/15/2008 | 1.01766 |
| 07/14/2008 | 08/15/2008 | 1.01511 |
| 08/14/2008 | 09/15/2008 | 1.01258 |
| 09/14/2008 | 10/15/2008 | 1.01015 |
| 10/14/2008 | 11/15/2008 | 1.00787 |
| 11/14/2008 | 12/15/2008 | 1.00575 |
| 12/14/2008 | 01/15/2009 | 1.00375 |
| 01/14/2009 | 02/15/2009 | 1.00183 |
| 02/14/2009 | 03/15/2009 | 1.00000 |
| 03/14/2009 | 04/15/2009 | 0.99820 |

For example, the midpoint of a cost reporting period beginning January 1, 2008, and ending December 31, 2008, is June 30, 2008. An adjustment factor of 1.01766 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 2008 and covered a period of less than 360 days or more than 370 days, we annualize the data to reflect a 1-year cost report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplishes annualization.

*Step 6*—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), section 1886(d)(8)(E), or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

*Step 7*—We divide the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

*Step 8*—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the proposed national average hourly wage (unadjusted for occupational mix) is $36.1697.

*Step 9*—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

*Step 10*—Following the process set forth above, we develop a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We add the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divide the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall proposed average hourly wage (unadjusted for occupational mix) of $15.3863 for Puerto Rico. For each labor market area in Puerto Rico, we calculate the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

*Step 11*—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 4D which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

2. Expiration of the Imputed Floor Policy

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the "imputed" floor as a temporary 3-year regulatory measure to address a concern by some individuals that hospitals in all-urban States were disadvantaged by the absence of rural hospitals to set a wage index floor in those States. There are two States that have no rural areas (New Jersey and Rhode Island). Rhode Island has only one urban area. In accordance with the imputed floor calculation (§ 412.64(h)(4) of the regulations), Rhode Island receives no benefit from the policy. As a result, the imputed floor policy only benefits one State—New Jersey. Although New Jersey may argue that it is disadvantaged by

the statutory rural floor because it has no rural areas, the imputed floor policy provides New Jersey with a guaranteed benefit that no other State has. In any given year, approximately one-half of the States have no hospitals that benefit from the rural floor provision. However, New Jersey benefits each year that the imputed floor policy is in place.

The imputed floor was originally set to expire in FY 2007, but we extended it an additional year in the FY 2008 IPPS final rule with comment period (72 FR 47321). In the FY 2009 IPPS final rule (73 FR 48570 through 48574 and 48584), we extended the imputed floor for an additional 3 years, through FY 2011, linking the extension to a policy to apply budget neutrality for the rural and imputed floors within each State, instead of nationally, over a 3-year transition period. Section 3141 of the Affordable Care Act replaced the statewide budget neutrality policy with the national budget neutrality policy that was in place during FY 2008. That is, section 3141 required that budget neutrality for the rural and imputed floor be applied "through a uniform, national adjustment to the area wage index" instead of within each State beginning in FY 2011 (75 FR 50160). However, we note that the Affordable Care Act did not include a provision to extend the imputed floor or to make the imputed floor permanent. Therefore, the imputed floor is set to expire with the FY 2011 wage index, and we are not proposing to extend the imputed floor policy. Thus, the imputed floor is not reflected in the table containing the proposed FY 2012 wage index, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

As we discussed in the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24786 and 72 FR 47322, respectively), the application of the national budget neutrality requirement for the rural and imputed floors requires a transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, we believe that the floor policy should apply only when required by statute. Thus, only States containing both rural areas and hospitals located in such areas (including any hospital reclassified as rural under § 412.103) would benefit from the rural floor, as required by section 4410 of Public Law 105–33.

In the proposed FY 2012 wage index, the rural floor will apply to 189 hospitals in 26 States. If the imputed floor policy was to continue into FY 2012, it would apply to 39 additional hospitals in New Jersey. We are seeking public comments regarding the expiration of the imputed floor.

3. Proposed FY 2012 Puerto Rico Wage Index

We note that, for the proposed FY 2012 wage index, there is one new hospital in rural Puerto Rico when previously there were none. However, this hospital has no cost reporting period beginning during FY 2008 and, therefore, has no wage data for inclusion in the proposed FY 2012 wage index calculation for rural Puerto Rico. We discussed in the FY 2005 IPPS final rule that, under these circumstances, we would determine a State's rural floor based on the imputed floor policy in § 412.64(h)(4) of the regulations. However, as discussed above, the imputed floor is set to expire with the FY 2011 wage index. We adopted the policy in the FY 2008 IPPS final rule with comment period (72 FR 47323) that if there are no hospitals' cost report wage data available to calculate a State's rural floor, and the imputed floor policy has expired, "we will use the unweighted average of the wage indices from all CBSAs (urban areas) that are contiguous to the rural counties of the State to compute the State's rural floor. (We define contiguous as sharing a border.)" Except for Fajardo, Puerto Rico (CBSA 21940), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2012 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2012 wage indices for the following urban areas: Aguadilla-Isabela-San Sebastián, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayagüez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San Germán-Cabo Rojo, PR (CBSA 41900), San Juan-Caguas-Guaynabo, PR (CBSA 41980), and Yauco, PR (CBSA 49500).

*G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2012 Occupational Mix Adjusted Wage Index*

As discussed in section III.C. of this preamble, for FY 2012, we are proposing to apply the occupational mix adjustment to 100 percent of the proposed FY 2012 wage index. We calculated the proposed occupational mix adjustment using data from the 2007–2008 occupational mix survey data, using the methodology described in section III.C.3. of this preamble.

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the proposed FY 2012 wage index results in a proposed national average hourly wage of $36.1406 and a proposed Puerto-Rico specific average hourly wage of $15.4107. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2008 Worksheet S–3 cost report data for use in calculating the proposed FY 2012 wage index, we calculated the proposed FY 2012 wage index using the occupational mix survey data from 3,165 hospitals. Using the Worksheet S–3 cost report data of 3,484 hospitals and occupational mix survey data from 3,165 hospitals represents a 90.8 percent survey response rate. The proposed FY 2012 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

| Occupational Mix Nursing Subcategory | Average Hourly Wage |
|---|---|
| National RN | 36.049427439 |
| National LPN and Surgical Technician | 20.850540193 |
| National Nurse Aide, Orderly, and Attendant | 14.611398009 |
| National Medical Assistant | 16.458374237 |
| *National Nurse Category* | 30.442540295 |

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $30.442540295. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of

greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2007–2008 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 44.31 percent, and the national percentage of hospital employees in the all other occupations category is 55.69 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 29.08 percent in one CBSA, to a high of 70.76 percent in another CBSA.

We compared the proposed FY 2012 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 209 (53.6 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred seven (27.4 percent) urban areas would increase by 1 percent or more, and 5 (1.3 percent) urban areas would increase by 5 percent or more. Seventeen (35.4 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the wage index values for 181 (46.4 percent) urban areas and 16 (33.3 percent) rural areas would decrease. Eighty-eight (22.6 percent) urban areas would decrease by 1 percent or more, and no urban area would decrease by 5 percent or more. Seven (14.6 percent) rural areas would decrease by 1 percent or more, and no rural areas would decrease by 5 percent or more. The largest positive impacts are 7.81 percent for an urban area and 2.90 percent for a rural area. The largest negative impacts are 3.95 percent for an urban area and 2.78 percent for a rural area. No urban or rural areas are unaffected. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the occupational mix adjustment than do urban areas (53.6 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2006, approximately one-third (33.3 percent) of rural CBSAs would still experience a decrease in their wage indices as a result of the occupational mix adjustment.

The proposed wage index values for FY 2012 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act) included in Tables 4A, 4B, 4C, and 4F, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, include the proposed occupational mix adjustment.

Tables 3A and 3B, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2010, 2011, and 2012 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, includes the adjusted average hourly wage for each hospital from the FY 2006 and FY 2007 cost reporting periods, as well as the FY 2008 period used to calculate the proposed FY 2012 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The proposed average hourly wages in Tables 2, 3A, and 3B, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also include the proposed national rural floor budget neutrality adjustment.

### *H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications*

#### 1. General

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion of the proximity requirements in the FY 2002 IPPS final rule (66 FR 39874 and 39875).)

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use average hourly wage data from the 3 most recently published hospital wage surveys in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106–554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at 42 CFR 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the labor market area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards for designating MSAs and if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs. In light of the CBSA definitions and the Census 2000 data that we implemented for FY 2005 (69 FR 49027), we undertook to identify those counties meeting these criteria. Eligible counties are discussed and identified under section III.H.5. of this preamble.

#### 2. Effects of Reclassification/Redesignation

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for

redesignated hospitals are applicable both to the hospitals deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C) of the Act, the wage index values were determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.
- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index). The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

CMS also has adopted the following policies:

- The wage data for a reclassified urban hospital is included in both the wage index calculation of the urban area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.
- In cases where hospitals have reclassified to rural areas, such as urban hospitals reclassifying to rural areas under 42 CFR 412.103, the hospital's wage data are: (a) included in the rural wage index calculation, unless doing so would reduce the rural wage index; and (b) included in the urban area where the hospital is physically located. The effect of this policy, in combination with the statutory requirement at section 1886(d)(8)(C)(ii) of the Act, is that rural areas may receive a wage index based upon the highest of: (1) Wage data from hospitals geographically located in the rural area; (2) wage data from hospitals geographically located in the rural area, but excluding all data associated with hospitals reclassifying out of the rural area under section 1886(d)(8)(B) or section 1886(d)(10) of the Act; or (3) wage data associated with hospitals geographically located in the area plus all hospitals reclassified into the rural area.

In addition, in accordance with the statutory language referring to "hospitals" in the plural under sections 1886(d)(8)(C)(i) and 1886(d)(8)(C)(ii) of the Act, our longstanding policy is to consider reclassified hospitals as a group when deciding whether to include or exclude them from both urban and rural wage index calculations.

3. FY 2012 MGCRB Reclassifications

a. FY 2012 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2012 reclassification requests. Based on such reviews, there were 280 hospitals approved for wage index reclassifications by the MGCRB for FY 2012. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2012, hospitals reclassified during FY 2010 or FY 2011 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 283 hospitals approved for wage index reclassifications in FY 2010 and 294 hospitals approved for wage index reclassifications in FY 2011. Of all of the hospitals approved for reclassification for FY 2010, FY 2011, and FY 2012, based upon the review at the time of this proposed rule, 857 hospitals are in a reclassification status for FY 2012.

Under 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. Generally stated, the request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2012 has to be received by the MGCRB within 45 days of the publication of the proposed rule. Hospitals also may cancel prior reclassification withdrawals or terminations in certain circumstances. For further information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer the reader to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR 50065). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and "fallback" reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2012 will be incorporated into the wage index values published in the FY 2012 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2013

Applications for FY 2013 reclassifications are due to the MGCRB by September 1, 2011. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2011, via the CMS Internet Web site at: *http://cms.hhs.gov/MGCRB/02_instructions_and_applications.asp,* or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

4. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more

urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties have been known as "Lugar" hospitals and the counties themselves are often referred to as "Lugar" counties. We provide the FY 2011 chart below with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act. For discharges occurring on or after October 1, 2011, hospitals located in the rural county in the first column of this chart will be redesignated for purposes of using the wage index of the urban area listed in the second column.

BILLING CODE 4120–01–P

**Rural Counties Containing Hospitals Redesignated as Urban under Section 1886(d)(8)(B) of the Act (Based on CBSAs and Census 2000 Data)**

| Rural County | CBSA |
|---|---|
| Cherokee, AL | Rome, GA |
| Macon, AL | Auburn-Opelika, AL |
| Talladega, AL | Anniston-Oxford, AL |
| Hot Springs, AR | Hot Springs, AR |
| Windham, CT | Hartford-West Hartford-East Hartford, CT |
| Bradford, FL | Gainesville, FL |
| Hendry, FL | West Palm Beach-Boca Raton-Boynton, FL |
| Levy, FL | Gainesville, FL |
| Walton, FL | Fort Walton Beach-Crestview-Destin, FL |
| Banks, GA | Gainesville, GA |
| Chattooga, GA | Chattanooga, TN-GA |
| Jackson, GA | Atlanta-Sandy Springs-Marietta, GA |
| Lumpkin, GA | Atlanta-Sandy Springs-Marietta, GA |
| Morgan, GA | Atlanta-Sandy Springs-Marietta, GA |
| Peach, GA | Macon, GA |
| Polk, GA | Atlanta-Sandy Springs-Marietta, GA |
| Talbot, GA | Columbus, GA-AL |
| Bingham, ID | Idaho Falls, ID |
| Christian, IL | Springfield, IL |
| DeWitt, IL | Bloomington-Normal, IL |
| Iroquois, IL | Kankakee-Bradley, IL |
| Logan, IL | Springfield, IL |
| Mason, IL | Peoria, IL |
| Ogle, IL | Rockford, IL |
| Clinton, IN | Lafayette, IN |
| Henry, IN | Indianapolis-Carmel, IN |
| Spencer, IN | Evansville, IN-KY |
| Starke, IN | Gary, IN |
| Warren, IN | Lafayette, IN |
| Boone, IA | Ames, IA |
| Buchanan, IA | Waterloo-Cedar Falls, IA |
| Cedar, IA | Iowa City, IA |
| Allen, KY | Bowling Green, KY |
| Assumption Parish, LA | Baton Rouge, LA |
| St. James Parish, LA | Baton Rouge, LA |
| Allegan, MI | Holland-Grand Haven, MI |
| Montcalm, MI | Grand Rapids-Wyoming, MI |
| Oceana, MI | Muskegon-Norton Shores, MI |
| Shiawassee, MI | Lansing-East Lansing, MI |

| Rural County | CBSA |
|---|---|
| Tuscola, MI | Saginaw-Saginaw Township North, MI |
| Fillmore, MN | Rochester, MN |
| Dade, MO | Springfield, MO |
| Pearl River, MS | Gulfport-Biloxi, MS |
| Caswell, NC | Burlington, NC |
| Davidson, NC | Greensboro-High Point, NC |
| Granville, NC | Durham, NC |
| Harnett, NC | Raleigh-Cary, NC |
| Lincoln, NC | Charlotte-Gastonia-Concord, NC-SC |
| Polk, NC | Spartanburg, SC |
| Los Alamos, NM | Santa Fe, NM |
| Lyon, NV | Carson City, NV |
| Cayuga, NY | Syracuse, NY |
| Columbia, NY | Albany-Schenectady-Troy, NY |
| Genesee, NY | Rochester, NY |
| Greene, NY | Albany-Schenectady-Troy, NY |
| Schuyler, NY | Ithaca, NY |
| Sullivan, NY | Poughkeepsie-Newburgh-Middletown, NY |
| Wyoming, NY | Buffalo-Niagara Falls, NY |
| Ashtabula, OH | Cleveland-Elyria-Mentor, OH |
| Champaign, OH | Springfield, OH |
| Columbiana, OH | Youngstown-Warren-Boardman, OH-PA |
| Cotton, OK | Lawton, OK |
| Linn, OR | Corvallis, OR |
| Adams, PA | York-Hanover, PA |
| Clinton, PA | Williamsport, PA |
| Greene, PA | Pittsburgh, PA |
| Monroe, PA | Allentown-Bethlehem-Easton, PA-NJ |
| Schuylkill, PA | Reading, PA |
| Susquehanna, PA | Binghamton, NY |
| Clarendon, SC | Sumter, SC |
| Lee, SC | Sumter, SC |
| Oconee, SC | Greenville, SC |
| Union, SC | Spartanburg, SC |
| Meigs, TN | Cleveland, TN |
| Bosque, TX | Waco, TX |
| Falls, TX | Waco, TX |
| Fannin, TX | Dallas-Plano-Irving, TX |
| Grimes, TX | College Station-Bryan, TX |
| Harrison, TX | Longview, TX |
| Henderson, TX | Dallas-Plano-Irving, TX |
| Milam, TX | Austin-Round Rock, TX |
| Van Zandt, TX | Dallas-Plano-Irving, TX |

| Rural County | CBSA |
|---|---|
| Willacy, TX | Brownsville-Harlingen, TX |
| Buckingham, VA | Charlottesville, VA |
| Floyd, VA | Blacksburg-Christiansburg-Radford, VA |
| Middlesex, VA | Virginia Beach-Norfolk-Newport News, VA |
| Page, VA | Harrisonburg, VA |
| Shenandoah, VA | Winchester, VA-WV |
| Island, WA | Seattle-Bellevue-Everett, WA |
| Mason, WA | Olympia, WA |
| Wahkiakum, WA | Longview, WA |
| Jackson, WV | Charleston, WV |
| Roane, WV | Charleston, WV |
| Green, WI | Madison, WI |
| Green Lake, WI | Fond du Lac, WI |
| Jefferson, WI | Milwaukee-Waukesha-West Allis, WI |
| Walworth, WI | Milwaukee-Waukesha-West Allis, WI |

BILLING CODE 4120–01–C

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals are permitted to compare the reclassified wage index for the labor market area in Table 4C (which is listed in section VI. of the Addendum to this proposed rule and available via the Internet) into which they would be reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB reclassification within 45 days of the publication of this proposed rule.

5. Reclassifications Under Section 1886(d)(8)(B) of the Act

As discussed in the FY 2009 IPPS final rule (73 FR 48588), Lugar hospitals are treated like reclassified hospitals for purposes of determining their applicable wage index and receive the reclassified wage index for the urban area to which they have been redesignated. Because Lugar hospitals are treated like reclassified hospitals, when they are seeking reclassification by the MGCRB, they are subject to the rural reclassification rules set forth at 42 CFR 412.230. The procedural rules set forth at § 412.230 list the criteria that a hospital must meet in order to reclassify as a rural hospital. Lugar hospitals are subject to the proximity criteria and payment thresholds that apply to rural hospitals. Specifically, the hospital must be no more than 35 miles from the area to which it seeks reclassification (§ 412.230(b)(1)); and the hospital must show that its average hourly wage is at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located (§ 412.230(d)(1)(iii)(C)). In accordance with the requirements of section 3137(c) of the Affordable Care Act, beginning with reclassifications for the FY 2011 wage index, a Lugar hospital must also demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation (§ 412.230(d)(1)(iv)(C)).

Hospitals not located in a Lugar county seeking reclassification to the urban area where the Lugar hospitals have been redesignated are not permitted to measure to the Lugar county to demonstrate proximity (no more than 15 miles for an urban hospital, and no more than 35 miles for a rural hospital or the closest urban or rural area for RRCs or SCHs) in order to be reclassified to such urban area. These hospitals must measure to the urban area exclusive of the Lugar County to meet the proximity or nearest urban or rural area requirement. We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to FY 2008 IPPS final rule with comment period (72 FR 47337) for a discussion of this policy.)

6. Reclassifications Under Section 508 of Public Law 108–173

Section 508 of Public Law 108–173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although section 508 originally was scheduled to expire after a 3-year period, Congress extended the provision several times, as well as certain special exceptions that would have otherwise expired. For a discussion of the original section 508 provision and its various extensions, we refer readers to the FY 2010 notice issued in the **Federal Register** on June 2, 2010 (75 FR 31118). Prior to the enactment of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) on December 15, 2010, the extension of the 508 provision was included in sections 3137(a) and 10317 of the Affordable Care Act (Pub. L. 111–148). Section 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends, through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expires on September 30, 2011, and will no longer be applicable effective with FY 2012.

7. Waiving Lugar Redesignation for the Out-Migration Adjustment

We have received several inquiries regarding the effect on a hospital's deemed urban status when a hospital waives its reclassification under section 1886(d)(8) of the Act in order to accept an out-migration adjustment to the wage index under section 1886(d)(13) of the Act. (We refer readers to a discussion of the out-migration adjustment under section III.I. of the preamble of this proposed rule.) In this proposed rule,

we are clarifying that Lugar hospitals will be required to waive their Lugar urban status in its entirety in order to receive the out-migration adjustment. We believe this represents a permissible reading of the statute, as section 1886(d)(13)(G) of the Act states that a hospital with an out-migration adjustment is not "eligible" for a reclassification under subsection (8). Therefore, beginning with FY 2012, we are proposing that an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.G. of this preamble.)

In addition, we are proposing to make a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the adjustment. We are making this proposal in response to public comments we received on the FY 2011 IPPS/LTCH proposed rule that discussed the burden of this annual request (74 FR 43840). Thus, under the proposed procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless prior to its second or third year of eligibility the hospital explicitly notifies CMS in writing, within 45 days from the publication of the proposed rule, that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment.

8. Other Geographic Reclassification Issues

a. Requested Reclassification for Single Hospital MSAs

Section 412.230 of the regulations sets forth criteria for an individual hospital to apply for geographic reclassification to a higher rural or urban wage index area. Specifically, under § 412.230(a)(3)(ii), an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to an urban area for the purpose of using the other area's wage index value. Such a hospital must also meet other criteria. One required criterion (under § 412.230(d)(1)(iii)(C) of the regulations) is that the hospital must demonstrate that its own average hourly wage is higher than the average hourly wage of hospitals in the area in which the hospital is located (108 percent for urban hospitals and 106 percent for rural hospitals). In cases where a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy this criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located (because there are no other hospitals in the area). For hospitals in the category described above, our current policy provides an alternative that allows hospitals to seek reclassification using the group reclassification rules under § 412.232 or § 412.234. Specifically, if a hospital is the single hospital in its area for the 3-year period over which the average hourly wage is calculated for the purpose of the comparison under § 412.230(d)(1)(iii)(C), the hospital may apply for geographic reclassification as a single hospital county group in accordance with the procedures set forth at § 412.232 or § 412.234. In addition to specifying the average hourly wage criteria, these regulations state that the county in which the hospital is located must be adjacent to the urban area to which it seeks redesignation. In addition, a certain level of economic integration needs to exist between the two areas. For example, for urban county group reclassifications (for FY 2008 and subsequent periods), § 412.234(a)(3)(iv) states that "hospitals located in counties that are in the same Combined Statistical Area (CSA) or Core-Based Statistical Area (CBSA) * * * as the urban area to which they seek redesignation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation."

Recently, we have been advised of a single hospital MSA scenario of concern to a particular hospital. In this scenario, an urban hospital located in an area in which there was only one other hospital had previously applied for and was granted a reclassification by the MGCRB to an adjacent urban area with a higher wage index. During the 3-year reclassification timeframe, the other hospital in its labor market area closed. After the expiration of its reclassification, the hospital became ineligible for reclassification to that same adjacent urban area with a higher wage index because it was no longer able to satisfy the wage data comparison criteria to reclassify individually under § 412.230(d)(1)(iii)(C). In addition, the hospital could not apply for redesignation under the urban county group regulation at § 412.234 because the hospital was not located in the same CSA or CBSA as the urban area to which it sought reclassification. In this example, the concern that was shared with CMS was that the hospital was competitively disadvantaged in competing for labor with neighboring hospitals where the hospital had a comparable average hourly wage, compared to the other hospitals in its surrounding area, because it receives a lower wage index.

We believe that the geographic reclassification regulations should not be revised to accommodate this situation. We have repeatedly rejected special rules to accommodate single hospital MSAs (69 FR 48915, 49109; 71 FR 47869, 48071 and 48072). In these explanations, we have highlighted the fact that hospitals in single hospital MSAs not only may be eligible for out-commuting adjustments, but that they also may apply to an adjacent MSA within the same CSA using the group reclassification rules without meeting the 108-percent test. Each year, we propose to adopt the OMB's statistical area definitions (75 FR 50162), so if a hospital in a single hospital MSA cannot meet group reclassification criteria because of the CSA standard, it means that OMB has determined that there is not a sufficient degree of employment interchange to suggest that the areas compete for the same labor. In addition, when we originally adopted the 108-percent test, we noted that "with respect to single hospital MSAs, a hospital in such an MSA receives a wage index value that is based entirely on its own wage data and, therefore, its actual wage levels. Since such a hospital is clearly not disadvantaged by its inclusion in a labor market area where its wage index is determined based on

its own wage levels, it is appropriate under this guideline that a hospital should not be reclassified if it is the only one in its area." (57 FR 39746) Allowing a hospital representing 100 percent of its area's wages to be exempt from the wage data comparison test could undermine the 108-percent test for hospitals in other circumstances where the standard cannot be met. Finally, we note that section 3137(c) of the Affordable Care Act prohibits us from altering average hourly wage comparison criteria for FY 2012. That provision states that "notwithstanding any other provision of law," the MGCRB is required to use the "average hourly wage comparison criteria used in making such decisions as of September 30, 2008," until the first fiscal year beginning on the date that is one year after the Secretary submits a report to Congress.

We are soliciting public comments on this issue. In particular, we invite comments on the types of regulatory solutions that could be made available to a hospital in this type of situation.

b. Requests for Exceptions to Geographic Reclassification Rules

Over the last several years, CMS has received numerous requests for exceptions to current Medicare law and regulation regarding geographic reclassification or requests to revise the existing regulations in order to allow a hospital or group of hospitals the ability to reclassify to a labor market area with a higher wage index. Section 3137(b) of the Affordable Care Act requires the Secretary to submit a report to Congress that includes a "plan to reform the hospital wage index." This report to Congress is due by December 31, 2011. As part of our efforts in this regard, we are soliciting public comments, to be considered only as part of our report to Congress and not to be addressed in the FY 2012 IPPS/LTCH PPS final rule, on ways to redefine the geographic reclassification requirements to more accurately define labor markets.

*I. Proposed FY 2012 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees*

In accordance with the broad discretion granted to the Secretary under section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the "out-migration" adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. Such adjustments to the wage index are effective for 3 years, unless a hospital requests to waive the application of the adjustment. A county will not lose its status as a qualifying county due to hospital wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in any given year may not necessarily qualify after the 3-year period, or it may qualify but receive a different adjustment to the wage index level. Hospitals that receive this adjustment to their wage index are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Adjustments under this provision are not subject to the budget neutrality requirements under section 1886(d)(3)(E) of the Act.

Hospitals located in counties that qualify for the wage index adjustment are to receive an increase in the wage index that is equal to the average of the differences between the wage indices of the labor market area(s) with higher wage indices and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any labor market area with a higher wage index. Beginning with the FY 2008 wage index, we use post-reclassified wage indices when determining the out-migration adjustment (72 FR 47339).

For the proposed FY 2012 wage index, we are proposing to calculate the out-migration adjustment using the same formula described in the FY 2005 IPPS final rule (69 FR 49064), with the addition of using the post-reclassified wage indices, to calculate the out-migration adjustment. This adjustment is calculated as follows:

*Step 1*—Subtract the wage index for the qualifying county from the wage index of each of the higher wage area(s) to which hospital workers commute.

*Step 2*—Divide the number of hospital employees residing in the qualifying county who are employed in such higher wage index area by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area. For each of the higher wage index areas, multiply this result by the result obtained in Step 1.

*Step 3*—Sum the products resulting from Step 2 (if the qualifying county has workers commuting to more than one higher wage index area).

*Step 4*—Multiply the result from Step 3 by the percentage of hospital employees who are residing in the qualifying county and who are employed in any higher wage index area.

These adjustments will be effective for each county for a period of 3 fiscal years. For example, hospitals that received the adjustment for the first time in FY 2011 will be eligible to retain the adjustment for FY 2012. For hospitals in newly qualified counties, adjustments to the wage index are effective for 3 years, beginning with discharges occurring on or after October 1, 2011.

Hospitals receiving the wage index adjustment under section 1886(d)(13)(F) of the Act are not eligible for reclassification under sections 1886(d)(8) or (d)(10) of the Act unless they waive the out-migration adjustment. Consistent with our FYs 2005 through 2011 IPPS final rules, we are specifying that hospitals redesignated under section 1886(d)(8) of the Act or reclassified under section 1886(d)(10) of the Act are deemed to have chosen to retain their redesignation or reclassification. Hospitals that reclassified under section 1886(d)(10) of the Act that wish to receive the out-migration adjustment, rather than their reclassification adjustment, are instructed to follow the termination/withdrawal procedures specified in 42 CFR 412.273 and section III.H.3. of the preamble of this proposed rule. Otherwise, they will be deemed to have waived the out-migration adjustment. Hospitals redesignated under section 1886(d)(8)(B) of the Act will be deemed to have waived the out-migration adjustment unless they explicitly notify CMS within 45 days from the publication of this proposed rule that they elect to receive the out-migration adjustment instead. These notifications should be sent to the following address: Centers for Medicare and Medicaid Services, Center for Medicare, Attention: Wage Index Adjustment Waivers, Division of Acute Care, Room C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Table 4J, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the proposed out-migration wage index adjustments for FY 2012. Hospitals that are not otherwise reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act will automatically receive the listed adjustment. In accordance with the procedures discussed above, redesignated/reclassified hospitals will be deemed to have waived the out-

migration adjustment unless CMS is otherwise notified within the timeframe stated above. In addition, hospitals eligible to receive the out-migration wage index adjustment and that withdraw their application for reclassification will automatically receive the wage index adjustment listed in Table 4J, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

*J. Process for Requests for Wage Index Data Corrections*

The preliminary, unaudited Worksheet S–3 wage data and occupational mix survey data files for the proposed FY 2012 wage index were made available on October 4 2010, through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this new file does not alter the current wage index process or schedule. We notified the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encouraged hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at: *http://www.cms.hhs.gov/OpenDoorForums/.*

In a memorandum dated October 13, 2010, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries/MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the October 4, 2010 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 6, 2010. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage index data files on the Internet, through the October 13, 2010 memorandum referenced above.

In the October 13, 2010 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2007–2008 occupational mix preliminary files posted to our Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its fiscal intermediary/MAC no later than December 6, 2010.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2011 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2011. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 22, 2011. Hospitals had until March 7, 2011, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal intermediaries/MACs as a result of the desk review, and to correct errors due to CMS's or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries/MACs are required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 13, 2011. The deadline for a hospital to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations is April 20, 2011.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2008 data used to construct the proposed FY 2012 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data and transmitted to CMS by March 2011.

We will release the final wage index data public use files in early May 2011 on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp.* The May 2011 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 13, 2011). If, after reviewing the May 2011 final files, a hospital believes that its wage or occupational mix data are incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital should send a letter to both its fiscal intermediary/MAC and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) must receive these requests no later than June 6, 2011.

Each request also must be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC will review requests upon receipt and contact CMS immediately to discuss any findings.

At this point in the process, that is, after the release of the May 2011 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries or the MACs on or before April 13, 2011.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 22, 2011 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 6, 2011) will be incorporated into the final wage index in the FY 2012 IPPS/LTCH PPS final rule, which will be effective October 1, 2011.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2012 payment rates. Accordingly, hospitals that do not meet

the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the fiscal intermediary's (or, if applicable, the MAC's) decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision. (See *W. A. Foote Memorial Hospital* v. *Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001) and *Palisades General Hospital* v. *Thompson,* No. 99–1230 (D.D.C. 2003).) We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appealing to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the fiscal intermediary's (or, if applicable, the MAC's) attention. Moreover, because hospitals have access to the final wage index data by early May 2011, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2012 wage index by August 2011, and the implementation of the FY 2012 wage index on October 1, 2011. If hospitals avail themselves of the opportunities afforded to provide and make corrections to the wage and occupational mix data, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after June 6, 2011, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the June 6 deadline for making corrections to the wage data for the following fiscal year's wage index. This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the fiscal intermediaries or the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when: (1) The fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the fiscal intermediary (or, if applicable, the MAC) and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 6, 2011 deadline for the FY 2012 wage index); and (3) CMS agreed that the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 6, 2011 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In other situations where our policies would allow midyear corrections, we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a judicial decision reverses a CMS denial of a hospital's wage index data revision request.

*K. Labor-Related Share for the Proposed FY 2012 Wage Index*

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates * * *" We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this "would result in lower payments to a hospital than would otherwise be made." However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate "from time to time" the proportion of hospitals' costs that are "attributable to wages and wage-related costs." We believe that this reflected Congressional intent that hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we rebased and revised the hospital market basket for operating costs. We established a FY–2006-based IPPS hospital market basket to replace the FY as 2002-based IPPS hospital market basket, effective October 1, 2009. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY as 2010. We also recalculated a labor-related share of 68.8 percent, using the FY 2006-based IPPS market basket, for

discharges occurring on or after October 1, 2009. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner, but consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this proposed rule, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive).

Therefore, for FY 2012, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and available via the Internet, reflect this labor-related share. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this employment "would result in lower payments to a hospital than would otherwise be made." Therefore, for all IPPS hospitals whose wage indices are less than 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 68.8 percent of the national standardized amount.

For Puerto Rico hospitals, the national labor-related share will always be 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0. In this proposed rule, we are proposing to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2011. This Puerto Rico labor-related share of 62.1 percent was also adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43857) at the time the FY 2006-based hospital market basket was established, effective October 1, 2009. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive) to determine the labor-related share. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a Puerto Rico-specific wage index of greater than 1.0, we will set the hospital's rates using a labor-related share of 62.1 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount will result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than 1.0 will be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share will result in higher payments. The Puerto Rico labor-related share of 62.1 percent for FY 2012 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet.

## IV. Other Proposed Decisions and Changes to the IPPS for Operating Costs and GME Costs

### *A. Hospital Inpatient Quality Reporting (IQR) Program*

#### 1. Background

##### a. Overview

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely-agreed upon quality measures. CMS has worked with relevant stakeholders to define measures of quality in almost every setting and measures various aspects of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, CMS implemented the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals, the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). CMS has also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program that links payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act so that the burden for reporting will be reduced.

We also are proposing to implement a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. On January 7, 2011, we issued a proposed rule to implement the Hospital VBP Program under section 1886(o) of the Act (76 FR 2454 through 2491) (the Hospital Inpatient VBP Program proposed rule). We are proposing additional policies for the Hospital VBP Program in section IV.B. of this proposed rule. In the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491), we proposed that hospitals would receive value-based incentive payments if they meet performance standards with respect to measures for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures specified under the Hospital IQR Program. The Hospital VBP Program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) of the Act.

The Hospital IQR Program is intertwined with the Hospital VBP Program because the measures and reporting infrastructure for both programs will overlap. We view the

Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare into an active purchaser of quality health care for its beneficiaries. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), in developing that proposed rule as well as other value-based payment initiatives, we applied the following principles for the development and use of measures and scoring methodologies:

*Purpose:*

• We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

*Use of Measures:*

• Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

• To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

• The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

• To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We invite public comment on these principles.

b. Statutory History and History of Measures Adopted for the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43860) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180) for detailed discussions of the history of the Hospital IQR Program, including the statutory history and the measures we have adopted for the Hospital IQR measure set through FY 2014.

Section 1886(b)(3)(B)(viii)(V) of the Act requires that, effective for payments beginning with FY 2008, the Secretary to add quality measures that reflect consensus among affected parties, and to the extent feasible and practicable, have been set forth by one or more national consensus building entities. We are seeking comments on an option that would allow us from time to time to consider a range of consensus endorsement entities or bodies that can assist us with our measure development process. We believe that this approach would provide for a diverse endorsement process and the best body of evidence to support quality measures used in our quality programs.

c. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org*. We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual, which is available at the HCAHPS On-Line Web site, *http://www.hcahpsonline.org*. We maintain the HCAHPS technical specifications by updating the HCAHPS *Quality Assurance Guidelines* manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

d. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We are proposing to display information regarding the measures (such as names of measures for which data will be displayed in the future) on the *Hospital Compare* Web site under this provision, and invite public comment on this proposal. We will continue our current practice of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov* after a 30-day preview period.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, and structural measures, all of which are featured on the *Hospital Compare* Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on *Hospital Compare* may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the *Hospital Compare* Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public

following a preview period. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare*.

2. Retirement of Hospital IQR Program Measures

a. Considerations in Retiring Quality Measures From the Hospital IQR Program

We generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets. We previously retired one "topped out" measure, PN–1: Oxygenation Assessment for Pneumonia, from the Hospital IQR Program on the basis of high unvarying performance among hospitals, because measures with very high performance among hospitals present little opportunity for improvement, and do not provide meaningful distinctions in performance for consumers.

We also have retired one measure from the Hospital IQR Program because it no longer "represent[ed] the best clinical practice," as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, we believe that it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly retire such a measure, confirm the retirement in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly retire measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos and e-mail notification and QualityNet Web site articles and postings.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), among the criteria that we consider when determining whether to retire Hospital IQR Program measures are the following: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program measures for retirement.

b. Proposed Retirement of Hospital IQR Program Measures for the FY 2014 Payment Determination and Subsequent Years

In order to reduce the reporting burden on hospitals, and in particular, the burden associated with reporting chart-abstracted measures, we have considered options to accommodate the expansion of the measure set through the retirement of additional Hospital IQR measures. Specifically, we have considered retiring one or more of the measures suggested by various commenters that were listed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43865). We noted in that final rule that commenters recommended for retirement 11 Hospital IQR Program chart-abstracted measures. Seven of these 11 measures were recommended by commenters for retirement based on their performance being uniformly high nationwide, with little variability among hospitals (topped-out measures). Based on our own analysis, we concluded that these measures are topped out and for this reason, we proposed not to include them in the FY 2013 Hospital VBP Program measure set (76 FR 2460). These measures are listed below:

- AMI–1 Aspirin at arrival
- AMI–3 ACEI/ARB for left ventricular systolic dysfunction
- AMI–4 Adult smoking cessation advice/counseling
- AMI–5 Beta-blocker prescribed at discharge
- HF–4 Adult smoking cessation advice/counseling
- PN–4 Adult smoking cessation advice/counseling
- SCIP INF–6 Appropriate Hair Removal

The methodology we used to determine that these measures are topped out is detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2460). We are proposing to retire these topped out measures from the Hospital IQR measure set. In addition, we proposed to not include an eighth measure in the FY 2013 Hospital VBP Program measure set because we believe that inclusion of this measure would result in the unintended consequence of inappropriate antibiotic use (76 FR 2462). This measure is PN–5c Timing of receipt of initial antibiotic following hospital arrival. We are also proposing to retire this measure from the Hospital IQR Program because of the potential for this negative unintended consequence.

For these reasons, we are proposing to retire these eight measures from the Hospital IQR measure set for FY 2014 and subsequent years, and that hospitals would no longer be required to submit data on these measures starting with January 1, 2012 discharges. We invite public comment on this proposal.

3. Proposed Measures for the FY 2014 and FY 2015 Hospital IQR Payment Determinations

a. Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

In general, we seek to adopt measures for the Hospital IQR Program that promote better, safer, more efficient care. Our measure development and selection activities for the Hospital IQR Program take into account national priorities, such as those established by the National Priorities Partnership, HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, as well as other widely accepted criteria established in medical literature. (We refer readers to the following Web sites regarding these priorities: *http://www.nationalprioritiespartnership.org/* (National Priorities Partnership); *http://www.hhs.gov/secretary/about/priorities/priorities.html* (HHS Strategic Plan); and *http://www.healthcare.gov/center/reports/quality03212011a.html* (National Strategy for Quality Improvement in Healthcare)). To the extent practicable, we have sought to adopt measures which have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers and other stakeholders. Because measures for the Hospital VBP Program must be selected from the measures specified for the Hospital IQR Program, the measures to be selected for inclusion in the Hospital VBP Program also reflect these priorities. In addition, we believe it is important to expand the pool of measures to include measures that are directed toward improving patient

safety. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[6] [7]

Section 3001(a)(2) of the Affordable Care Act amended the Act by adding a new section 1886(b)(3)(B)(viii)(VIII) of the Act. This section states that, "[e]ffective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions." Section 3001(a)(2) of the Affordable Care Act also added new sections 1886(b)(3)(B)(viii)(IX)(aa) and (bb) of the Act. These sections state that "* * * effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a) [of the Act]," and "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." In the FY 2011 IPPS/LTCH PPS final rule, we established that all of the measures adopted in that rule for the FY 2013 and FY 2014 payment determinations meet these standards (75 FR 50200).

We have previously acknowledged the data collection burden for hospitals participating in the Hospital IQR Program, and reiterated our desire to expand the Hospital IQR Program measure set while minimizing burden and seeking to provide alternative mechanisms for data submission (75 FR 50189). We also stated that in future expansions and updates to the Hospital IQR Program measure set, we would be taking into consideration several important goals. These goals include: (a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital IQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases; and, (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program.

Specifically, we give priority to measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and, (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We have used and continue to use these criteria to guide our decisions regarding what measures to add to the Hospital IQR Program measure set. In addition, in selecting measures, we seek to address the six quality aims of effective, safe, timely, efficient, patient-centered, and equitable healthcare. Current and long term priority topics include: Prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections (HAIs) and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.

Hospital IQR Program measures were initially based solely on a hospital's submission of chart-abstracted quality measure data. However, in recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources. This approach supports our goal of expanding the measures for the Hospital IQR Program while minimizing the burden on hospitals and, in particular, without significantly increasing the chart abstraction burden.

In addition to structural measures and claims-based measures, we previously noted that registries are potential alternative sources of hospital data for the Hospital IQR Program. (A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.) We envisioned that instead of requiring hospitals to submit the same data to CMS that many hospitals are already submitting to registries, we would collect the data directly from the registries. This could enable the expansion of the Hospital IQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. We have previously adopted structural measures of registry participation, and we continue to evaluate the feasibility of leveraging registry-based data collection mechanisms for the Hospital IQR Program.

We also stated our intention to explore mechanisms for data submission using electronic health records (EHRs) (73 FR 48614; 74 FR 43866, 43892; and 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that at a future date, such as FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We reiterate our commitment to pursue our goals to expand and update quality measures under the Hospital IQR Program and also to minimize burden. We note that in addition to the input we described above, we take into consideration the measures adopted by the Hospital Quality Alliance (HQA) as well as an array of input from the public. The HQA is a national public-private collaboration that is committed to making meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality. We appreciate HQA's integral efforts to

[6] OEI–06–09–00090, "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human Services, Office of Inspector General, November 2010.

[7] 2009 National Healthcare Quality Report, pp. 107–122. "Patient Safety," Agency for Healthcare Research and Quality.

improve hospital quality of care and its support of our public quality reporting programs.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50191 through 502192), we finalized our proposal to adopt measures for the Hospital IQR Program for three consecutive payment determinations. The intent of this policy was to provide greater certainty for hospitals to plan to meet future reporting requirements and implement related quality improvement efforts. Aside from giving hospitals more advance notice in planning quality reporting, this 3-year approach also provides more time for us to prepare, organize and implement the infrastructure needed to collect data on the measures and make payment determinations. We indicated, however, that these preliminary measure sets could still be updated through the rulemaking process should we need to respond to agency and/or legislative changes.

Finally, in section IV.A.5.a.(2) of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219 through 50220), we adopted a proposal to make Hospital IQR Program payment determinations beginning with FY 2013 using one calendar year of data for chart-abstracted measures. We will use this approach, which synchronizes the quarters for which data on these measures must be submitted during each year with the quarters used to make payment determinations with respect to a fiscal year beginning with January 1, 2011 discharges. However, it will not affect our payment determinations until FY 2013.

Section 1886(o)(2)(A) of the Act requires the Secretary to select measures, other than readmission measures, for the Hospital VBP Program from the measures specified under the Hospital IQR Program. Section 1886(o)(2)(B)(i)(I) of the Act states that, for FY 2013, the selected measures must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), Surgeries, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-associated infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services. Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital Inpatient Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. We will focus on selecting measures that we believe will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes.

In addition, in order to support HHS priorities such as patient safety and reduction of HAIs and readmissions, and meet more of the widespread goals of the Affordable Care Act in terms of improving the quality of care provided to Medicare beneficiaries, we are proposing in this proposed rule to adopt measures for the FY 2014 and FY 2015 Hospital IQR payment determinations. However, we note that the final measure sets to be used for these years' payment determinations could be changed via future rulemaking. This allows CMS the flexibility to accommodate changes in program needs and legislative changes. We invite public comment on these proposals.

b. Proposed Hospital IQR Program Measures for the FY 2014 Hospital IQR Payment Determination

(1) Proposed Retention of 52 Hospital IQR Program Measures Finalized in the FY 2011 IPPS/LTCH PPS Final Rule for the FY 2014 Payment Determination

We previously finalized 60 measures for the FY 2014 Hospital IQR Program measure set. However, as we discussed above, we are proposing to retire 8 measures from the FY 2014 measure set. We are proposing to retain the remaining 52 the 60 quality measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination. We invite public comment on our proposal to retain 52 quality measures for the FY 2014 payment determination.

(2) Proposed Additional Hospital IQR Program Measures for the FY 2014 Payment Determination

(A) Proposed CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the U.S. The Centers for Disease Control (CDC) estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[8] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs.

HAIs are largely preventable with widely publicized interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, the public reporting of HAIs has been of great interest to many health care consumers and advocacy organizations because it promotes awareness and permits health care consumers to choose the hospitals with lower HAI rates, as well as gives hospitals an incentive to improve infection control efforts. To maximize the efficiency and improve the coordination of HAI prevention efforts across the Department, HHS established in 2008 a senior-level Steering Committee for the Prevention of Healthcare-Associated Infections. In 2009, the Steering Committee, along with scientists and program officials across the government, developed the HHS Action Plan to Prevent Healthcare-Associated Infections, providing a roadmap for HAI prevention in acute care hospitals. In the first iteration of the Action Plan, the Steering Committee chose to focus on infections in acute care hospitals because the associated morbidity and mortality was most severe in that setting and the scientific information on prevention and the capacity to measure improvement was most complete. Thus, prevention of HAIs in acute care hospitals became the first phase of the Action Plan and it focuses on six high priority HAI-related areas.

In addition, the Steering Committee included in the Action Plan five-year goals for nine specific measures of improvement tied to the six HAI prevention priority areas. Since the release of the first Action Plan in June 2009, the Steering Committee has been developing a successor plan in collaboration with public and private partners which is expected to incorporate advances in science and technology and expand the scope to the outpatient environment. The successor plan is also expected to address the health and safety of healthcare personnel, as well as the risks of influenza transmission from healthcare personnel to patients. The second Action Plan is due for publication in 2011.

We also note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its "pay for reporting" system two infection control measures developed by the

[8] McKibben L, Horan T. Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26

Hospital Quality Alliance (HQA)—Central line-associated bloodstream infections and a surgical site infection rate (H. Rep. No. 111–220, at 159 (2009)). In the report, the Committee stated that "if the measures are included in *Hospital Compare,* the public reporting of the data is likely to reduce HAI occurrence, an outcome demonstrated in previous research."

In the FY 2011 IPPS/LTCH PPS final rule, we adopted the two HAI measures identified by the House Committee on Appropriations in its 2009 report: Central Line [catheter] Associated Blood Stream Infection (CLABSI) measure, and Surgical Site Infection (SSI) measure. The CLABSI measure is currently part of the FY 2013 Hospital IQR measure set, and data submission on the measure began with January 2011 events.[9] The Surgical Site Infection (SSI) measure is currently part of the FY 2014 Hospital IQR measure set, and data submission on the measure will begin with January 2012 events.

In this proposed rule, we are proposing to adopt two additional HAI measures for the FY 2014 Hospital IQR measure set. These proposed measures were developed by the CDC and are currently collected by the CDC via the NHSN. These measures are: (1) Central Line Bundle Compliance (NQF #0298) (referred to by the CDC and in this proposed rule as Central Line Insertion Practices, or CLIP); and (2) Catheter Associated Urinary Tract Infection (CAUTI) (NQF #138). Both measures are high priority HAI measures that are included among the prevention metrics established in the HHS Action Plan to Prevent HAIs which, as we noted above, underscores the importance of reducing HAIs. As detailed below, both measures also meet Hospital IQR Program statutory requirements for measure selection. Furthermore, both measures are currently collected by the NHSN, which is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the U.S., including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN enables healthcare facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use NHSN as a means for healthcare facilities to submit patient-level data on the measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using NHSN, and CDC provides support to more than 4,000 hospitals that are using NHSN. NHSN data collection occurs via a Web-based tool hosted by CDC provided free of charge to providers. In addition, data submission for HAI measures through EHRs may be possible in the near future.

(i) Central Line Insertion Practice Adherence Percentage (CLIP)

Central line associated blood stream infections (CLABSIs) can be prevented through proper management of the central line. The CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections* recommends evidence-based central line insertion practices known to reduce the risk of subsequent central line-associated bloodstream infection.[10] These include hand-washing by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing that skin antiseptic to dry before catheter insertion. Despite the scientific evidence supporting these practices, several reports suggest that adherence to these practices remains low in United States hospitals. The proposed CLIP process measure is a companion measure to the previously adopted CLABSI measure, and it assesses the extent to which a facility employs practices consistent with CDC/HICPAC recommendations that are known to reduce CLABSI. There are 2 States that currently require facilities to report to NHSN at least one month of CLIP data.

The CLIP measure is used in State reporting initiatives and is an NQF-endorsed measure (NQF #298) that is operationalized for collection via the NHSN. Therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. This CLIP prevention metric is also listed in the HHS Action Plan to Prevent HAIs and, as we detailed above, has been widely identified as a high priority for public reporting.

(ii) Catheter Associated Urinary Tract Infection (CAUTI)

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[11] Healthcare-associated urinary tract infections (UTIs) are commonly attributed to catheterization of the urinary tract. CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[12] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections.* The NQF-endorsed CAUTI measure we are proposing is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals. There are 3 States that require facilities to report to NHSN at least one month of CAUTI data.

Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that effective for payments beginning with FY 2013, each measure specified by the Secretary for inclusion in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless the exception set forth in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies. The NQF currently holds the contract under section 1890(a) of the Act, and the NQF has endorsed this CAUTI measure (NQF #138). For this reason, we believe that this measure satisfies the endorsement requirement applicable to the Hospital IQR Program. This proposed measure is currently risk stratified,and therefore is consistent with section 1886(b)(3)(B)(viii)(VIII) of the Act. Risk stratification means that it is calculated using different categories of patients with varying risk of developing an infection. At the time of this proposed rule, this CAUTI measure (NQF #138) is undergoing measure maintenance review by the NQF and we note that the review may result in changes to the specifications. We invite

[9] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

[10] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.,* Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR–10:1–26).

[11] Klevens RM, Edward JR, *et al.,* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[12] Wong ES., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981;2:126–30.

public comment on our proposal to adopt these two HAI measures into the Hospital IQR Program for the FY 2014 payment determination. We are proposing that hospitals would begin submitting data on these measures beginning with events that occur on or after January 1, 2012. We are also proposing that hospitals use the NHSN infrastructure and protocols, as well as the specifications (available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf*) to report the measures for Hospital IQR Program purposes. The proposed reporting mechanism for these HAI measures is discussed in greater detail in section IV.A.5.i. of this proposed rule.

(B) Proposed New Claims-Based Measure

We are proposing to add the following new claim-based measure to the Hospital IQR Program measure set for the FY 2014 payment determination: Medicare Spending per Beneficiary. The details of this measure are discussed below.

(i) Medicare Spending per Beneficiary Measure

Healthcare costs consume an ever-increasing amount of our Nation's resources, straining family, business, and government budgets. Healthcare costs take up a growing share of Federal and State budgets and imperil the governments' long-term fiscal outlooks. In the U.S., the sources of inefficiency that are leading to rising healthcare costs include payment systems that reward medical inputs rather than outcomes. Medicare is transforming from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation.

In order to further this transformation and help address the critical issue of health care costs, we are proposing to add a measure of Medicare spending per beneficiary to the Hospital IQR Program measure set for the FY 2014 payment determination. This proposed Medicare spending per beneficiary measure addressing the cost of care is a type of measure that is not currently included in the Hospital IQR Program. We are not aware that the NQF or any other consensus organizations under section 1886(b)(3)(B)(viii)(IX) of the Act have currently endorsed any Medicare spending per beneficiary measures. We will give due consideration under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act to any Medicare spending per beneficiary measures that become endorsed in the future. It is important that the cost of care be explicitly measured so that, in conjunction with other measures that we have adopted and are proposing to adopt for the Hospital IQR Program, we can recognize hospitals that are involved in the provision of high quality care at lower cost.

We are proposing that this Medicare spending per beneficiary measure would be calculated using claims data for hospital discharges occurring between May 15, 2012 and February 14, 2013. Therefore, the addition of this proposed measure would not increase the data submission burden on hospitals. We outline below the methodology that we are proposing to use to calculate the measure, if finalized.

• The Medicare Spending per Beneficiary Episode

In order to calculate the Medicare spending per beneficiary for each hospital, we believed that it would be necessary to determine: (1) The timeframe, or length of the "spending per beneficiary episode" during which Medicare payments would be aggregated; (2) the types of Medicare payments to be aggregated over this timeframe; and (3) how to adjust or standardize these payments across hospitals (for example, risk adjustment).

• Length of the Medicare Spending per Beneficiary Episode

We are proposing an episode that runs from three days prior to an inpatient PPS hospital admission (the index admission) through 90 days post hospital discharge. We are proposing to include the time period 90 days post hospital discharge in order to emphasize the importance of care transitions and care coordination in improving patient care. We believe inclusion of this time period surrounding the hospital admission would reinforce the need to reduce adverse outcomes, including readmissions. Encouraging delivery of coordinated care in an efficient manner is an important goal which can best be achieved through inclusion of Medicare payments made outside the timeframe of the hospital inpatient stay.

We recognize that some outcome measures are based on an episode that runs 30 days post discharge. We considered proposing 30 days as the post discharge time period for the episode. However, we believe this shorter time period does not place sufficient emphasis on longer term care transitions and care coordination. Nevertheless, while we are proposing a 90 day post discharge period, we seek public comment on an alternative 30 day time period for the initial implementation of this measure that would be more consistent with the 30 day time period currently in use for some outcome measures.

• Medicare Payments Included in the Spending per Beneficiary Episode

In order to calculate the Medicare spending per beneficiary, it is necessary to define the Medicare payments included in the spending per beneficiary episode. Subject to the adjustments described below, we are proposing to include all Medicare Part A and Part B payments made for services provided to the beneficiary during the episode, including payments made by beneficiaries that we can determine using our claims data, such as Part B deductibles and coinsurance amounts. As with the 90 day post discharge period, we believe that this comprehensive inclusion of Medicare Part A and Part B spending emphasizes the importance of care coordination in improving patient care. Encouraging delivery of coordinated care in an efficient manner over an extended time period is an important goal which can best be achieved through the inclusion of comprehensive Medicare Part A and Part B spending.

We also are proposing that transfers, readmissions, and additional admissions that began during the 90-day post discharge window of an index admission would be included in the episode used for calculating the measure.

We are proposing to exclude from the Medicare spending per beneficiary calculation episodes where at any time during the episode the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, including if the beneficiary is enrolled in a Medicare Advantage plan at any time during the episode or becomes deceased. We also are proposing to exclude any episodes where the beneficiary is covered by the Railroad Retirement Board. We also propose to exclude any episodes where Medicare is a secondary payer. The rationale for exclusion of these episodes from the calculation of the Medicare spending per beneficiary is that we do not have full payment data to identify and standardize spending which would otherwise be attributable to these episodes.

• Adjusting the Medicare Payments Included in the Spending per Beneficiary Episode

Section 1886(o)(2)(B)(ii) of the Act requires that a Medicare spending per beneficiary measure adopted for the Hospital VBP Program be "adjusted for factors such as age, sex, race, severity of

illness, and other factors that the Secretary determines appropriate." Consistent with these statutory requirements, we are proposing to adjust the proposed Medicare spending per beneficiary measure for age and severity of illness. We are proposing to adjust for severity of illness based on the hierarchical condition categories (HCCs) for the period 90 days prior to the episode and based on the MS–DRG during the index admission. Adding the MS–DRG to the use of the HCC improves the severity of illness adjustment and better standardizes the data, allowing for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. Note that we would exclude episodes where the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, for the 90 days prior to the episode because we would not be able to capture all the data necessary for the severity of illness adjustment.

We are not proposing to adjust the Medicare spending per beneficiary for sex and race, consistent with our understanding of NQF's position strongly discouraging adjusting measures based on these factors.

In addition, we are proposing to exclude geographic payment rate differences (for example, based on the wage index and geographic practice cost index) in order to standardize the spending per beneficiary. Note, we are not proposing to adjust for geographic differences in spending that are unrelated to geographic payment rate differences. However, we seek comment on whether there are geographic factors other than payment rate differences that should be considered in the spending per beneficiary measure. We also propose to standardize spending by excluding the portion of IPPS payments resulting from the payment differentials caused by Hospital-Specific Rates, IME, and DSH. Note that we are not proposing to exclude spending for hospitals that are paid Hospital-Specific Rates, rather we are proposing to exclude the differential additional spending that results from the use of the Hospital-Specific Rates. Again, making these adjustments allows for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. For example, without adjusting for geographic payment rate differences, a hospital might have higher or lower spending per beneficiary amounts compared to other hospitals based on its wage index and not its performance.

• Calculating a Hospital's Medicare Spending per Beneficiary Amount

For each subsection (d) hospital participating in the Hospital IQR Program, we are proposing to add together all the adjusted Medicare Part A and Part B payments, as defined above, included in all the Medicare spending per beneficiary episodes, as defined above, for that hospital. We would then divide this sum by the total number of Medicare Spending per Beneficiary episodes for that hospital. The resulting amount would constitute the hospital's Medicare spending per beneficiary amount for the period. The discharge period that we are proposing to apply the proposed measure for the FY 2014 Hospital IQR Program is May 15, 2012 through February 14, 2013.

• Calculating a Hospital's Medicare Spending per Beneficiary Ratio

We are proposing to calculate a hospital's Medicare spending per beneficiary ratio as the hospital's Medicare spending per beneficiary amount divided by the median Medicare spending per beneficiary amount across all hospitals.

As noted above, we are also proposing to adopt this proposed measure for the Hospital VBP Program FY 2014 measure set. The proposed method for scoring and incorporating this Medicare spending per beneficiary ratio into the hospital's total performance score for the Hospital VBP Program is fully described in section IV.B.3.b.(3)(C) of this proposed rule.

(C) Proposed New Web-Based Structural Measure

Structural measures assess the characteristics and capacity of the provider to deliver quality health care. In the FY 2009 IPPS final rule, we finalized the "Participation in a Systematic Database for Cardiac Surgery" measure (73 FR 48609) for the FY 2010 payment determination. This measure does not require the hospital to actually participate in a cardiac surgery registry, instead, it only requires the hospital to report whether or not it participates in a cardiac surgery registry. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43871 and 43872), we adopted two more structural measures: Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care under the Hospital IQR Program for the FY 2011 payment determination. Based on public comments, we collect these structural measures once annually.

We are now proposing to include a new structural measure, Participation in a Systematic Clinical Database Registry for General Surgery, in the Hospital IQR Program beginning with the FY 2014 payment determination. The Participation in a Systematic Clinical Database Registry for General Surgery measure would require each hospital that participates in Hospital IQR Program to indicate whether it is participating in a Systematic Clinical Database Registry for General Surgery and, if so, to identify the registry. This measure, like two of the previously adopted structural measures on registry participation (Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care), is an application of an NQF-endorsed measure (NQF #0493) "Participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures" to the inpatient facility.

We recognize that the NQF has endorsed this measure for the physician/clinician setting, but believe that this measure is highly relevant to the hospital setting, in that participation in a systematic clinical database registry for various topics is quite common in hospitals. Therefore, we previously adopted the Stroke and Nursing Sensitive Care registry participation measures as applications of the measure appropriate to the hospital inpatient setting. We reviewed the NQF's consensus endorsed measures, as well as measures endorsed or adopted by another consensus organization, and were unable to identify any other measures specifically for participation in a systematic clinical database registry for general surgery that have been endorsed for the hospital inpatient setting. Having given due consideration to other measures that have been endorsed or adopted by a consensus entity, we are proposing to adopt an application of this non-NQF endorsed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We are proposing to adopt the measure under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. Additionally, we believe that, for the same reasons, the previously adopted structural measures for Stroke and Nursing Sensitive Care registries also meet the requirements under this authority and propose to continue collecting them on that basis.

We are proposing that annual data submission for this proposed structural

measure via a Web-based collection tool would begin in July 2012 with respect to the time period January 1, 2012, through June 30, 2012. We believe that participation in a registry provides hospitals with valuable ongoing quality improvement information and demonstrates a commitment to improve. Many registries also collect outcome data and provide feedback to hospitals about their performance. We invite public comment on this proposal to include this structural measure for the FY 2014 payment determination.

In summary, we are proposing to retire 8 measures from the measure set for the FY 2014 payment determination that was finalized in the FY 2011 IPPS/LTCH PPS final rule, and we are proposing to add 4 measures to the measure set for the FY 2014 payment determination: 2 HAI measures collected through the NHSN, 1 claims-based measure (Medicare Spending Per Beneficiary), and 1 structural measure, for a total of 56 measures for the FY 2014 Hospital IQR payment determination. These 56 measures are listed below.

BILLING CODE 4120–01–P

| Topic | Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures |
|---|---|
| Acute Myocardial Infarction (AMI) | |
| | ● AMI-2 Aspirin prescribed at discharge |
| | ● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival |
| | ● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) |
| | ● AMI-10 Statin Prescribed at Discharge |
| Heart Failure (HF) | |
| | ● HF-1 Discharge instructions |
| | ● HF-2 Evaluation of left ventricular systolic function |
| | ● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction |
| Pneumonia (PN) | |
| | ● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital |
| | ● PN-6 Appropriate initial antibiotic selection |
| Surgical Care Improvement Project (SCIP) | |
| | ● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision |
| | ● SCIP INF-2: Prophylactic antibiotic selection for surgical patients |
| | ● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) |
| | ● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose |
| | ● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero |
| | ● SCIP INF-10: Surgery patients with perioperative temperature management |
| | ● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period |
| | ● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered |
| | ● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery |
| Mortality Measures (Medicare Patients) | |
| | ● Acute Myocardial Infarction (AMI) 30-day mortality rate |
| | ● Heart Failure (HF) 30-day mortality rate |
| | ● Pneumonia (PN) 30-day mortality rate |

| Topic | Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures |
|---|---|
| Patients' Experience of Care | |
| | ● HCAHPS survey |
| Readmission Measure (Medicare Patients) | |
| | ● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure |
| | ● Heart Failure 30-day Risk Standardized Readmission Measure |
| | ● Pneumonia 30-day Risk Standardized Readmission Measure |
| AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures | |
| | ● PSI 06: Iatrogenic pneumothorax, adult |
| | ● PSI 11: Post Operative Respiratory Failure |
| | ● PSI 12: Post Operative PE or DVT |
| | ● PSI 14: Postoperative wound dehiscence |
| | ● PSI 15: Accidental puncture or laceration |
| | ● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) |
| | ● IQI 19: Hip fracture mortality rate |
| | ● Complication/patient safety for selected indicators (composite) |
| | ● Mortality for selected medical conditions (composite) |
| AHRQ PSI and Nursing Sensitive Care | |
| | ● PSI 04 Death among surgical inpatients with serious treatable complications |
| Structural measures | |
| | ● Participation in a Systematic Database for Cardiac Surgery |
| | ● Participation in a Systematic Clinical Database Registry for Stroke Care |
| | ● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care |
| | ● Participation in a Systematic Clinical Database Registry for General Surgery** |
| Healthcare-Associated Infections | |
| | ● Central Line Associated Bloodstream Infection |
| | ● Surgical Site Infection* |
| | ● Central Line Insertion Practices Percentage** |
| | ● Catheter-Associated Urinary Tract Infection** |
| Hospital Acquired Condition Measures | |
| | ● Foreign Object Retained After Surgery |
| | ● Air Embolism |
| | ● Blood Incompatibility |
| | ● Pressure Ulcer Stages III & IV |
| | ● Falls and Trauma: (Includes: Fracture Dislocation Intracranial |

| Topic | Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures |
|---|---|
| | Injury Crushing Injury Burn Electric Shock) |
| | • Vascular Catheter-Associated Infection |
| | • Catheter-Associated Urinary Tract Infection (UTI) |
| | • Manifestations of Poor Glycemic Control |
| Emergency Department Throughput | |
| | • ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital* |
| | • ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status* |
| Prevention: Global Immunization Measures | |
| | • Immunization for Influenza * |
| | • Immunization for Pneumonia* |
| Cost Efficiency | |
| | • Medicare Spending per Beneficiary** |

* Measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination
** Additional measures proposed in this proposed rule for FY 2014 payment determination

BILLING CODE 4120–01–C

c. Proposed Hospital IQR Program Quality Measures for the FY 2015 Payment Determination

(1) Proposed Retention of FY 2014 Payment Determination Measures for the FY 2015 Payment Determination

We generally retain the Hospital IQR Program measures from one year to the next. Consistent with this approach, we are proposing to retain all of the proposed measures for the FY 2014 payment determination, if finalized, for the FY 2015 payment determination. We invite public comment on this proposal.

(2) Proposed New Hospital IQR Program Measures for the FY 2015 Payment Determination

(A) Proposed New CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures for the 2015 Payment Determination

For the FY 2015 payment determination, we are proposing to adopt three additional HAI measures that are currently collected by CDC via the NHSN. These measures are: (1) Methicillin-resistant Staphylococcus Aureus (MRSA) Bacteremia measure; (2) C. *Difficile* SIR; and (3) Healthcare Personnel (HCP) Influenza Vaccination and the specifications for these 3 measures are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* Like the CLIP and the CAUTI measures that we are proposing for the FY 2014 payment determination, all three proposed HAI measures are high priority HAI measures listed in the HHS Action Plan to Prevent HAIs and were listed in previous rulemaking as possible quality measures for future payment determinations.

Our review indicated that there are no measures for MRSA or C. *Difficile* SIR that have been endorsed by the NQF or another consensus entity for the hospital inpatient setting. Therefore, we are proposing to adopt this non-NQF-endorsed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We are proposing to adopt these two CDC-developed measures (MRSA and C. *Difficile* SIR) under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act.

The HCP Influenza Vaccination measure is NQF-endorsed (NQF #0431) for the hospital setting. Therefore, this measure meets the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

(1) Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia Measure

There are different types of staphylococcus aureus bacteria, commonly called "staph." Staph bacteria are normally found on the skin or in the nose. The bacteria are generally harmless unless they enter the body through a cut or other wound, and even then they usually cause only minor skin problems in healthy people. MRSA infection is caused by a strain of staph bacteria that has become resistant to the antibiotics commonly used to treat ordinary staph infections. Older adults with weakened immune systems and patients in hospital or nursing home settings are most vulnerable to MRSA infections. Health care-associated MRSA infections typically are associated with invasive procedures or devices, such as surgeries, intravenous tubing, urinary catheters, or artificial joints. MRSA infections account for about 60 percent of skin infections seen in United States emergency departments and invasive MRSA infections may cause about 18,000 deaths during a hospital stay a year.[13] Currently, there are 6 States that require facilities to report MRSA

[13] Catherine Liu, Arnold Bayer, *et al.*, Clinical practice Guidelines by the for the treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adult and Children. Infectious Disease Society of America 2011; 52:e18.

information to NHSN. As stated above, we were unable to identify any other measures specifically for MRSA that have been endorsed by the NQF for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we are proposing to adopt this non-NQF-endorsed and CDC-developed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic, under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. The proposed reporting mechanism for the MRSA measure is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on this proposed HAI measure.

(2) C. *Difficile* SIR Measure

Clostridium *Difficile* (C. *difficile*) is a bacterium that can cause symptoms ranging from diarrhea, pseudo-membranous colitis, and toxic megacolon to life-threatening sepsis and even death. Illness from C. *Difficile* most commonly affects older adults in hospitals or in long term care facilities where germs spread easily, antibiotic use is common and people are especially vulnerable to infection. Illness from C. *Difficile* typically occurs after use of antibiotic medications. C. *Difficile* spreads mainly on hands from person to person, but also on commonly touched services such as cart handles, bedrails, bedside tables, toilets, sinks, stethoscopes, thermometers, and telephones. In recent years, C. *Difficile* infections have become more frequent, more severe and more difficult to treat. Each year, tens of thousands of people in the United States get sick from C. *Difficile,* including some otherwise healthy people who are not hospitalized or taking antibiotics. Healthcare providers have become more aware of the C. *Difficile* infection and therefore, more testing is being done for symptomatic patients. The C. *Difficile* pathogens may require specialized monitoring to evaluate if intensified infection control efforts are required to reduce the occurrence of these organisms and related infections. Currently, there are 3 States that require facilities to report C. *Difficile* data to NHSN. Our goal for this proposed C. *Difficile* SIR measure is to provide a common mechanism (CDC/NHSN) for all hospitals including hospitals participating in the Hospital IQR Program to report and analyze these data that will inform infection control staff of the impact of targeted prevention efforts. The NHSN is listed in the HHS Action Plan to Prevent HAIs as the data source for HAI measures. As stated above, we were unable to identify any other measures specifically for C. *Difficile* SIR that have been endorsed by the NQF for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we are proposing to adopt this non-NQF-endorsed and CDC-developed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic, under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. We have chosen to leverage existing NHSN reporting system to collect HAI measures since we have already established a mechanism for reporting to the NHSN.

The proposed reporting mechanism for these proposed HAI measures is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on these proposed HAI measures.

(3) Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431)

For the FY 2015 payment determination, we are proposing to adopt one additional HAI measure that is currently collected by CDC via the NHSN: Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431). This measure assesses the percentage of HCP employed at the facility that received a prophylactic vaccination for influenza. This measure is NQF endorsed, and therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[14] [15] [16]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[17] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[18] [19] [20] Such findings have led some to call for mandatory influenza vaccination of HCP.[21] [22] [23] [24] [25]

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of 60 percent,[26] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in

[14] Maltezou HC, Drancourt M., Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[15] Hurley JC, Flockhart S., An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[16] Salgado CD, Farr BM, Hall KK, Hayden FG., Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[17] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC., Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

[18] Salgado CD, Giannetta ET, Hayden FG, Farr BM., Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[19] Potter J, Stott DJ, Roberts MA, *et al.,* Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[20] Hayward AC, Harling R, Wetten S, *et al.,* Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241–1246.

[21] Talbot TR, Bradley SF, Cosgrove SE, *et al.,* SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890.

[22] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. *http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf.*

[23] Greene LR, Cain TA, Dolan SA *et al.,* APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008. *http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf*

[24] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. *http://www.npsf.org/pr/pressrel/2009-11-18.php.*

[25] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. *http://www.idsociety.org/HCWimmunization/.*

[26] Walker FJ, Singleton JA, Lu P, Wooten KG, Strikas RA., Influenza vaccination of healthcare workers in the United States, 1989–2002. Infection Control and Hospital Epidemiology 2006; 27:257–265.

2009–2010.[27] Only 37 percent reported receiving the 2009 pandemic A/H1N1 vaccine.[28]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[29] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have "offer" laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have "ensure" laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[30]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[31] Currently, participation in either module is voluntary. The current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

We are proposing to adopt the Healthcare Provider Influenza Vaccination measure that is currently collected by the CDC via the NHSN because of its importance in preventing influenza not only among healthcare workers but also patients that they attend.. As stated earlier, this measure assesses the percent of Healthcare Personnel employed at the facility that received a prophylactic vaccination for influenza. Detailed specifications for the proposed measure are available at: *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* As we also stated above, this measure is NQF-endorsed for the hospital setting. The proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on this proposed HAI measure.

(B) Proposed New Chart-Abstracted Measures for the FY 2015 Payment Determination

We are proposing to adopt two sets of chart-abstracted measures for the FY 2015 payment determination: the Stroke and Venous Thromboembolism (VTE) measure sets. All of these proposed measures have either previously been proposed for the Hospital IQR Program, or have been listed as being under consideration for future adoption into the program. In addition, with one exception (STK–1: VTE Prophylaxis), all of the measures in these two measure sets have been electronically specified and are among the measures adopted for the EHR Incentive Program for eligible hospitals. While we are proposing to adopt these for chart-abstracted submission in 2013 for the FY 2015 payment determination, we believe that by a future date, such as 2015, hospitals will be able to switch to EHR-based submission of these and all other chart-abstracted measures submitted for the Hospital IQR Program, and, as we discuss in greater detail below, we intend to work toward this goal over the next few years.

The Stroke measure set we are proposing to adopt consists of 8 measures; and the VTE measure set consists of 6 measures. Both measure sets are NQF-endorsed and their specifications are currently available in the Specifications Manual, which can be found on QualityNet. We believe that both of the proposed measure sets compliment the data elements in our current SCIP VTE and AMI measure sets.

(i) Stroke Measure Set

Stroke is a topic of great relevance to the Medicare population due to its impact on morbidity and mortality, and it is an area with great potential for quality improvement for hospitals caring for stroke patients. Stroke is the third most common cause of death in the United States and is one of the top 20 conditions contributing to Medicare costs. Approximately 8 to 12 percent of ischemic strokes are fatal,[32] and

[27] *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm.* Influenza Vaccination of Health-Care Personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices.

[28] Centers for Disease Control and Prevention., Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009–January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357–362. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm.*

[29] Adapted from: Pearson ML., Bridges CB., Harper SA.,: Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1–16. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm.*

[30] For additional information regarding healthcare facilities' influenza vaccine policies, please see: *http://www.immunize.org/honor%2Droll/.*

[31] Available at: *http://www.cdc.gov/nhsn/hps.htm.*

[32] American Heart Association, Heart Disease and Stroke Statistics—2009 Update. American Heart Association, 2009: p. 1–36.

mortality following stroke is influenced by the quality of care provided to patients during their initial hospitalization.[33] In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 8 Stroke measures as being under consideration for adoption for the FY 2012 Hospital IQR payment determination. Numerous commenters encouraged us to adopt the listed stroke measures which they see as evidence-based measures that accurately measure the care of the stroke patient (74 FR 43875 through 43876). Commenters believed that the measures are widely recognized for their roles in minimizing secondary strokes and other complications.

We are proposing to adopt a stroke measure set with 8 NQF-endorsed process-of-care measures for the FY 2015 payment determination. The table below lists and describes each of these eight proposed measures.

| 8 Proposed Stroke Measures | |
|---|---|
| STK-1: Venous Thromboembolism (VTE) Prophylaxis for patients with ischemic or hemorrhagic stroke (NQF #0434) | Percent of patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two. |
| STK-2: Ischemic stroke patients discharged on antithrombotic therapy. (NQF #0435) | Percent of patients with an ischemic stroke prescribed antithrombotic therapy at discharge. |
| STK-3: Anticoagulation therapy for atrial fibrillation/flutter. (NQF #0436) | Percent of patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy. |
| STK-4: Thrombolytic Therapy for Acute ischemic stroke patients. (NQF #0437) | Percent of acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well. |
| STK-5: Antithrombotic therapy by the end of hospital day two. (NQF #0438) | Percent of patients with ischemic stroke who receive antithrombotic therapy by the end of hospital day two. |
| STK-6: Discharged on statin medication. (NQF #0439) | Percent of ischemic stroke patients with LDL >/= 100 mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization are discharged on a statin medication. |
| STK-8: Stroke education. (NQF #0440) | Percent of patients with ischemic or hemorrhagic stroke or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of emergency. |
| STK-10: Assessed for rehabilitation services. (NQF #0441) | Percent of patients with an ischemic stroke or hemorrhagic stroke who were assessed for rehabilitation services. |

Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF-endorsement, we believe that the inclusion of the proposed stroke measure set in the Hospital IQR Program would provide a comprehensive view of how well stroke care is being managed in a hospital setting. As stated earlier, detailed measure specifications for these

[33] Weir, N.U., *et al.,* Variations between countries in outcome after stroke in the International Stroke Trial (IST). Stroke, 2001. 32(6): p. 1370–7.

8 proposed measures are available in the Specifications Manual located in QualityNet. We invite public comment on the proposed stroke measure set.

(ii) VTE Measure Set

It is widely agreed that VTE is the number one preventable cause of hospital death in the United States and the cost of VTE when it occurs is very high. A recent study from AHRQ in Health Affairs highlighted that when an acute VTE event occurs, it increases the costs of care by 25 percent. In 2008, the Surgeon General issued a Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. (This document can be found at: *http://www.surgeongeneral.gov/topics/deepvein/calltoaction/call-to-action-on-dvt-2008.pdf.)* VTE prevention with pharmacologic agents can impact the cost effectiveness of care. Specifically, patients who received anti-coagulant medication during hospitalization have less likelihood of recurrence of VTEs upon discharge to home. Parenteral anticoagulation is the first line of therapy because of its rapid onset of action. Because the oral anticoagulant medication has a very slow onset of action, it cannot be used as mono-therapy for acute VTE. A minimum of five days of parenteral anticoagulation is recommended as "overlap therapy" while oral anticoagulant medication is being initiated. More thrombotic complications and higher costs are associated with treatment in patients demonstrating a subtherapeutic aPTT. Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) has significantly advanced the use of UFH with the demonstrated ability to achieve therapeutic aPTTs more rapidly than with standard UFH dosing. When this occurs, patients can be discharged sooner. However, anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that includes patient/caregiver involvement may reduce the risk of adverse drug events.

The Hospital IQR Program currently has 2 measures of VTE prophylaxis for surgical patients (SCIP–VTE–1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients; and SCIP–VTE–2: VTE prophylaxis within 24 hours pre/post surgery) in the SCIP measure set. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 5 VTE measures (VTE–1; Venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of potentially-preventable venous Thromboembolism) as possible new quality measures for the FY 2012 payment determination. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50213 through 50218), we listed 6 VTE measures (VTE–1; Venous thromboembolism prophylaxis; VTE–2: Intensive care unit venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of potentially-preventable venous thromboembolism) as measures we were considering for possible future adoption into the program.

We are now proposing to adopt for the FY 2015 Hospital IQR measure set 6 VTE measures which are aimed at preventing the incidence of potentially preventable VTE. These 6 measures are listed and described below.

BILLING CODE 4120–01–P

| 6 Proposed Venous Thromboembolism (VTE) Measures | |
|---|---|
| VTE-1: Venous thromboembolism prophylaxis (NQF #0371) | Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission. |
| VTE-2: Intensive care unit venous thromboembolism prophylaxis (NQF #0372) | Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). |
| VTE-3: Venous thromboembolism patients with anticoagulation overlap therapy (NQF #0371) | Percent of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) = 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications. |
| VTE-4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol (NQF #0371) | Percent of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. |
| VTE-5: Venous thromboembolism discharge instructions (NQF #0371) | Percent of patients diagnosed with confirmed VTE that are discharged to home, to home with home health or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions. |
| VTE-6: Incidence of potentially-preventable venous Thromboembolism (NQF #0371) | Percent of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. |

These 6 measures were endorsed in a 2008 NQF project titled: National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Additional Performance Measures. Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF-endorsement, we believe that the inclusion of the VTE measure set in the Hospital IQR Program would provide a comprehensive view of how well VTE care is being managed in a hospital setting. Detailed measure specifications for these 6 proposed measures are available in the Specifications Manual located on QualityNet. We invite public comment on the proposed VTE measure set.

In summary, for the FY 2015 payment determination, we are proposing to retain all of the FY 2014 measures (56 measures if all of the measures are finalized), to adopt 3 HAI measures, and 14 chart-abstracted measures for a total of 73 measures for the FY 2015 payment determination. The measures proposed for the Hospital IQR Program for the FY 2015 payment determinations are set forth below.

| Topic | Proposed Hospital IQR Program Measures for FY 2015 Payment Determination |
|---|---|
| Acute Myocardial Infarction (AMI) Measures | |
| | ● AMI-2 Aspirin prescribed at discharge |
| | ● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival |
| | ● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) |
| | ● AMI-10 Statin Prescribed at Discharge |
| Heart Failure (HF) Measures | |
| | ● HF-1 Discharge instructions |
| | ● HF-2 Evaluation of left ventricular systolic function |
| | ● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction |
| Stroke Measure Set | |
| | ● STK-1 VTE prophylaxis** |
| | ● STK-2 Antithrombotic therapy for ischemic stroke** |
| | ● STK-3 Anticoagulation therapy for Afib/flutter** |
| | ● STK-4 Thrombolytic therapy for acute ischemic stroke** |
| | ● STK-5 Antithrombotic therapy by the end of hospital day 2** |
| | ● STK-6 Discharged on Statin** |
| | ● STK-8 Stroke education** |
| | ● STK-10 Assessed for rehab** |
| VTE Measure Set | |
| | ● VTE-1 VTE prophylaxis** |
| | ● VTE-2 ICU VTE prophylaxis** |
| | ● VTE-3 VTE patients with anticoagulation overlap therapy** |
| | ● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol** |
| | ● VTE-5 VTE discharge instructions** |
| | ● VTE-6 Incidence of potentially preventable VTE** |
| Pneumonia (PN) Measures | |
| | ● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital |
| | ● PN-6 Appropriate initial antibiotic selection |
| Surgical Care Improvement Project (SCIP) Measures | |
| | ● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision |
| | ● SCIP INF-2: Prophylactic antibiotic selection for surgical patients |
| | ● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) |
| | ● SCIP INF-4: Cardiac surgery patients with controlled 6AM |

| Topic | Proposed Hospital IQR Program Measures for FY 2015 Payment Determination |
|---|---|
| | postoperative serum glucose |
| | ● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero |
| | ● SCIP INF-10: Surgery patients with perioperative temperature management |
| | ● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period |
| | ● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered |
| | ● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery |
| Mortality Measures (Medicare Patients) | |
| | ● Acute Myocardial Infarction (AMI) 30-day mortality rate |
| | ● Heart Failure (HF) 30-day mortality rate |
| | ● Pneumonia (PN) 30-day mortality rate |
| Patients' Experience of Care Measure | |
| | ● HCAHPS survey |
| Readmission Measures (Medicare Patients) | |
| | ● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure |
| | ● Heart Failure 30-day Risk Standardized Readmission Measure |
| | ● Pneumonia 30-day Risk Standardized Readmission Measure |
| AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures | |
| | ● PSI 06: Iatrogenic pneumothorax, adult |
| | ● PSI 11: Post Operative Respiratory Failure |
| | ● PSI 12: Post Operative PE or DVT |
| | ● PSI 14: Postoperative wound dehiscence |
| | ● PSI 15: Accidental puncture or laceration |
| | ● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) |
| | ● IQI 19: Hip fracture mortality rate |
| | ● Complication/patient safety for selected indicators (composite) |
| | ● Mortality for selected medical conditions (composite) |
| AHRQ PSI and Nursing Sensitive Care | |
| | ● PSI-4 Death among surgical inpatients with serious treatable complications |
| Structural Measures | |
| | ● Participation in a Systematic Database for Cardiac Surgery |
| | ● Participation in a Systematic Clinical Database Registry for Stroke Care |

| Topic | Proposed Hospital IQR Program Measures for FY 2015 Payment Determination |
|---|---|
| | ● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care |
| | ● Participation in a Systematic Clinical Database Registry for General Surgery* |
| Healthcare-Associated Infections Measures | |
| | ● Central Line Associated Bloodstream Infection |
| | ● Surgical Site Infection |
| | ● Central Line Insertion Practice Percentage* |
| | ● Catheter-Associated Urinary Tract Infection* |
| | ● MRSA Bacteremia** |
| | ● Clostridium Difficile (C.Diff)** |
| | ● Healthcare Personnel Influenza Vaccination** |
| Hospital Acquired Condition Measures | |
| | ● Foreign Object Retained After Surgery |
| | ● Air Embolism |
| | ● Blood Incompatibility |
| | ● Pressure Ulcer Stages III & IV |
| | ● Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock) |
| | • Vascular Catheter-Associated Infection |
| | ● Catheter-Associated Urinary Tract Infection (UTI) |
| | ● Manifestations of Poor Glycemic Control |
| Emergency Department Throughput Measures | |
| | ● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital |
| | ● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status |
| Prevention: Global Immunization Measures | |
| | ● Immunization for Influenza |
| | ● Immunization for Pneumonia |
| Cost Efficiency | |
| | ● Medicare Spending per Beneficiary* |

* New proposed quality measures for the FY 2014 payment determination
** New Proposed quality measures for FY 2015 payment determination

4. Possible New Quality Measures and Measure Topics for Future Years

Looking forward, we anticipate that as EHR technology evolves, and more infrastructure is put in place, we will have the capacity to accept electronic reporting of all of the clinical chart-abstracted quality measures that are currently in the Hospital IQR Program or have been proposed for adoption into the program. We intend for this future progress to significantly reduce the administrative burden on hospitals under the Hospital IQR Program. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures that we proposed. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems. We believe that at a future date, such as 2015, CMS and hospitals will be able to switch to complete EHR-based reporting of all chart-abstracted measures to CMS for the Hospital IQR Program, and we intend to work diligently toward this goal. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals. We invite public comment and suggestions on this topic.

In future rules, it is our intention to propose to adopt outcome measures for stroke and joint replacement surgery which we have developed and anticipate submitting for NQF review. In addition, we intend to propose additional HAI measures as they gain NQF endorsement. We also invite public comment on the following quality measures and topics set out below that we are considering for the future. We seek to limit the number of chart-abstracted measures and topics in the near future, in order to facilitate the transition to EHR-based reporting.

| Possible Hospital IQR Program Future Measures and Topics | |
|---|---|
| **Measurement Topic** | **Measure Title/ Description/Concept** |
| Mortality/Complications | |
| | ● Acute stroke 30-day mortality rate |
| | ● Total Hip and Total Knee arthroplasty 30-day complications |
| Readmissions | |
| | ● Stroke 30-Day Risk Standardized Readmission Measure |
| | ● Total Hip and Total Knee Arthroplasty 30-Day Risk Standardized Readmission Measure |
| Patient Safety | |
| | ● Surgical checklist use for surgical procedures |
| | ● NQF approved Serious Reportable Events |
| Medication Safety | |
| | ● Universal Documentation and Verification of Current Medications in the Medical Record |
| | ● Drug-Drug interaction |
| | ● Medication Reconciliation |
| Surgical Outcome Measures | |
| | ● Lower Extremity Bypass Complications |
| | ● ICD Complications |
| | ● Risk Adjusted Case Mix Adjusted Elderly surgery outcomes |
| | ● Risk Adjusted Case Mix Adjusted Colorectal surgery outcomes |
| Healthcare-Associated Infections | |
| | ● Ventilator Associated Pneumonia |
| | ● Post Procedure Pneumonias |
| | ● Multi Drug Resistant Organisms—VRE, Klebsiella, Acinetobacter |
| Readmissions | |
| | ● COPD 30-day Risk Standardized Readmission Rate |
| | ● CABG 30-day Risk Standardized Readmission Rate |
| | ● Other Vascular Condition 30-day Risk Standardized Readmission |
| | ● Percutaneous Coronary Intervention (PCI) 30-day Risk Standardized Readmission Rate |
| | ● All-Patient Condition-Specific Readmission Rates for AMI, Heart Failure, Pneumonia, CABG, COPD, PCI, other vascular conditions |
| | ● All-condition 30-day readmission rate |
| Average Length of Stay | |
| | ● Overall inpatient hospital average length of stay (ALOS) and ALOS by medical service category |
| Mortality | |

| Possible Hospital IQR Program Future Measures and Topics | |
|---|---|
| **Measurement Topic** | **Measure Title/ Description/Concept** |
| | ● 30-day Risk Standardized Mortality Rate following PCI for STEMI/shock patients. |
| | ● 30-day risk-standardized mortality rate following PCI for non-STEMI/non-shock patients. |
| SCIP | |
| | ● Short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose |
| Care Coordination | |
| | ● Cardiac Rehabilitation Referral for AMI, HF, Cardiac Surgery |
| Heart Failure | |
| | ● Symptom and Activity Assessment |
| | ● Symptom Management |
| | ● Patient Education |
| | ● Combination Medical Therapy for LVSD |
| | ● Beta Blocker Therapy for LVSD |
| | ● Counseling Regarding ICD for Patients with LVSD |
| Tobacco & Alcohol Cessation | |
| | ● TAM-1: Tobacco Use Screening |
| | ● TAM-2: Tobacco Use Treatment |
| | ● TAM-3: Tobacco Use Treatment Management at Discharge |
| | ● TAM-4: Assessing Status after Discharge |
| | ● TAM-5: Alcohol Use Screening |
| | ● TAM-6: Alcohol Use Brief Intervention |
| | ● TAM-7: Alcohol and other Drug dependence-Treatment Management at Discharge |
| | ● TAM-8: Substance Use - Assessing Status after Discharge |
| Nursing Sensitive (remainder of measures) | |
| | ● NSC-2: Patients surveyed on an eligible reporting unit that have at least one stage II or greater [National Ulcer Advisory Panel (NPUAP)] nosocomial pressure ulcer on the day of the prevalence study |
| | ● NSC-3: Number of patient falls, with or without injury to the patient, by type of Unit during the calendar month x 1000. |
| | ● NSC-4: Number of patient falls with an injury level of minor or greater by Type of Unit during the calendar month x 1,000. |
| | ● NSC-5: Patients surveyed on the eligible reporting unit that have a vest restraint and/or limb restraint (upper or lower or both) on the day of the prevalence study |
| | ● NSC-12: Number of productive hours worked as specified in the Set Measure Identifier |

| Possible Hospital IQR Program Future Measures and Topics | |
|---|---|
| **Measurement Topic** | **Measure Title/ Description/Concept** |
| | • NSC-13: Total number of productive hours worked by nursing staff (stratified by type of certification RN, LPN/LVN, UAP) with direct patient care responsibilities by Type of Unit during the calendar month. |
| | • NSC-14: Nursing satisfaction survey |
| | • NSC 15: The total number of voluntary separations (as specified under the Performance Measure Identifier and Description above) during the calendar month |
| Cardiac Surgery measures | |
| | • Post-operative Renal Failure |
| | • Surgical Re-exploration |
| | • Anti-Platelet Medication at Discharge |
| | • Beta Blockade at Discharge |
| | • Anti-Lipid Treatment Discharge (Statin at Discharge) |
| | • Risk-Adjusted Operative Mortality for CABG |
| | • Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR) |
| | • Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR) |
| | • Risk-Adjusted Operative Mortality MVR+CABG Surgery |
| | • Risk-Adjusted Operative Mortality for AVR+CABG |
| | • Surgical Volume - a. Isolated Coronary Artery Bypass Graft (CABG) Surgery, b. Valve Surgery, c. CABG+Valve Surgery |
| | • Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients |
| | • Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients |
| | • Pre-Operative Beta Blockade |
| | • Duration of Prophylaxis for Cardiac Surgery Patients |
| | • Prolonged Intubation (ventilation) |
| | • Deep Sternal Wound Infection Rate |
| | • Stroke/Cerebrovascular Accident |
| | • CABG Composite Score |

BILLING CODE 4120–01–C

5. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase, for FY 2007 and each subsequent fiscal year, shall be reduced by 2.0 percentage points (or, beginning with FY 2015, by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (*https://www.QualityNet.org*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for FY 2012 Payment Determinations and Subsequent Years

The proposed Hospital IQR Program procedural requirements are, for the most part, the same as the procedures adopted in the FY 2011 IPPS/LTCH PPS final rule for the Hospital IQR Program. Hospitals must comply with the following procedural requirements to participate—

• Register with QualityNet, before participating hospitals initially begin

reporting data, regardless of the method used for submitting data.

• Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (*http://www.QualityNet.org*).

• Complete a Notice of Participation. New subsection (d) hospitals and existing hospitals that wish to participate in the Hospital IQR Program for the first time must complete an online Notice of Participation (formerly known as "Reporting Hospital Quality Data for Annual Payment Update Notice of Participation," also referred to as IPledge) that includes the name and address of each hospital campus that shares the same CMS Certification Number (CCN). We revise the Notice of Participation periodically as needed and provide appropriate notification of any revisions to hospitals and QIOs through the routine Hospital IQR Program communication channels, which include memo and e-mail notification and QualityNet Web site articles and postings.

• Any hospital that receives a new CCN on or after October 15, 2009 (including new subsection (d) hospitals and hospitals that have merged) that wishes to participate in the Hospital IQR Program and has not otherwise submitted a Notice of Participation using the new CCN must submit a completed Notice of Participation no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Online System Certification and Reporting (OSCAR) system to participate in the Hospital IQR Program. We are proposing regulation text to codify this requirement.

• We will accept Hospital IQR Program withdrawal forms for the FY 2013 payment determination from hospitals any time from October 1, 2011 until August 15, 2012. The August 15, 2012 deadline will give us sufficient time to update the FY 2013 payment to hospitals starting on October 1, 2012. If a hospital withdraws from the program for the FY 2013 payment determination, it will receive a reduction of 2.0 percentage points to the FY 2013 applicable percentage increase. Once a hospital has submitted a Notice of Participation, it is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS.

• We will determine if a hospital has complied with our data submission requirements by looking at whether the hospital has properly submitted data to the appropriate data warehouses for HCAHPS, CDC/NHSN, chart-abstracted measures, and structural measure quality measure data during the four calendar year quarters of FY 2012.

The Hospital IQR Program procedural requirements have remained relatively unchanged for the past several years and we are proposing to codify them at 42 CFR 412.140. We invite public comment on this proposal.

c. Proposed Procedural Requirements for FY 2013 and Subsequent Years

We are proposing that hospitals that have an open date (as noted on the approved CMS OSCAR system) before March 31, 2009 that did not participate in the Hospital IQR Program in FY 2011 or FY 2012 but that wish to participate in the Hospital IQR Program for the FY 2013 payment determination must submit a completed Notice of Participation to CMS on or before December 31, 2011. These hospitals, unlike hospitals that receive a new CCN, do not need to get their operations up and running. Therefore, we believe this is a reasonable deadline that will enable these hospitals to decide whether they want to participate in the Hospital IQR Program while also enabling us to collect enough data from them to make an accurate FY 2013 payment determination. We are proposing regulation text that provides that hospitals that would like to participate in the Hospital IQR program for the first time, or that previously withdrew from the program and would like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which they would like to participate.

d. Proposed Data Submission Requirements for Chart-Abstracted Measures

We are proposing to reduce the quarterly submission deadline for chart-abstracted quality measures from 4½ months to 104 days. In other words, for FY 2014 payment determinations, the quarterly deadline for the quality measures under the topic that require chart abstraction (AMI, HF, PN, SCIP, Emergency Department Throughput (EDT), and Global Immunization (GIM) will be 104 days following the last discharge date in the calendar quarter. We are proposing to reduce the data submission deadline in order to allow for a correction period, which we will propose in future rulemaking. We also believe that this proposed change will encourage hospitals to utilize quality measure information in a more rapid manner to facilitate quality improvement. We also want to provide hospitals sufficient notice of any proposed changes to our submission deadline, since we recognize the advance time needed by hospitals to modify their recordkeeping and abstraction practices to comply with this proposed requirement. We also are proposing to change the aggregate population and sampling deadline from 4 months to 3 months to align with the corresponding proposal to change the data submission deadline from 135 to 104 days.

We will continue to require hospitals to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (currently AMI, HF, PN, and SCIP) (75 FR 50221). Starting with the FY 2014 payment determination, we are proposing to change the submission deadline for hospitals to submit aggregate population and sample size count data for the measures requiring chart abstraction from four months to three months following the last discharge date in the calendar quarter. We are proposing this three-month deadline for submission of the aggregate population and sample size counts data to provide CMS with information necessary to notify hospitals about their data completeness status. Specifically, we currently provide a Provider Participation Report the day after the submitted file is processed, which includes a calculation of the number of hospital submitted cases by topic, hospital self-reported aggregate population and sample size count, and Medicare FFS claims by clinical topic and SCIP surgical category. We expect that hospitals will use this report after submission to assess their patient-level data completeness and will submit additional patient-level cases before the proposed quarterly patient-level deadline. We are proposing to provide hospitals with the same 14-day period after the proposed aggregate population and sample size count deadline to submit the required patient-level records.

e. Proposed Sampling and Case Thresholds Beginning With the FY 2015 Payment Determination

We are proposing to continue the requirement for hospital submission of population and sampling data for the FY 2015 payment determination and future years. Hospitals must submit to CMS quarterly aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (AMI, HF, PN, SCIP, EDT and GIM). Hospitals are required to

submit their aggregate population and sample size count for each topic area.

In accordance with the policy we adopted in the FY 2011 IPPS/LTCH PPS final rule, hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a zero for its quarterly aggregate population and sample count for that topic in order to meet the requirement. We view it as vital for hospitals to determine accurately their aggregate population and appropriate sampling size data in order for CMS to assess hospitals' data reporting completeness for their total population of cases, Medicare and non-Medicare.

In order to reduce the burden on hospitals that treat a low number of patients in a Hospital IQR Program topic area, a hospital that has five or fewer discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted would not be required to submit patient-level data for that topic area for the quarter. The hospital must still submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas each quarter. Hospitals meeting the five or fewer patient discharge exception may voluntarily submit these data.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

f. Proposed HCAHPS Requirements for the FY 2013, FY 2014, and FY 2015 Payment Determinations

Beginning with discharges occurring in third quarter CY 2011, we are proposing to move the HCAHPS data submission deadline forward by one week in order to allow for a review and correction period, which we will propose in future rulemaking. Currently, hospitals have about 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. If this proposal is adopted, hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

Other than this proposed change, we are not proposing any other changes to the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations, which were adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220). For FY 2015 Hospital IQR payment determinations, we are proposing to continue the HCAHPS requirements as follows. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at *http://www.hcahpsonline.org*. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: *http://www.hcahpsonline.org*. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2015 Hospital IQR Program, we are proposing that the HCAHPS data will be based on discharges from January 1, 2013 through December 31, 2013.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS survey administration.) Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested "no publicity" status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We wish to emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS–DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS *Quality Assurance Guidelines*.

We note that the HCAHPS *Quality Assurance Guidelines* require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

Hospitals must submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by a footnote on the *Hospital Compare* Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time and the data has been accepted into the QIO Clinical Warehouse.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS *Quality Assurance Guidelines.* All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone

and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and, (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We wish to point out that the HCAHPS *Quality Assurance Guidelines* state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We again are encouraging hospitals to regularly check the HCAHPS Web site at *http://www.hcahpsonline.org* for program updates and information.

We proposed that HCAHPS scores become part of the Hospital VBP Program in FY 2013. As HCAHPS scores become incorporated in hospital payment, we believe that a neutral third-party should administer the survey for hospitals whose annual payment updates will be affected by their HCAHPS scores. It is our belief that an experienced survey vendor will be best able to ensure reliable results. Therefore, we are considering whether to allow only non-subsection (d) hospitals to self-administer the HCAHPS survey. We invite public comment that will inform our future policy on this issue.

g. Proposed Procedures for Claims-Based Measures

CMS is proposing to adopt a new claims-based measure for FY 2014, the Medicare Spending per Beneficiary Measure, which is included in the chart below.

BILLING CODE 4120–01–P

| Topic | FY 2014 Payment Determination: Adopted and Proposed Claims-Based Quality Measures (No Additional Hospital Data Submission Required) |
|---|---|
| Mortality Measures (Medicare Patients) | |
| | ● Acute Myocardial Infarction (AMI) 30-day mortality rate |
| | ● Heart Failure (HF) 30-day mortality rate |
| | ● Pneumonia (PN) 30-day mortality rate |
| | |
| Complications | |
| | |
| Readmission Measure (Medicare Patients) | |
| | ● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure |
| | ● Heart Failure 30-day Risk Standardized Readmission Measure |
| | ● Pneumonia 30-day Risk Standardized Readmission Measure |
| | |
| | |
| AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures | |
| | ● PSI 06: Iatrogenic pneumothorax, adult |
| | ● PSI 11: Post Operative Respiratory Failure |
| | ● PSI 12: Post Operative PE or DVT |
| | ● PSI 14: Postoperative wound dehiscence |
| | ● PSI 15: Accidental puncture or laceration |
| | ● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) |
| | ● IQI 19: Hip fracture mortality rate |
| | ● Complication/patient safety for selected indicators (composite) |
| | ● Mortality for selected medical conditions (composite) |
| AHRQ PSI and Nursing Sensitive Care | |
| | ● PSI 04 Death among surgical inpatients with serious treatable complications |
| Hospital Acquired Condition Measures | |
| | ● Foreign Object Retained After Surgery |
| | ● Air Embolism |
| | ● Blood Incompatibility |
| | ● Pressure Ulcer Stages III & IV |
| | ● Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock) |
| | ● Vascular Catheter-Associated Infection |
| | ● Catheter-Associated Urinary Tract Infection (UTI) |
| | ● Manifestations of Poor Glycemic Control |
| Cost Efficiency | |
| | ● Medicare Spending per Beneficiary* |

*New proposed measure for FY 2014

BILLING CODE 4120–01–C

We are not proposing to change the procedures and time periods we adopted in the FY 2011 IPPS/LTCH PPS final rule for the FY 2012, FY 2013 and FY 2014 payment determinations. For the FY 2014 payment determination, we are proposing to use up to 3 years of Medicare FFS claims data to calculate the measures, as appropriate for the measure.

Hospitals are encouraged to regularly check the QualityNet Web site, *http://www.QualityNet.org,* for program updates and information.

h. Proposed Data Submission Requirements for Structural Measures

Structural measures assess the characteristics and capacity of the provider to deliver quality healthcare. We are proposing to add one additional structural measure for the FY 2014 payment determination, Participation in a Systematic Clinical Database Registry for General Surgery, and to align the submission deadline for all structural measures with the submission deadline for the fourth quarter of the chart-abstracted measures. We are proposing to update the period of data collection that hospitals will submit the required registry participation information once annually for the structural measures via a Web-based collection tool between April 1, 2012 and May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. This proposal will give CMS a more complete picture of registry participation as well as synchronize data submissions for structural and chart-abstracted measures. These measures do not require the hospital to participate in a registry.

Below is the list of structural measures we have adopted or are proposing to adopt for the FY 2014 payment determination:

| Topic | FY 2014 Payment Determination: Adopted and Proposed Structural Measures |
|---|---|
| Cardiac Surgery | |
| | ● Participation in a Systematic Database for Cardiac Surgery |
| Stroke Care | |
| | ● Participation in a Systematic Clinical Database Registry for Stroke Care |
| Nursing Sensitive Care | |
| | ● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care |
| General Surgery | |
| | ● Participation in a Systematic Clinical Database Registry for General Surgery* |

*New proposed measures for FY 2014

i. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

As discussed above, we are proposing to adopt 2 new HAI measures for the FY 2014 payment determination and 3 HAI measures for FY 2015 payment determination. For FY 2014, the two proposed measures are Central Line Insertion Practices Adherence Percentage and Catheter Associated Urinary Tract Infection. For FY 2015, the three proposed measures are: Healthcare Provider Influenza Vaccination, MRSA Bacterimia and C. Difficile. Below is the list of HAI measures we are proposing to adopt for the FY 2014 and FY 2015 payment determinations:

| Topic | FY 2014 and 2015 Payment Determination: Proposed and Adopted Healthcare-Associated Infection Measures (CDC/NHSN) |
|---|---|
| | Surgical Site Infection* |
| | Central Line Insertion Practices Adherence Percentage** |
| | Catheter Associated Urinary Tract Infection** |
| | Clostridium Difficile*** |
| | Healthcare Provider Influenza Vaccination*** |
| | MRSA Bacteremia*** |

* Measures adopted for FY 2014 payment determination in the FY 2011 IPPS/LTCH PPS final rule

** Measures proposed for FY 2014 payment determination in this proposed rule

*** Measures proposed for FY 2015 payment determination in this proposed rule

We are proposing to update the current data submission and reporting requirements for these proposed measures. Specifically, we are proposing to utilize the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of these measures to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently utilized by hospitals, including hospitals complying with 28 State HAI reporting requirements. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination, which we are proposing to use for the HAI measures we have proposed above, are shown below. Hospitals must submit their quarterly data to NHSN for Hospital IQR Program purposes on or around the dates shown in the table below (updates to this will be posted on the QualityNet Web site).

| Submission Timeframes for HAI Measures for the FY 2014 Payment Determination | | |
|---|---|---|
| **CY 2012 Infection Events, and Central Line Insertion Practices** | **CDC-NHSN Collection and Quarterly Report Generation Timeframe** | **Final Submission Deadline for Hospital IQR Program FY 2014 Payment Determination** |
| Q1 (Jan-Mar 2012) | January 31st – August 15th | August 15, 2012 |
| Q2 (Apr-Jun 2012) | April 30th – November 15th | November 15, 2012 |
| Q3 (Jul-Sep 2012) | July 31st – Feb-15th | February 15, 2013 |
| Q4 (Oct-Dec 2012) | October 31st – May 15th | May 15, 2013 |

Hospitals would have until the Hospital IQR Program final submission deadline to submit their quarterly data to NHSN. After the final Hospital IQR Program submission deadline has occurred for each CY 2012 quarter, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

We invite public comment on this proposal.

6. Proposed Chart Validation Requirements for Chart-Abstracted Measures

a. Proposed Changes to the Chart Validation Requirements and Methods for the FY 2012 Payment Determination and Subsequent Years

We are proposing several changes to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229) for the FY 2012 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a "zero" validation score to each measure in a missing record. We are proposing to change the time period given to hospitals to submit medical records to the CDAC contractor to 30 calendar days, and we are proposing to codify this proposal at 42 CFR 412.140(d)(1). This proposed change in submission timeframe will align the current process with the requirements in 42 CFR 476.78(b)(2), which currently allow only 30 days for chart submission in the context of reviews by QIOs. We are proposing this deadline modification to reduce the time we need to complete validation, and provide hospitals with feedback on their abstraction accuracy. We believe that this linkage between Hospital IQR Program validation discharge quarters and the same fiscal year's Hospital VBP Program proposed performance period would improve the reliability and accuracy of the Hospital VBP Program's chart-abstracted measures. Hospitals that are subject to Hospital IQR payment reduction due to not passing our validation requirement would be excluded from receiving a Hospital VBP performance score and corresponding incentive payment under section 1886(o)(1)(C)(ii)(I) of the Act. Thus, CMS would ensure that the data submitted on chart-abstracted measures we adopt for the Hospital VBP Program is accurate by virtue of validating it under the validation procedures we have adopted for the Hospital IQR Program.

b. Proposed Supplements to the Chart Validation Process for the FY 2014 Payment Determination and Subsequent Years

We are proposing to continue to use the supplements to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) for FY 2014 payment determinations and future years with several proposed modifications.

We are proposing to add hospitals to our validation sample if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation samples. We are proposing this addition to supplement

our validation approach to ensure that all eligible Hospital IQR Program hospitals are selected for validation at least once every 4 years. We are proposing this addition starting in FY 2015 because FY 2015 would be the fourth year that CMS would have used the random validation approach (which begins in FY 2012 as adopted in the FY 2011 IPPS/LTCH PPS final rule). We invite public comment on this proposal.

We believe that this proposed Hospital IQR Program validation process meets the requirements set forth in section 1886(b)(3)(B)(viii)(XI) of the Act. This section states that "the Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital."

Starting with the FY 2012 payment determination and continuing in subsequent fiscal years, the chart validation process audits 800 randomly selected hospitals for the discharge quarters. This sample size is sufficient to validate more than 22 percent of subsection (d) hospitals in an applicable fiscal year and ensure accuracy of the Hospital IQR Program quality data.

For FY 2014 payment determination, we are proposing to validate 24 chart-abstracted measures including 19 currently validated measures, and 5 proposed additional measures. The FY 2014 proposed validation reflects the 5 measures we are proposing to add (2 EDT measures, Central Line Associated Blood Stream Infection, Global Influenza Immunization, and Global Pneumonia Immunization measures) and the 8 measures we are proposing to retire (AMI–1, AMI–3, AMI–4, AMI–5, HF–4, PN–4, PN–5c, and SCIP Infection 6).

Validation of the HCAHPS measure is conducted through our oversight activities. We provide oversight of all HCAHPS survey vendors and hospitals self-administering the survey in order to ensure that the data collection protocols are followed. We also provide oversight and validation through our review of Quality Assurance Plans, site visits, conference calls and detailed data analyses each quarter to ensure there are no anomalies found in the data. In particular, we use site visits to review all data collection activities, including data reviews to track a discharged patient from sampling to survey administration to data submission.

We are proposing, starting with FY 2014 payment determinations, a modest increase to the current Hospital IQR Program validation sample of SCIP, AMI, HF, and PN cases. Specifically, we are proposing to add three charts per selected hospital per quarter to the validation sample. This additional quarterly sample would enable us to validate the CLABSI measure that we added to the Hospital IQR Program measure set beginning with the FY 2014 payment determination. CLABSI is a relatively rare event compared to SCIP, AMI, HF, and PN cases. In 2009, about 18,000 CLABSIs occurred in ICU patients in the United States, and these infections were a major contributor to prolonged hospital stays and inpatient mortality. We are proposing a process to validate the CLABSI measure that takes into account the relative infrequency of this event and the case-finding methodology for it, specifically the requirements for a positive blood culture result and the presence of a central venous catheter in the patient at the time of, or within 48 hours before, onset of the infection. We recognize that the current validation process and sample size for AMI, HF, PN, and SCIP measures is not likely to be sufficiently reliable to detect systematic underreporting of CLABSI. Unlike the current AMI, HF, PN, and SCIP chart abstracted process of care measures, CLABSI is a rarely occurring infection among acute care inpatient discharges. We estimate that between 0.1 percent to 0.2 percent of all acute care inpatient patient discharges nationwide involve patients who are infected with a CLABSI. We believe that our current Hospital IQR AMI, HF, PN, and SCIP sample sizes and sample methods would not reliably validate CLABSI measure rates at the hospital level because of the relatively rare occurrence of these events. We also seek to target validation of the CLABSI measure to minimize hospital burden in complying with our sample size proposals, for which hospitals must find, photocopy, and return requested medical records to CMS. If CMS did not utilize this targeted validation approach for the CLABSI measure, hospitals would have to submit 200 to 300 additional randomly selected cases in order to effectively validate this measure, given its rare occurrence. We believe that our proposed CLABSI validation process addresses these limitations through the use of a targeted incremental validation sample comprised of three charts of possible CLABSI events, and will reliably validate the Hospital IQR Program CLABSI measure while not overly burdening hospitals with medical record requests.

Specifically, we are proposing to identify sampled hospitals' three quarterly potential CLABSI charts using a two-step selection process that would target intensive care unit patients with bloodstream infection (positive blood culture results) and a Central Venous Catheter (CVC) provided by sampled hospitals to CMS. In the first step of this process, a CMS contractor would require the 800 randomly sampled hospitals to provide a quarterly list of all blood cultures positive for infection status taken from intensive care units conducting CLABSI surveillance during the discharge quarter. We are aware that this list will include both reported CLABSI events and many non-CLABSI events, including patients with and without CVCs. In clinical terms, our intent in reviewing these positive blood culture lists is to identify the information needed to determine whether the blood culture isolate is a likely pathogen found at least once, or a common skin commensal (CSC) found in two or more positive blood cultures drawn on separate occasions. CSC's are microorganisms that are commonly found on the skin and often indicate contamination of the blood culture media rather than infection by the microorganism when it is identified in a single blood culture test. Two sets of blood cultures are needed to differentiate true infection from contamination. The list of CSCs is comprised of the following organisms: diphtheroids (*Corynebacterium* spp.); *Bacillus* spp. (not *B. anthracis*); *Priopionibacterium* spp.; coagulase negative staphylococci including *S. epidermidis;* viridans group streptococci; *Aerococcus* spp.; and *Micrococcus* spp. This list of CSCs is also found at the NHSN Web site, *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.* We would also require hospitals to self-identify intensive care unit patients with a CVC that are on this blood culture list. Using all of this information, we would be able to identify intensive care unit patients with a bloodstream infection and with a CVC (that is, candidate CLABSI events) for subsequent sampling.

In the second step of this process, we would randomly sample these candidate CLABSI events (ICU patients with a CVC and where a pathogen was recovered at least once or the same CSC was cultured from 2 or more blood cultures drawn on separate occasions). Specifically, the CMS CDAC would require hospitals to submit up to 3 medical records each quarter meeting

these criteria, randomly selected by CMS from among eligible charts. This number of medical records is sufficient to detect unreported CLABSI events based on our sample size analysis and experience from State health department validation efforts. This proposed process utilizes the validation experience from at least ten current State health department validation initiatives. In addition, we are proposing to randomly validate CLABSI data by abstracting all necessary quality data from the 12 quarterly medical records in our AMI, HF, PN, and SCIP targets already collected for IQR validation as well as the 3 additional records we later propose to collect for ED throughput/Immunization. Our intent in validating all currently requested quarterly medical records for CLABSI is to assess reliability of CLABSI measure rates from a random sample of patients independent from the proposed 3 record sample selected using blood culture lists and CVC presence to target underreporting of CLABSI events to the CDC's NHSN. In our proposed 12 record random sample of CLABSI events, we will not use blood culture list and CVC presence in our sampling, since this sample is already drawn from the AMI, HF, PN, and SCIP hospital reported data reported to CMS. By combining a random and targeted sampling approach using two independent sources to validate CLABSI data, we believe that we are adequately assessing the accuracy and reliability of the CLABSI measure in accordance with section 1886(b)(3)(B)(viii)(XI) of the Act.

We are proposing to determine the CLABSI validation score using a process that begins with the CMS contractor validation coordinator comparing the CDAC's CLABSI infection status to the hospital's event data reported to NHSN for the applicable quarter. For each medical record reviewed, a hospital would receive a match only if the CMS contractor validation coordinator determines equivalency between the CMS contractor's determination of infection status and the infection status reported to NHSN. For example, if one of the CMS-requested validation medical records revealed CLABSI and the event was not reported to the NHSN, then the hospital would receive a zero score for the CLABSI measure for that validated record. If the CMS contractor discovered that a second record in the CMS validation sample indicated no CLABSI event, but a CLABSI was reported to the NHSN for the record, the hospital would also receive a zero score for the CLABSI measure for that validation record. Thus, Hospitals would only receive a 100% CLABSI validation score for individual records if their CMS validation records' CLABSI status was consistent with the information reported, or not reported, to NHSN. In the above example, if the CMS quarterly validation process identified that 13 out of 15 total sampled records accurately reported the presence of a CLABSI or did not report a CLABSI where none was present, then the hospital's CLABSI validation score would be 13/15, or about 87 percent.

Starting with FY 2014 payment determination, we are also proposing to add a sixth quarterly sample, which would enable us to validate the EDT measures and the Immunization for Influenza and Immunization for Pneumonia global measures that we added to the Hospital IQR Program measure set. We are proposing to modify the current process (75 FR 50225–75 FR 50229) for these measures in two ways. First, we are proposing to select 3 additional records each quarter from the records submitted by the 800 annually sampled hospitals. These records would only include principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for validation sampling in these four topic areas. Second, we would abstract EDT and the Immunization for Influenza and Immunization for Pneumonia global measure data from the 15 quarterly AMI, HF, PN, SCIP and CLABSI records already submitted by hospitals for IQR validation. We would validate 18 records per quarter for these measures. With the addition of this sample of three records, we would ensure that all hospitals that reported chart-abstracted Hospital IQR data in all principal procedure and diagnosis codes would be eligible for sample selection for these global measures, thus, starting in FY 2014, we would be validating a total of 18 records per quarter per validated hospital in 6 strata (1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures.

7. Proposed QIO Regulation Changes for Provider Medical Record Deadlines Possibly Including Serious Reportable Events

Our Hospital IQR validation requirement has utilized 42 CFR 476.78 authority and deadlines to require participating hospitals to return requested medical record information in a timely manner. Our State QIOs use this information to educate hospitals on medical record abstraction accuracy, and identify potential opportunities for quality improvement through medical record review. It is our goal to improve the alignment of QIO work in the Hospital IQR Program, quality improvement assistance, beneficiary (or beneficiary representative) requested QIO quality of care reviews, and QIO medical necessity reviews to improve the following three aims: (1) Improve individual care; (2) improve health for populations; and (3) lower cost through improvement. QIOs serve a critical role in advancing these three aims through their work with Medicare providers and beneficiaries to advance quality care and health.

Moreover, because we developed our validation process based on the requirements of the QIO program regulations, we are also proposing corresponding changes to 42 CFR 476.78(b), along with minor editorial revisions. This section includes requirements related to the submission of medical information as well as other information associated with the prospective payment system. Specifically, we are proposing to add a new § 478.78(b)(2)(ii) that would require the submission of medical information within 21 days in those situations in which a "serious reportable event" or other circumstance has been identified during the course of a QIO review. For purposes of this subsection, we are proposing to define the term "serious reportable event" to be consistent with the NQF's definition of a serious reportable event in its report "Serious Reportable Events in Healthcare 2006 Update." These events include the following:

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative death in an ASA Class I patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient leaving the facility without permission
- Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

Care Management Events

- Patient death or serious disability associated with a medication error (for example, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- Patient death or serious disability associated with a hemolytic reaction (abnormal breakdown of red blood cells) due to the administration of ABO/HLA—incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability associated with failure to identify and treat hyperbilirubinemia (condition where there is a high amount of bilirubin in the blood) in newborns
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of a healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility

This proposed 21 day medical record deadline would be used when, for example, in the QIO's judgment, delays in receiving medical information could negatively undermine its efforts to evaluate the quality of care provided or the facility's adherence to payment policies. It also would enable QIOs to better utilize, and respond to, information about adverse events gained from the quality reporting program, in a timely fashion so that QIOs can have an improved and more immediate impact on the quality of health care.

We also are proposing a technical correction to 42 CFR 476.78(a) to correct a cross reference.

We invite public comment on our proposal to improve patient care through QIO access to more rapid provider information about "serious reportable events" and our proposed technical correction to 42 CFR 476.78(a).

8. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2012 Payment Determination and Subsequent Years

We are proposing to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. However, we are proposing to change the submission deadline to be used for the FY 2012 Hospital IQR Program payment determination and subsequent years. This proposal will allow us to align the submission deadline with the final quarter of the chart-abstracted measures. Hospitals will continue to submit the required electronic acknowledgment attesting that the data provided to meet the FY 2012 Hospital IQR Program data submission requirements is accurate and complete to the best of the hospital's knowledge at the time of data submission. We are proposing to make the submission deadline for the Data Accuracy and Completeness Acknowledgement May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. We invite public comment on this proposal.

9. Proposed Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

We are proposing to continue, for the FY 2014 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site *http://www.hospitalcompare.hhs.gov,* but on occasion are reported on other CMS Web sites. We require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

We invite public comment on this proposal.

10. Proposed Reconsideration and Appeal Procedures for the FY 2012 Payment Determination

We are proposing to continue, for the FY 2012 payment determination and subsequent years, the general approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for reconsideration and appeal procedures for the FY 2011 payment determination. We also are proposing to codify the requirements under this process at 42 CFR 412.140(e). We discuss each of the regulatory provisions being proposed, as well as specific changes, below.

We are proposing that the general deadline for submitting a request for reconsideration in connection with the FY 2012 payment determination will be 30 days from the date of receipt of the payment determination notification. Historically, most reconsideration requests are based on the failure to meet established data submission deadlines. While we want to ensure that hospitals have an opportunity to request reconsiderations when warranted, we also need to balance this goal with our need to complete the reconsideration

process in a timely manner and with the hospitals' desire to obtain final decisions on their requests in a timely manner. Therefore, we are proposing to reduce the reconsideration and appeal period from a deadline of November 1st 2012 to 30 days after hospital receipt of the payment determination notification. Notifications will be sent via a trackable mail option such as Certified U.S. Mail or Registered Mail. We include this change in the proposed § 412.140(e)(1).

As discussed more fully below, we are proposing that all hospitals submit a request for reconsideration and receive a decision on that request before they can file an appeal with the Provider Reimbursement Review Board (PRRB). For the FY 2012 payment determination, we are proposing to continue utilizing many of the same procedures that we utilized for the FY 2011 requests for reconsideration. We are, however, clarifying that a hospital must submit all documentation and evidence that supports its request for reconsideration at the time that it submits its request. This includes copies of any communications, such as e-mails that the hospital believes demonstrate its compliance with the program requirements, as well as all paper medical records that support the hospital's rationale for seeking reconsideration. The information that must be included when a hospital submits a reconsideration request has been listed in proposed § 412.140(e)(2). Under these proposed procedures, the hospital must:

—Submit to CMS, via *QualityNet,* a Reconsideration Request form (available on the *QualityNet* Web site) containing the following information:
—Hospital CMS Certification number (CCN).
—Hospital Name.
—CMS-identified reason for failure (as provided in the CMS notification of failure letter to the hospital).
—Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the Hospital IQR Program requirements and should receive the full update to the standardized amount.
—CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box). We note that to the extent a hospital can submit a request for reconsideration on-line, the burden on our staff would be reduced and, as a result, we can more quickly review the request.
—QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).
—Paper medical record requirement for reconsideration requests involving validation. We are proposing that if a hospital asks us to reconsider an adverse Hospital IQR Program payment decision made because the hospital failed the validation requirement, the hospital must submit paper copies of all the medical records that it submitted to the CDAC contractor each quarter for purposes of the validation. Hospitals must submit this documentation to a CMS contractor. The contractor will be a QIO support contractor, which has authority to review patient level information under 42 CFR part 480. We will post the address where hospitals can ship the paper charts on the QualityNet Web site after we issue the FY 2012 IPPS/LTCH PPS final rule.

Hospitals submitting a Hospital IQR Program validation reconsideration request will have all data elements to be reconsidered reviewed by CMS, and not their State QIO. (The State QIO is available to conduct a quarterly validation appeal if requested to do so by a hospital.)

Hospitals must provide a written justification for each appealed data element classified during the validation process as a mismatch. We will review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request.

As we mentioned above, hospitals that submit a reconsideration request to CMS must receive a decision on that request prior to submitting a PRRB appeal. We believe that the reconsideration process is less costly for both CMS and hospitals, and that it decreases the number of PRRB appeals by resolving issues earlier in the reconsideration and appeals process. We have proposed language at § 412.140(e)(3) stating that a hospital that receives an adverse decision on its reconsideration request may appeal that decision to the PRRB.

Following receipt of a request for reconsideration, we will—

• Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received.

• Provide written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 90 days from the receipt of the reconsideration request.

We are proposing to continue for the FY 2012 Hospital IQR reconsideration and future years the scope of review when a hospital requests reconsideration because it failed our validation requirements, which we adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43892). The scope of this review will be as follows:

1. *Hospital requests reconsideration for CDAC contractor-abstracted data elements classified as mismatches affecting validation scores.* Hospitals must timely submit a copy of the entire requested medical record to the CDAC contractor during the quarterly validation process for the requested case to be eligible to be reconsidered on the basis of mismatched data elements. Only hospitals that fail to meet the passing threshold for the quarterly validation would receive an opportunity to appeal the validation results to their State QIO.

2. *Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections.* Invalid record selections are defined as medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the CDAC contractor (in other words, the contractor determines that the hospital returned a medical record that is different from that which was requested). If the CDAC contractor determines that the hospital has submitted an invalid record selection case, it awards a zero validation score for the case because the hospital did not submit the entire copy of the medical record for that requested case. During the reconsideration process, our review of invalid record selections will initially be limited to determining whether the record submitted to the CDAC contractor was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record, then we would abstract data elements from the medical record submitted by the hospital.

3. *Hospital requests reconsideration for medical records not submitted to the CDAC contractor within the proposed 30 calendar day deadline.* Our review will initially be limited to determining whether the CDAC contractor received the requested record within the proposed 30 calendar days, and whether

the hospital received the initial medical record request. If we determine during reconsideration that the CDAC contractor did receive a paper copy of the requested medical record within the proposed 30 calendar days, then we would abstract data elements from the medical record submitted by the hospital. If we determine that the hospital received a request for medical records and did not submit the requested records within the proposed 30 day period, CMS will not accept these records as part of the reconsideration. CMS will not abstract data from charts not received timely by the CMS contractor. Please note that this proposed language is also designed to address those instances where the hospital's request is based on "invalid record selections," which we have defined as medical records submitted during the quarterly validation process that do not match the patient's episode of care information as determined by the CMS contractor as described above in situation 2, above "Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections."

In sum, we are proposing to continue to initially limit the scope of our reconsideration reviews involving validation to information already submitted by the hospital during the quarterly validation process, and we will not abstract medical records that were not submitted to the CMS contractor during the quarterly validation process. We would expand the scope of our review only if we find during the initial review that the hospital correctly and timely submitted the requested medical records. In that case, we would abstract data elements from the medical record submitted by the hospital as part of our review of its reconsideration request.

If a hospital is dissatisfied with the result of a Hospital IQR Program reconsideration decision, the hospital may file an appeal under 42 CFR Part 405, Subpart R (a PRRB appeal). We invite public comment on the extent to which these proposed procedures will be less costly for hospitals, and whether they will lead to fewer PRRB appeals.

11. Proposed Hospital IQR Program Disaster Waivers

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances or unduly increase their burden during these times. Therefore, we are proposing to continue, for the FY 2014 and subsequent years payment determinations, the process we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225), for hospitals to request and for CMS to grant waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. Under the process, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data for one or more quarters, a hospital would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO and any other designated personnel contact information, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital will again be able to submit Hospital IQR Program data, and a justification for the proposed date.

The request form must be signed by the hospital's CEO. We are proposing that a request form must be submitted within 30, rather than 45, days of the date that the extraordinary circumstance occurred. The QIO in the hospital's state will forward the request form to CMS. Following receipt of the request form, CMS will: (1) provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision.

This proposal does not preclude CMS from granting waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. If CMS makes the determination to grant a waiver or extension to hospitals in a region or locale, CMS proposes to communicate this decision through routine communication channels to hospitals, vendors and QIOs, including but not limited to issuing memos, e-mails and notices on the QualityNet Web site. We are proposing to include an overview of this process in proposed 42 CFR 412.140(c)(2). We invite public comment on this proposal.

12. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), 2 of which were previously

selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The remainder of the measures for these incentive programs are being proposed for the Hospital IQR Program for the FY 2015 payment determination.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, quality measures via hospital EHRs for Hospital IQR Program measures in the future.

The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to the Hospital IQR Program for eligible hospitals. To the extent that quality measures are included in both the Hospital IQR Program and the EHR Incentive Programs, this would mean that Hospital IQR Program would need to transition to use of certified EHR technology rather than manual chart abstraction. We are considering what the most practical approach to effect such a transition might be. One option is to select a date after which chart-abstracted data would no longer be used in the Hospital IQR Program. This would require sufficient advance notice to hospitals for hospitals to report the data via certified EHR technology. At that point, we believe that it is likely that nearly all IPPS hospitals will have implemented certified EHR technology as incentivized by the HITECH Act. Another option would be to allow hospitals to submit the same measure for the Hospital IQR Program based on either chart-abstraction or EHR-based reporting. This would require extensive testing to ensure equivalence given that the data for the Hospital IQR Program supports both the public reporting of such information and the Hospital VBP Program. We are concerned that this option would not be feasible. We invite public comment on the approach of selecting a date such as calendar year 2015 after which chart-abstracted data would no longer be accepted for the Hospital IQR Program.

Ultimately, we do not anticipate having two different sets of clinical quality measures for the EHR Incentive Program and the Hospital IQR Program. Rather, we anticipate a single set of hospital clinical quality measures, most of which we anticipate would be electronically specified. We envision a single reporting infrastructure for electronic submission in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for hospitals. We note that some important Hospital IQR Program quality measures such as HCAHPS experience of care measures are based on survey data and do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current Hospital IQR Program readmission measures, are based on claims rather than clinical data. Thus, not all Hospital IRP quality measures will necessarily be capable of being submitted through EHRs. As a consequence, not all Hospital IQR Program measures would necessarily be appropriate for inclusion in the EHR Incentive Programs.

We again note that the provisions in this FY 2012 IPPS/LTCH PPS proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

*B. Hospital Value-Based Purchasing (VBP) Program*

1. Background

Section 1886(o) of the Act requires the Secretary to establish a Hospital Inpatient VBP Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act.

Section 1886(o)(1)(C) of the Act provides that the Hospital Inpatient VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the Hospital Inpatient VBP Program Proposed Rule

On January 7, 2011, we issued the Hospital Inpatient VBP Program proposed rule to implement section 1886(o) of the Act (76 FR 2454 through 2491). This proposed rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled "Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program" (November 21, 2007). This report is available on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf*. The report takes into account input from both stakeholders and other interested parties.

As described more fully in the Hospital Inpatient VBP Program proposed rule (76 FR 2458 through 2463), we proposed to initially adopt for the FY 2013 Hospital Inpatient VBP Program 18 measures that we have already adopted for the Hospital IQR Program, categorized into two domains. We proposed to group 17 of the proposed measures, which are clinical process of care measures, into a Clinical Process of Care domain, and proposed to place 1 measure, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, into a Patient Experience of Care domain. We also proposed to use a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these proposed measures for purposes of the FY 2013 Hospital Inpatient VBP Program and to determine whether hospitals meet the proposed performance standards for these measures by comparing their performance during the proposed performance period to their performance during a proposed 9-month (3-quarter) baseline period from July 1, 2009 through March 31, 2010.

We proposed to implement a methodology for assessing the total

performance of each hospital based on performance standards, under which we will score each hospital based on achievement and improvement ranges for each applicable measure. In addition, we proposed for FY 2013 to calculate a total performance score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, multiplying each domain score by a proposed weight (clinical process of care: 70 percent, patient experience of care: 30 percent), and adding together the weighted domain scores. We proposed to convert each hospital's total performance score into a value-based incentive payment utilizing a linear exchange function. We refer readers to the Hospital Inpatient VBP Program proposed rule for greater detail on all of these proposals.

3. Proposed FY 2014 Hospital Inpatient VBP Program Measures

a. Background

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital Inpatient VBP Program measures, other than readmission measures, from the measures specified under section 1886(b)(3)(B)(viii) of the Act for the Hospital IQR Program. Section 1886(o)(2)(B)(i) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2013, to ensure that the selected measures cover at least the following specified conditions or topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); Surgeries, as measured by the Surgical Care Improvement Project (SCIP); Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (available at: *http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html)* (or any successor plan); and HCAHPS. Section 1886(o)(2)(B)(ii) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2014 or a subsequent year, to ensure that Hospital Inpatient VBP Program measures include efficiency measures, including measures of Medicare spending per beneficiary.

Section 1886(o)(2)(C)(i) of the Act provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least one year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) of the Act provides that a measure selected under section 1886(o)(2)(A) of the Act shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

b. Proposed Efficiency Measure—Medicare Spending per Beneficiary Measure—for the FY 2014 Hospital Inpatient VBP Program

(1) Introduction

Section 1886(o)(2)(B)(ii) of the Act requires the Secretary to ensure that, for Hospital Inpatient VBP discharges occurring during FY 2014 or a subsequent year, the measures selected "include efficiency measures, including measures of 'Medicare spending per beneficiary'. * * *" Therefore, for the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a Medicare spending per beneficiary measure. This measure also is proposed for inclusion in the Hospital IQR Program in this proposed rule and is described in detail above in section IV.A.3.b.(2)(B)(v). The proposed approach to scoring this measure and including it in the Hospital Inpatient VBP Program is described below.

(2) Scoring the Medicare Spending Per Beneficiary Measure

Section 1886(o)(5)(B)(ii) of the Act requires that the hospital performance score be determined using the higher of its achievement or improvement score for each measure. Therefore, we are proposing to calculate each hospital's achievement score and improvement score on the proposed Medicare spending per beneficiary measure, in order to determine which score will be used to calculate the total performance score for the hospital.

We are proposing this scoring methodology because it is generally similar to the methodology proposed for scoring the Clinical Process of Care and Outcome Measures in the Hospital Inpatient VBP Program proposed rule (76 FR 2465 through 2471).

(A) Scoring Based on Achievement

We are proposing to calculate a Medicare per beneficiary spending ratio of the Medicare spending per beneficiary amount for each hospital to the median Medicare spending per beneficiary amount across all hospitals during the performance period. We are proposing that a hospital would earn between 1 and 10 achievement points on the Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls at or between the achievement threshold and the achievement benchmark for the measure. We are proposing to set the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. We are proposing to set the benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period. A hospital whose individual Medicare spending per beneficiary ratio falls below the achievement threshold would score 0 achievement points on the measure, and a hospital whose individual Medicare spending per beneficiary ratio falls at or above the achievement benchmark would score the maximum of 10 achievement points on the measure. A hospital whose individual Medicare spending per beneficiary ratio falls at or above the achievement threshold, but below the benchmark, would score between 1–9 points according to the following formula:

[9 * ((Hospital's performance period score − achievement threshold)/(benchmark − achievement threshold))] + .5

(B) Scoring Based on Improvement

We are proposing that a hospital would earn between 1 and 9 improvement points on the proposed Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls within the improvement range. We are proposing to set the threshold for improvement at the hospital's own Medicare spending per beneficiary ratio, as calculated during the baseline period. We are proposing a baseline period of May 15, 2010 through February 14, 2011 for the Medicare spending per beneficiary measure and discuss this proposal in section IV.B.3.b.(4) of the preamble of this proposed rule. We are proposing that the improvement benchmark would be equal to the achievement benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals. A hospital whose Medicare spending per beneficiary ratio is equal to or lower than its baseline period Medicare spending per beneficiary ratio would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period was greater than its baseline period score but below the benchmark (within the improvement range), the hospital would receive a score of 0–9 according to the following formula:

[10 * ((Hospital performance period score − Hospital baseline period score)/(Benchmark − Hospital baseline period score))] − .5

(C) Example of Scoring the Medicare Spending per Beneficiary Measure

If Hospital A had the following spending per beneficiary amounts during the baseline and performance period:

Baseline = $10,105
Performance = $9,125;

and the median spending per beneficiary amounts across all hospitals for the baseline and performance periods were:

Median Baseline = $11,672
Median Performance = $12,467;

then the Medicare spending per beneficiary ratios for Hospital A in the baseline and performance periods would be:

Baseline Ratio = 0.866
Performance Ratio = 0.732.

With an achievement threshold of 1.0 and an achievement benchmark of 0.712, we would then calculate attainment and improvement points for Hospital A as follows:

Attainment Points = 9 * (1.0 − 0.732)/(1.0 − 0.712) + 0.5 = 8.868
Improvement Points = 10 * (0.866 − 0.732)/(0.866 − 0.712) − 0.5 = 8.185

These points are rounded to yield 9 attainment points and 8 improvement points.

Because section 1886(o)(5)(B)(ii) of the Act, as added by section 3001 of the Affordable Care Act, requires that the hospital performance score will be determined using the higher of attainment or improvement score for each measure, the hospital in this example would receive 9 points on the Medicare spending per beneficiary measure.

(D) Incorporation of Medicare Spending per Beneficiary Measure Score Into the Overall Hospital Total Performance Score

We are proposing to incorporate the Medicare spending per beneficiary measure score into the FY 2014 Hospital Inpatient VBP Program as part of a new domain: The "Efficiency" domain. The Medicare spending per beneficiary measure score would be the Efficiency domain score for purposes of the FY 2014 Hospital Inpatient VBP Program. Consistent with the domain scoring method proposed in the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491), we are proposing to determine the total earned points for the Efficiency domain in general by adding the points earned for each domain measure and dividing by the total possible points, then multiplying that number by 100 percent. However, because we are proposing to adopt only one measure for the Efficiency domain for the FY 2014 Hospital Inpatient VBP Program, the total points earned for the domain would be the points earned on the Medicare spending per beneficiary measure. We are proposing that the total possible points that a hospital could earn for the Efficiency domain for FY 2014 would be 10, which is equal to the total possible points that the hospital could earn for the Medicare spending per beneficiary measure. We are proposing that the Efficiency domain percentage score would be calculated for FY 2014 as follows: Efficiency domain score = Total points earned on the Medicare spending per beneficiary measure divided by 10, then multiplied by 100 percent.

Once the Efficiency domain score has been determined, we are proposing to assign it a weight for use in the calculation of the total performance score. We intend to propose FY 2014 domain weighting, any additional FY 2014 measures, and other FY 2014 proposals for the Hospital Inpatient VBP Program in the CY 2012 Hospital Outpatient Prospective Payment System proposed rule.

4. Proposed Efficiency Domain (Medicare Spending per Beneficiary Measure) Performance Period and Baseline Period

Section 1886(o)(2)(C)(i) of the Act prohibits the Secretary from selecting a measure for the Hospital Inpatient VBP Program with respect to a performance period unless it has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least 1 year prior to the beginning of such performance period. Section 1886(o)(8) of the Act requires that hospitals be notified of the calculation of their value-based incentive payment no later than 60 days prior to the fiscal year involved. In order to comply with these statutory requirements for the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a 9-month period of performance from May 15, 2012 through February 14, 2013 for the proposed Medicare spending per beneficiary measure. If the measure is adopted, this would allow for a 1-year display period on *Hospital Compare,* a 60-day notification period, and would allow the time needed for administrative processes. We note that this would mean that only IPPS discharges occurring from May 15, 2012 through 90 days prior to February 14, 2013 would count as index stays for purposes of creating the Medicare spending per beneficiary episodes. The Medicare spending per beneficiary episode is described in section IV.A.3.b.(2).(B).(v) of this proposed rule.

For the purposes of calculating improvement points on the proposed Medicare spending per beneficiary measure, it is necessary to establish the baseline period to which the performance period score will be compared. For purposes of the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a baseline period of May 15, 2010 through 90 days prior to February 14, 2011 for this proposed measure. The proposed baseline period is consistent with the baseline period that has been proposed for the FY 2013 clinical process of care and patient experience of care measures in the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491) because it precedes the performance period by 2 years.

We invite public comment on all of our proposals related to the Efficiency Domain and Medicare spending per beneficiary measure.

5. Proposal to Simultaneously Specify Additional Measures for the Hospital Inpatient VBP Program and Adoption Into the Hospital IQR Program

We are proposing to simultaneously specify additional measures for the Hospital Inpatient VBP Program and adoption into the Hospital IQR Program, as appropriate for usage in both programs. Our rationale is to improve patient safety and quality of care in an expedited manner that is compliant with applicable statutory guidance. We are currently utilizing this approach in this rule by proposing to add the Medicare Spending per Beneficiary measure to both Hospital Inpatient VBP and Hospital IQR Programs. We will provide all associated regulatory impact and policy rationale in future proposals for both programs. We believe that this proposal notifies stakeholders through rulemaking and welcome comments on this proposal.

*C. Hospital Readmissions Reduction Program*

1. Background

a. Overview

CMS is committed to promoting high quality health care and improving patient health outcomes. Readmission to a hospital may be an adverse event for patients and many times imposes a

financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve quality of care while simultaneously decreasing costs. Hospitals can work with their communities to lower readmission rates and improve patient care in a number of ways, such as ensuring patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.[34 35 36] These types of efforts taken during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally, [37 38] as well as for multiple specific conditions. Moreover, such interventions can be cost saving. For example, in the case of heart failure, improved hospital [39] and post-discharge care,[40 41] including pre-discharge planning,[42 43] home-based follow-up, and patient education,[44 45] have been shown to lower heart failure readmission rates, suggesting that heart failure readmission rates might be reduced if proven interventions were more widely adopted. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.[46]

In its 2007 "Report to Congress: Promoting Better Efficiency in Medicare," [47] MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. MedPAC identified 7 conditions and procedures that accounted for almost 30 percent of potentially preventable readmissions: heart failure; chronic obstructive pulmonary disease; pneumonia; acute myocardial infarction; coronary artery bypass graft surgery; percutaneous transluminal coronary angioplasty; and other vascular procedures. To promote quality of care, CMS developed hospital quality of care measures that compare patient outcomes across different hospitals. These measures, including hospital risk-standardized readmission measures for Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN), were originally developed for public reporting as a part of the Hospital IQR Program. We adopted the HF readmission measure for the Hospital IQR Program in the FY 2009 IPPS final rule for the FY 2010 payment determination (73 FR 48606) and the AMI and PN readmission measures in the CY 2009 OPPS/ASC final rule with comment period for the FY 2010 payment determination (73 FR 68781). Details about the methodology used for these measures may be found online at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

As described above, readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care. The above hospital risk-standardized readmission measures are endorsed by the National Quality Forum (NQF) and have been publicly reported on *Hospital Compare* Web site since 2009 (*http://www.hospitalcompare.hhs.gov*) to encourage quality improvement and lower readmission rates. As discussed in detail below, we are now proposing that the readmission measures for these three conditions be used for the Hospital Readmission Reduction Program under section 1886(q) of the Act, as added by Section 3025 of the Affordable Care Act.

b. Statutory Basis for the Hospital Readmission Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the "Readmission Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

In this year's IPPS rulemaking, we address: (i) Those aspects of the program that relate to the conditions and readmissions to which the program will apply for the first program year beginning October 1, 2012; (ii) the readmission measures and related methodology used for those measures, as well as the calculation of the readmission rates; and (iii) public reporting of the readmission data. Specific information regarding the payment adjustment required under section 1886(q) of the Act will be proposed in next year's IPPS/LTCH PPS proposed rule. Although we are not proposing specific policies regarding the payment adjustment under the Hospital Readmissions Reduction Program in this proposed rule, we believe that it is still important to set forth the general framework of the Hospital Readmissions Reduction Program, including the payment adjustment provisions, in

[34] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[35] McAlister FA, Lawson FM, Teo KK, Armstrong PW.: A systematic review of randomized trials of disease management programs in heart failure. AmJMed. 2001;110(5):378–384.

[36] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[37] Coleman EA, Parry C, Chalmers S, Min SJ.: The care transitions intervention: results of a randomized controlled trial. Arch Intern Med. 2006;166:1822–8.

[38] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS.: Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. JAMA. 1999;281:613–20.

[39] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH.: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[40] Lappe JM, Muhlestein JB, Lappe´ DL, *et al.:* Improvements in 1-year cardiovascular clinical outcomes associated with a hospital-based discharge medication program. Ann Intern Med. 2004;141(6):446–453.

[41] Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR.: Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a metaanalysis [published correction appears in JAMA. 2004;292(9):1022]. JAMA. 2004;291(11): 1358–1367.

[42] Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM.: A multi disciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med. 1995;333(18):1190–1195.

[43] Schneider JK, Hornberger S, Booker J, Davis A, Kralicek R.: A medication discharge planning program: measuring the effect on readmissions. Clin Nurs Res. 1993;2(1):41–53.

[44] Koelling TM, Johnson ML, Cody RJ, Aaronson KD.: Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation. 2005;111(2):179–185.

[45] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[46] Coleman EA.: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

[47] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

order for the public to understand how the proposed measures outlined in this rulemaking will affect certain hospital payments beginning in FY 2013.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to "applicable hospitals" will be adjusted to account for excess readmissions. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and the adjustment factor for the hospital for the fiscal year. That is, the "base operating DRG payments" are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of "the base operating DRG payment amount" and "the adjustment factor" for the hospital in a given fiscal year. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)." Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) refer to outlier payments, IME payments, DSH payments, and payments for low volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining "the payment amount that would otherwise be made under subsection (d)" for certain hospitals. Specifically, section 1886(q)(2)(B) of Act states that "[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital * * * the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5)." We intend to propose regulations to implement the statutory provisions related to the definition of "base operating DRG payment amount" in the FY 2013 IPPS/LTCH PPS proposed rule.

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of "(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C)." Section 1886(q)(3)(B) of the Act in turn describes the ratio used to calculate the adjustment factor. It states that the ratio is "equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges. * * *" Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act as "the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the "Excess Readmission Ratio* * * for such hospital for such applicable period minus 1." The "Excess Readmission Ratio" is a hospital-specific ratio hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the Excess Readmission Ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of "applicable condition," "expansion of applicable conditions," "applicable hospital," "applicable period," and "readmission." The term "applicable condition," which we address in detail in this proposed rule, is defined as a "condition or procedure selected by the Secretary among conditions and procedures for which: (i) readmissions * * * represent conditions or procedures that are high volume or high expenditures * * * and (ii) measures of such readmissions * * * have been endorsed by the entity with a contract under section 1890(a) * * * and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." The term "expansion of the applicable condition" refers to the Secretary's authority, beginning with fiscal year 2015, "to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed * * * to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary."

Section 1886(q)(5)(C) of the Act defines "applicable hospital," that is, a hospital subject to the readmission reduction program, as a "subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be." The term "applicable period," as defined by section 1886(q)(5)(D) of the Act, "means, with respect to a fiscal year, such period as the Secretary shall specify." As explained in this proposed rule, the "applicable period" is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for "specified hospitals" in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Implementation of the Hospital Readmissions Reduction Program

a. Overview

We intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

b. Proposed Provisions in the FY 2012 IPPS/LTCH PPS Rulemaking

As explained above, the adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we are able to implement the Hospital Readmission Reduction Program over two years. We are first addressing issues such as the selection of readmission measures and the calculation of the excess readmission ratio, which will then be used, in part, to calculate the readmission payment adjustment factor. Specifically, in the FY 2012 IPPS

rulemaking, we are addressing portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of "readmission;"
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the Excess Readmission Ratio;
- Public reporting of the readmission data; and
- Definition of "applicable period."

With respect to the topics of "measures for readmission" for the applicable conditions, and "methodology for calculating the Excess Readmission Ratio," we will specifically address the following:

- Index hospitalizations;
- Risk Adjustment;
- Risk Standardized Readmission Rate;
- Data sources; and
- Exclusion of Certain Readmissions.

c. Proposed Provisions To Be Included in the FY 2013 IPPS/LTCH PPS Proposed Rule

In the FY 2013 IPPS rulemaking, we will address the provisions in section 1886(q) of the Act that are related to the payment adjustment, as well as the rest of the provisions in section 1886(q) of the Act that are not addressed in the FY 2012 IPPS/LTCH PPS rulemaking. Specifically, in the FY 2013 IPPS/LTCH proposed rule, we plan to address section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions;
- Applicable hospital; and

We believe it is appropriate to first address the readmission measures and the calculation of the excess readmission ratio that will then be used, in part, to calculate the readmission payment adjustment factor and the application of the readmission payment adjustment factor to inpatient hospital payments. We believe the 2-year rulemaking schedule provides adequate time and opportunities for careful consideration of the various aspects of this program by both CMS and stakeholders prior to implementation of the Hospital Readmission Reduction Program in FY 2013.

d. Proposed Expansion of the Applicable Conditions To Be Included in the Future Rulemaking

Pursuant to section 1886(q)(5)(B) of the Act, the Secretary "shall, to the extent practicable," expand the list of applicable conditions beyond the 3 conditions for which measures have been endorsed and add 4 conditions that have been identified by MedPAC for the Hospital Readmission Reduction Program. We plan to implement this section of the Act in later rulemaking.

3. Proposed Provisions for the Hospital Readmission Reduction Program

a. Proposed Applicable Conditions for the FY 2013 Hospital Readmission Reduction Program

Section 1886(q) of the Act sets forth payment adjustments for applicable hospitals to account for excess readmissions, for applicable conditions, that are high volume or high expenditure, in the hospital. These payment adjustments are determined based on the occurrence of readmissions for "applicable conditions." When selecting "applicable conditions," the Secretary must select among conditions and procedures for which (1) readmissions are "high volume or high expenditure; and (2) "measures of such readmissions" have been endorsed by the entity with a contract under section 1890(a) of the Act (currently NQF) and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge. Consistent with these requirements, we are proposing to include AMI, HF and PN as "applicable conditions" for the Hospital Readmissions Reduction Program in FY 2013 and subsequent fiscal years. As set forth below, we believe these conditions meet the criteria for "applicable conditions" under section 1886(q)(5)(A) of the Act. We also note that in the 2007 Report to Congress that we referred to earlier in the overview section, MedPAC listed three conditions: AMI, HF, and PN, as priorities for hospital-specific public reporting of readmission rates.[48]

With regards to the first criterion, that readmissions of "applicable conditions" be "high volume or high expenditure," MedPAC identified AMI, HF, PN as being among the seven conditions and procedures associated with approximately 30 percent of potentially preventable readmissions,[49] based on an 3M analysis conducted for MedPAC of 2005 MedPAR (Medicare FFS hospital claims). Of these seven conditions and procedures, HF and PN were the highest in terms of volume and expenditures.

Additionally, in our analysis of the 235 diagnostic categories for hospitalization based on 2008 Medicare hospital claims data, HF and PN were first and second, respectively, as the most frequent diagnostic category for both total admissions and total readmissions. AMI was ninth among the 235 conditions in terms of frequency of admission and 8th in frequency of readmission. We therefore believe that AMI, HF and PN consitute high volume and high expenditure conditions particularly as relates to hospital admission and readmission.

With regards to the second criterion, we believe that measures of readmissions for these applicable conditions also meet the statutory requirements. Section 1886(q)(5)(A)(i) of the Act requires that each "applicable condition" have "measures of readmissions" that "(I) have been endorsed by the entity with a contract under section 1890(a); and (II) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge." As discussed in section IV.C.3.c. below, we believe that our proposal to select AMI, HF, and PN as "applicable conditions" is consistent with this statutory requirement. The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed "measures of readmissions" for each of these three conditions, and those NQF-endorsed measures "have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)."

We believe AMI, HF, and PN meet both prongs of the definition of "applicable condition." Therefore, we are proposing to include AMI, HF, and PN as "applicable conditions" for the Hospital Readmissions Reduction Program for FY 2013 and subsequent fiscal years. We invite public comment on this proposal.

b. Proposed Definition of "Readmission"

Section 1886(q)(5)(E) of the Act defines "readmission" as, "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge." The definition further states that "[i]nsofar as the discharge relates to an applicable condition for which there is an endorsed measure * * * such time period (such as 30 days) shall be

[48] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

[49] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

consistent with the time period specified for such measure."

The three NQF-endorsed readmission measures define a readmission as occurring when a patient is discharged from the applicable hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization. The time period specified for these measures is 30 days. Because the measures as endorsed by NQF are calculated based on readmissions occurring within 30 days, we are proposing 30 days as the time period specified from the date of discharge for the purpose of defining readmission for the purpose of the Hospital Readmissions Reduction Program. This is in compliance with the statutory requirement that the time period specified by the Secretary from the date of discharge for the purpose of defining readmission be consistent with the time period specified for the endorsed measures. We invite public comment on our proposal to adopt, without revision, a proposed definition of readmission with a time period of 30 days from the date of discharge from the index hospital as set forth in the existing NQF-endorsed measures.

c. Proposed Readmission Measures and Related Methodology

(1) Proposed Readmission Measures for Applicable Conditions

As explained above, section 1886(q)(5)(A)(ii) of the Act requires that each "applicable condition" selected by the Secretary have "measures of readmissions" that "have been endorsed by the entity with a contract under section 1890(a)" and that "such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge." We are proposing to adopt three NQF-endorsed, hospital risk-standardized readmission measures for AMI, HF, and PN which are currently included in the Hospital IQR Program. These existing measures are:

- Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF# 0505);
- Heart Failure 30-day Risk Standardized Readmission Measure (NQF#0330); and
- Pneumonia 30-day Risk Standardized Readmission Measure (NQF#0506).

CMS adopted these measures for the Hospital IQR Program in the FY 2009 IPPS/LTCH final rule for FY 2010 payment determination (73 FR 48606) and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68781). The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed each of these "measures of readmissions" and, as explained in more detail below, those NQF-endorsed measures "have exclusions for readmissions that are unrelated to the prior discharge." Therefore, we believe these measures meet the statutory requirements for selection for the Hospital Readmissions Reduction Program, and we are proposing them, without modification, as measures for the program.

(2) NQF Endorsement of Measures of Readmissions

We note that these measures and their underlying methodologies were endorsed by NQF. We are proposing to adopt, for purposes of the Hospital Readmissions Reduction Program, the measures and related methodologies as they are currently endorsed by NQF. This includes the currently endorsed 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions that comprise the measures. We believe that this proposal to adopt, without modification, these measures of readmission is consistent with the statutory language, which requires the measures of readmissions to be "endorsed by the entity with a contract under section 1890(a)." If we were to modify the endorsed measures, we are concerned that they would no longer be considered "endorsed." If the NQF were to later endorse a revised measure for one of these conditions, we would then propose through notice and comment rulemaking that the revised measure be used prospectively for purposes of the Hospital Readmissions Reduction Program.

We welcome public comment on this proposal to use, for each of the proposed applicable conditions, existing measures as endorsed by the NQF.

(3) Endorsed Measures With Exclusions for Unrelated Readmissions

Section 1886(q)(5)(A)(i)(ii)(II) of the Act requires that each of the readmission measures also has "exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." The three NQF-endorsed readmission measures that we are proposing for inclusion in the Hospital Readmissions Reduction Program have exclusions that meet this statutory requirement. Under each measure, certain unrelated readmissions are not taken into account when determining the number of readmissions under the measures.

The AMI 30-day risk standardized readmission measure, as endorsed by the NQF and as proposed in this rule, has exclusions for certain unrelated readmissions. Because admissions for Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Artery Bypass Graft (CABG) may be staged or are typically scheduled readmissions for patients initially admitted for AMI, the AMI 30-day risk standardized readmission measure does not count as readmissions those admissions after discharge that include PTCA or CABG procedures, unless the principal discharge diagnosis for the readmission is one of the following diagnoses that are not consistent with a scheduled readmission: heart failure, acute myocardial infarction, unstable angina, arrhythmia, and cardiac arrest (that is, readmissions with these diagnoses and a PTCA or CABG procedure are counted as readmissions). We adopted this approach when first developing this measure after consultation with clinical experts, including cardiologists, and review of relevant readmissions data.

During the development of the readmission measures for both HF and PN, we similarly asked clinical experts to identify planned readmissions for these conditions, that is, those which would not count as a readmission, after an admission for HF or PN. Specifically, the clinical experts were asked whether there were common follow-up causes of readmissions for a scheduled procedure that represented a continuation of care after either a HF or PN admission, respectively. No such related, planned procedures were identified as occurring commonly after the index admissions for HF or PN at the time of the development of the IQR measures. Therefore, no similar exclusions exist for the HF and PN measures of readmissions as they are currently endorsed.

Under the three NQF-endorsed risk-standardized readmission measures that we are proposing in this proposed rule, transfers to other acute care facilities are excluded from each of the readmission measures. The NQF-endorsed proposed measures consider these multiple contiguous hospitalizations to be a single acute episode of care. The measures attribute the readmission for transferred patients to the hospital that ultimately discharges the patient to a non-acute care setting (for example, to home or a skilled nursing facility). Thus, in the case of a patient who is transferred between two or more hospitals, if the patient is readmitted in the 30 days following the final

hospitalization, the measures attribute such a readmission to the hospital that discharged the patient to a non-acute care setting. We believe that the exclusion of transfers to other applicable hospitals under the measures is sufficient to meet the requirement set forth in section 1886(q)(5)(A)(ii)(II) of the Act that certain "unrelated" readmissions be excluded from the measures selected for use in the program. We invite public comment on our proposal to adopt, without revision or modification, the exclusions for unrelated admissions set forth in the existing NQF-endorsed measures.

(4) Methodology of Proposed Readmission Measures

In the following section, we describe the major components of the measure methodology of the three NQF-endorsed risk-standardized readmission measures for AMI, HF and PN proposed for the implementation of the Hospital Readmissions Reduction Program. Additional details about each of these measures may be found online at *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies. This Web page is located at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

Briefly, as is described in more detail in the sections below, the measures are risk-standardized rates of readmission. For each hospital qualifying index hospitalizations are identified based on the principal discharge diagnosis of the patient and the inclusion/exclusion criteria (section IV.C.3.c.(4)(A), Index hospitalization). Each hospitalization is evaluated for whether the patient had a readmission to an acute care setting in the 30-days following discharge (section IV.C.3.c.(4)(B), Readmission). Patient-risk factors, including age, and chronic medical conditions are also identified from inpatient and outpatient claims for the 12-months prior to the hospitalization for risk-adjustment (section IV.C.3.c.(4)(D), Risk-Adjustment). The readmissions, sample size for each hospital, and patient risk-factors are then used to calculate a risk-standardized readmission ratio for each hospital. For the purposes of publicly-reporting the measures, this risk-standardized readmission ratio is then multiplied by the national crude rate of readmission for the given condition to produce a risk-standardized readmission rate (RSRR) (section IV.C.3.c.(5)(B)).

As stated above, we invite public comment on our selection of the three readmission measures, as endorsed by the NQF, and as described in more detail below.

(A) Index Hospitalization

An index hospitalization for each of the readmission measures is the hospitalization from which we evaluate the 30 days after discharge for possible readmissions. The measures, as endorsed by the NQF, evaluate eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital (as defined by section 1886(q)(5)(C) of the Act) having a principal discharge diagnosis for the measured condition in an applicable period. The NQF endorsed measures, as specified, exclude patients under 65 years of age.

The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are listed in the *2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.* They also are posted on the QualityNet Web site: *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies. See *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

The current NQF-endorsed CMS 30-day risk standardized readmission measures exclude the following admissions from the group of index hospitalizations:

- Hospitalizations for patients with an in-hospital death (because they are not eligible for readmission);
- Hospitalizations for patients without at least 30 days post-discharge enrollment in Medicare FFS (because the 30-day readmission outcome cannot be assessed in this group);
- Hospitalizations for patients discharged against medical advice (because providers did not have the opportunity to deliver full care and prepare the patient for discharge).

(B) Readmission

As explained above, the initial hospitalization assessed for a readmission is called the index hospitalization. The proposed measures, as endorsed by the NQF, define readmission as a second admission to another acute care hospital within 30-days of the index hospitalization. Under the proposed measure, as endorsed by the NQF, a patient who is readmitted twice within 30 days simply is counted as having been readmitted; this patient's readmissions are not counted differently than a patient with a single readmission within 30 days of discharge.

With the exception of the exclusions discussed previously (transfers and planned readmissions, as discussed in the Exclusions for Unrelated Readmissions section above), the proposed measures, as currently endorsed by the NQF, include readmissions for all causes, without regard to the principal diagnosis of the readmission. There are several reasons for this approach. First, from the patient's perspective, readmission from any cause is an adverse event. We want the measures to be patient-centered measures. Second, although we would expect few hospitals to use gaming strategies, we strive to make sure that measures do not create incentives for them to do so. Limiting the readmissions to particular diagnoses creates an opportunity for hospitals to potentially avoid having readmissions counted by changing coding practices. Further, do so could create a perverse incentive whereby hospitals begin to avoid patients with conditions that are part of the readmissions measures. Third, there are not clinically and technically sound and accepted strategies for accurately identifying readmission that are unrelated to hospital quality based on the documented cause of readmission. For example, a patient with HF who develops an HAI may ultimately be readmitted for sepsis. It would be inappropriate to consider the readmission as unrelated to the care the patient received for HF. Finally, we believe it is important that hospitals strive to reduce readmissions from all causes, not just those that are readmissions measures; while the measures do not presume that each readmission is preventable, interventions have generally shown reductions in all types of readmissions. The NQF measures are intended to provide incentives for hospitals to reduce readmissions and not to achieve zero readmissions.

(C) Time Window

The three proposed measures, as endorsed by the NQF, count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization. This is the standard time period to be considered a readmission. The timeframe of 30 days is a clinically meaningful period for hospitals, in collaboration with their medical communities, to reduce readmission risk. This time period for assessing readmission is an accepted standard in research and measurement. We believe

that during this 30-day time period, hospital and community partners can take steps to reduce risk by ensuring patients are clinically ready to be discharged, improving communication across providers, reducing risks of infections, and educating patients on symptoms to monitor whom to contact with questions and where and when to seek follow-up care can influence readmission rates.

(D) Risk Adjustment

Section 1886(q)(4)(C)(i)(I) of the Act requires that the number of readmissions used in the Excess Readmission Ratio be risk adjusted. This language requires us, when comparing hospitals' readmission rates, to account for differences in the severity of illness of the patients that hospitals treat. Risk adjustment essentially "levels the playing field" for comparing hospital performance by taking into account that some hospitals' patients are sicker than others on admission and therefore have a higher risk of readmission.

The methodology for calculating the RSRRs under the NQF-endorsed measures that we are proposing adjust for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient co-existing medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables.

A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available in the publicly-available technical documentation of the existing measures for AMI, HF, and pneumonia. The risk adjustment variables for each condition are presented in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30–Day Risk-Standardized Readmissions Measures that are posted on *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > Resources. The variables used are Condition Categories that group ICD–9–CM codes into clinically coherent variables. The 2010 Condition Category-ICD–9–CM Crosswalk provides a map to the specific ICD–9–CM codes in each variable and is also posted on *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > Measure Calculation Methodology or readers may use the following Web site address: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*

(E) Applicable Period

Section 1886 (q)(5)(D) of the Act authorizes the Secretary to specify the "applicable period" with respect to a fiscal year. Currently, for Hospital IQR Program public reporting purposes, we use three years of data (three 12-month increments) to calculate the three proposed readmission measures. This provides substantially more data than a one or two year time frame and increases the precision of the measure in distinguishing performance among hospitals. This is advantageous in the display of the three proposed readmission measures on *Hospital Compare* where we categorize hospital performance into one of three discrete categories: "Better than the US national rate," "No different than the US national rate," and "Worse than the US national rate."

For the FY 2013 Hospital Readmissions Reduction Program, we are proposing to use 3 years of data for discharges from July 1, 2008 through June 30, 2011 as the applicable period upon which to calculate excess readmission ratios for each of the three proposed measures. Based on our experience with the IQR program, we believe that this timeframe increases the precision of the measures in distinguishing performance among hospitals. However, for purposes of the Hospital Readmissions Reduction Program, we will not be categorizing hospital performance in three categories; rather, we will be using the measures to calculate excess readmission ratios for the three conditions. We are currently conducting analyses to determine an appropriate data period (for example, 1 year, 2 years, 3 years) that will yield reliable excess readmission ratios for the three proposed measures. We intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. Should our analysis or public comment indicate that a shorter data period yields excess readmission ratios with acceptable reliability, we may consider finalizing a shorter time period.

We invite public comment and suggestions on the topic of an appropriate length for the applicable period to consider using for the three proposed readmission measures for the FY 2013 payment determination.

(F) Data Sources

As discussed above, the adjustment under section 1886(q) of the Act is made to the "base operating DRG payment amount," and components of the ratio used to determine a hospital's adjustment factor also use that payment amount. Payments under section 1886 of the Act, including the "base operating DRG payment amount, are made for services furnished to Medicare's fee-for-service population under part A. Therefore, for purposes of implementing the Hospital Readmissions Program under section 1886(q) of the Act, we are proposing to use Medicare claims data for the Medicare FFS population only. This is the same universe of claims used for calculating the endorsed measures for the purposes of the IQR program.

The administrative data sources for the risk adjustment analyses are Medicare administrative claims datasets that contain FFS inpatient and outpatient (Medicare Parts A and B) claims information in the prior 12 months and subsequent one month for patients admitted in each of these years. We are proposing to use claims from the index hospitalization included the measure and from the prior 12 months from all of these data sources to gather risk factors. If the patient does not have any claims in the 12 months prior to the index hospitalization admission, only comorbidities from the included admission are used.

We welcome public comment on this proposal.

(G) Minimum Number of Discharges for Applicable Conditions

Section 1886 (q)(4)(C)(II)(ii) of the Act authorizes the Secretary to exclude readmissions for an applicable condition for which there are "fewer than a minimum number (as determined by the Secretary)." Currently, for public reporting purposes under the IQR program, only hospitals with at least 25 discharges for each of the three proposed applicable conditions are included in the display of the three proposed readmission measures on *Hospital Compare.* We chose this number of discharges for the IQR based on our findings that using fewer cases did not provide sufficiently reliable information on hospital performance. In general the larger the number of cases, the more reliable is the information. We are currently conducting additional analyses to determine further evaluate the appropriate minimum number of discharges needed to yield reliable excess readmission ratios for the three

proposed measures. However, based on our experience with the IQR program, we are proposing to use the current threshold of 25 discharges for each of the three measures for the Hospital Readmissions Reduction Program. However, should our analysis or public comment indicate that a different minimum number of discharges would be more appropriate for this program, we would consider finalizing a different number.

We invite public comment and suggestions on the topic of appropriate minimum number of discharges to consider for the three proposed readmission measures.

(H) Reporting Hospital-Specific Readmission Rates

Section 1886(q)(6)(A) of the Act requires the Secretary to "make information available to the public regarding readmission rates of each subsection (d) hospital under the readmission reduction program." Section 1886(q)(6)(B) of the Act requires the Secretary to "ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public with respect to the hospital * * * prior to such information being made public." Section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information on the *Hospital Compare* Web site in an easily understandable format.

We currently report information on the three readmission rates we are proposing in this proposed rule on the *Hospital Compare* Web site for each subsection (d) hospital. We provide hospitals with an opportunity to preview their readmission rates for 30-days prior to posting on the Web site. We propose to use a similar process and timeframe for the rates calculated for the Hospital Readmissions Reduction Program. Through this process hospitals will be able to review the information and submit to CMS corrections in advance of the information to be made public. We will carefully review all such correction submissions and determine the appropriateness of any revisions. We will inform the hospital requesting corrections of our findings and we will make any appropriate revisions to the information to be made available to the public regarding the hospital's readmission rates.

We invite public comment on this proposal.

(I) Readmission Rates for All Patients

Section 1886(q)(8)(A) of the Act requires the Secretary to calculate readmission rates for all patients for a "specified hospital" for an applicable condition and "other conditions deemed appropriate by the Secretary for an applicable period." Section 1886(q)(8)(D)(ii) of the Act defines "specified hospital" as: subsection (d) hospitals; hospitals described in clauses (i) through (v) of subsection (d)(1)(B) (psychiatric hospitals, rehabilitation hospitals, children's hospitals, LTCHs, and cancer hospitals); and, "as determined feasible and appropriate by the Secretary, other hospitals." Such information is to be calculated in the same manner as used to calculate readmission rates for hospitals with respect to the postings on the CMS *Hospital Compare* Web site. Section 1886(q)(8)(C) of the Act requires specified hospitals, or a State or an appropriate entity on behalf of the hospitals, to submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary to calculate the all patient readmission rates. Section 1886(q)(8)(D) of the Act defines "all patients" to mean patients who are treated on an inpatient basis and discharged from a specified hospital. We are not proposing any specific policies to implement section 1886(q)(8) of the Act at this time, but we invite public comment and suggestions for issues related to implementation of these provisions, such as the mechanisms to collect the all-patient data, the collection of patient identifiers to track patient care history across multiple settings to conduct risk adjustment for outcome measures, what entities could submit all patient data on behalf of hospitals, and more generally, the requirement for all patient data submission.

(5) Proposed Excess Readmission Ratio

(A) Statutory Background

Section 1886(q)(4)(C) of the Act requires the Secretary to develop a risk-adjusted "Excess Readmission Ratio." The Excess Readmission Ratio will be used in the calculation of "aggregate payments for excess readmissions" as required under section 1886(q)(4)(A)(iii) of the Act, which, in turn, is used to determine the adjustment factor under section 1886(q)(3). Specifically, section 1886(q)(4)(C)(i) states that the term "'Excess Readmission Ratio' means * * * with respect to an applicable condition for a hospital for an applicable period * * * the ratio of * * * risk adjusted readmissions based on actual readmissions * * * to * * * the risk adjusted expected readmissions." The statute also requires that the numerator and denominator of the ratio, that is, "risk adjusted readmissions based on actual readmissions" and the "risk adjusted expected readmissions," be determined "consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I)."

(B) Proposed Excess Readmission Ratio Methodology

We are proposing to use the risk-standardized ratio calculated for the NQF-endorsed measures for AMI, HF, and PN as the "excess readmission ratio." This risk-standardized ratio (excess readmission ratio), as required by statute, is a ratio of "risk adjusted readmission based on actual" to "risk adjusted expected readmissions." Moreover, use of this ratio meets the statutory requirement that the numerator and denominator of the ratio be determined in a manner that is "consistent with" an NQF-endorsed readmission measure methodology.

The proposed ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than one. If a hospital performs worse than average, the ratio will be greater than one. Hospitals with a ratio greater than one have excess readmissions relative to average quality hospitals with similar types of patients

As part of the Hospital IQR Program, the risk-standardized ratio to the measure result is reported on *Hospital Compare* Web site. The risk-standardized ratio is the unique result produced by the measures for each hospital for each condition to assess relative hospital performance. Hospitals may not be familiar with this ratio, because the measure result reported on Hospital Compare for each hospital and each condition is this ratio multiplied by a constant (the national raw rate of readmission for the condition), and it is currently presented as the risk-standardized readmission rate (RSRR). Multiplying by a constant transforms the ratio into a rate (the risk-standardized readmission rate) that is better understood by consumers. Thus *Hospital Compare* results for CMS readmission measures are computed as follows:

[Hospital risk-standardized ratio] X [national raw readmission rate] (i) Numerator and Denominator of the Risk-Standardized Ratio (Excess Readmission Ratio)

The NQF-endorsed measures, which we are proposing for the Hospital Readmissions Reduction Program, calculate this risk-standardized ratio (excess readmission ratio) using hierarchical logistic modeling, which is a widely accepted statistical method that evaluates relative hospital performance based on outcomes such as readmission. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospitals' patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in quality. The detailed methodology for these measures is publicly-available and the calculation SAS packs are made available upon request. This is the calculation software that permits the measures to be calculated. We describe the key details of the methodology here.

In order to model the extent to which hospitals affect patients' risk of readmission, this statistical model first analyzes data on all the patients discharged from all hospitals for a given condition that indicate for each patient what comorbidities were present when the patient was admitted and whether or not the patient was readmitted and calculates:

- How much variation in hospital readmission rates overall is accounted for by variation across hospitals in patients' individual risk factors (such as age and other medical conditions); a risk weight (beta-coefficient) is calculated for each patient risk factor at all hospitals. The specific approach and variables used in the risk adjustment are discussed below.
- How much variation in readmission rates is accounted for by hospitals' contribution to readmission risk, after adjusting for differences in readmission due to differences in patients' risk factors. The model estimates the amount by which a specific hospital increases or decreases patients' risk of readmission relative to an average hospital based on the hospitals actual readmission relative to hospitals with similar patients. The estimated amount each hospital contributes (or subtracts) from its patients readmission risk compared to hospitals with similar patients is called the "hospital-specific readmission effect." It is used only in the numerator to estimate the adjusted actual readmissions. The hospital-specific effect will be negative for a better than average hospital, positive for a worse than average hospital, and close to zero for an average hospital. If there are no quality differences resulting in excess readmissions among hospitals (if all hospitals had the same readmission rates relative to hospitals with similar patients), the hospital-specific effects for all hospitals will be zero and the ratio for all hospitals will be one.

(ii) Numerator Calculation—Adjusted Actual Readmissions

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. This estimated probability of readmission for each patient is calculated using:

- The hospital-specific effect (increase, decrease, or no change in probability of readmission relative to the probability of readmission at an average hospital);
- The intercept term for the model (the same for all hospitals and for both numerator and denominator equations);
- The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X)

Mathematically, the numerator equation can be expressed as:

**Numerator: Adjusted Actual Readmissions**

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Za}}$

$Z_a$ = hospital-specific effect + Xβ

***intercept + risk-adjustment coefficients***

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

(iii) Denominator Calculation—Expected Readmissions (at an Average Quality Hospital Treating the Same Patients)

The denominator of the risk-standardized ratio (excess readmission ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This probability is calculated using:

- The intercept term for the model (the same for all hospitals and for both numerator and denominator equations); and
- The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X).

This can be expressed mathematically as:

**Denominator: Expected Readmissions**

Step 1:

Calculate each patient's expected probability of readmission = $\frac{1}{1 + e^{-Ze}}$

$Z_e = X\beta$

***intercept + risk-adjustment coefficients***

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one.

Because the ratio is risk-adjusted, a hospital may have high crude readmission rates (number of 30-day readmissions among patients with the applicable condition divided by number of admissions for patients with the applicable condition) yet have a risk-standardized ratio (excess readmission ratio) less than one. For example, if a hospital with a higher than average raw readmission rate cares for very sick patients, the ratio may show that the adjusted actual number of readmissions (the numerator), which accounts for the case-mix, is actually lower than what would be expected for an average hospital caring for these patients (denominator) and therefore the Excess Readmission Ratio, as proposed, will be less than one, demonstrating that this hospital performs better than average, despite having a high crude readmission rate, and does not have excess readmissions. Similarly, if a hospital has a seemingly low unadjusted readmission rate but cares for a very low risk population of patients, it may be found to have an adjusted actual number of readmissions that is higher than the expected number of readmissions, and therefore a ratio greater than one.

In summary, we are proposing to use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the Excess Readmission Ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

We welcome public comment on our proposal to use this methodology for calculating the "risk adjusted readmissions based on actual readmissions" as well as the "risk adjusted expected readmissions" used to determine the Excess Readmission Ratio, as set forth in section 1886(q)(5)(C) of the Act.

*D. Rural Referral Centers (RRCs) (§ 412.96)*

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as an RRC. For discharges that occurred before October 1, 1994, RRCs received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount (as discussed in the FY 1993 IPPS final rule (59 FR 45404 through 45409)). Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, RRCs continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, "[a]ny hospital classified as an RRC by the Secretary * * * for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year." In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of "urban" and "rural" specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the

hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2012 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2012 are the median CMI values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2010 (October 1, 2009 through September 30, 2010), and include bills posted to CMS' records through December 2010.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, they must have a CMI value for FY 2010 that is at least—

- 1.5292; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table:

| Region | Case-Mix Index Value |
|---|---|
| 1. New England (CT, ME, MA, NH, RI, VT) | 1.3247 |
| 2. Middle Atlantic (PA, NJ, NY) | 1.3723 |
| 3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 1.4579 |
| 4. East North Central (IL, IN, MI, OH, WI) | 1.4624 |
| 5. East South Central (AL, KY, MS, TN) | 1.4001 |
| 6. West North Central (IA, KS, MN, MO, NE, ND, SD) | 1.4419 |
| 7. West South Central (AR, LA, OK, TX) | 1.5689 |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) | 1.6292 |
| 9. Pacific (AK, CA, HI, OR, WA) | 1.5151 |

The preceding numbers will be revised in the FY 2012 IPPS final rule to the extent required to reflect the updated FY 2010 MedPAR file, which will contain data from additional bills received through March 2011.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2009 (that is, October 1, 2008 through September 30, 2009), which are the latest cost report data available at the time this proposed rule was developed.

Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, must have, as the number of discharges for its cost reporting period that began during FY 2009, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table.

| Region | Number of Discharges |
|---|---|
| 1. New England (CT, ME, MA, NH, RI, VT) | 8,141 |
| 2. Middle Atlantic (PA, NJ, NY) | 11,919 |
| 3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 11,504 |
| 4. East North Central (IL, IN, MI, OH, WI) | 8,395 |
| 5. East South Central (AL, KY, MS, TN) | 7,337 |
| 6. West North Central (IA, KS, MN, MO, NE, ND, SD) | 8,102 |
| 7. West South Central (AR, LA, OK, TX) | 5,847 |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) | 9,608 |
| 9. Pacific (AK, CA, HI, OR, WA) | 8,900 |

These numbers will be revised in the FY 2012 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals under this proposed rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2011, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2009.

*E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)*

1. Background

Section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is "in addition to any payment calculated under this section." Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume add-on payment amount is based on all other per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For SCHs and MDHs, the low-volume add-on payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. Sections 3125 and 10314 of the Affordable Care Act amended the definition of a low-volume hospital under section 1886(d)(12)(C) of the Act. Sections 3125 and 10314 of the Affordable Care Act also revised the methodology for calculating the payment adjustment for low-volume hospitals.

Prior to the amendments made by the Affordable Care Act, section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as "a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year." Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term "discharge" means "an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A." Therefore, the term "discharge" refers to total discharges, not merely Medicare discharges. Furthermore, under section 406(a) of Public Law 108–173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that a multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the low-volume adjustment of an additional 25 percent would continue to be provided for qualifying hospitals with less than 200 discharges.

2. Temporary Changes for FYs 2011 and 2012

Section 1886(d)(12) of the Act was amended by sections 3125 and 10314 of the Affordable Care Act. The changes made by these sections of the Affordable Care Act are effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital payment adjustment and qualifying criteria, as implemented in FY 2005, will resume. Specifically, as discussed above, the provisions of the Affordable Care Act revised the definition of a low-volume hospital and also revised the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2011 and 2012.

Sections 3125(3) and 10314(1) of the Affordable Care Act amended the

qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to make it easier for hospitals to qualify for the low-volume adjustment. Specifically, the revised provision specifies that, for FYs 2011 and 2012, a hospital qualifies as a low-volume hospital if it is "more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year." In addition, section 1886(d)(12)(D) of the Act, as added by section 3125(4) and amended by section 10314 of the Affordable Care Act, provides that the payment adjustment (the applicable percentage increase) is to be determined "using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year."

Section 3125(3)(A) of the Affordable Care Act revised the distance requirement of "25 road miles" to "15 road miles" for FYs 2011 and 2012 such that a low-volume hospital is required to be only more than 15 road miles, rather than more than 25 road miles, from another subsection (d) hospital for purposes of qualifying for the low-volume payment adjustment in FYs 2011 and 2012. The mileage requirement will revert back to "more than 25 road miles" for fiscal years after FY 2012.

Sections 3125(3)(B) and 10314(1) of the Affordable Care Act revised the discharge requirement for FYs 2011 and 2012 to less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. Prior to enactment of the Affordable Care Act, under section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, the discharge requirement to qualify as a low-volume hospital is less than 800 total discharges annually, which includes discharges of both Medicare and non-Medicare patients. This discharge requirement will apply also for fiscal years after FY 2012.

Section 3125(4) of the Affordable Care Act added section 1886(d)(12)(D) to the Act, and section 10314(2) of the Affordable Care Act further modified that section of the Act. Section 1886(d)(12)(D) of the Act, as modified, revises the methodology for calculating the payment adjustment under section 1886(d)(12)(A) of the Act for low-volume hospitals for discharges occurring in FYs 2011 and 2012. For FY 2010 and prior fiscal years, and beginning again in FY 2013, sections 1886(d)(12)(A) and (B) of the Act require the Secretary to determine an applicable percentage increase for low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus requires the Secretary to develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent. Based on analyses we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102) and the FY 2006 IPPS final rule (70 FR 47432 through 47434), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. However, section 1886(d)(12)(D) of the Act, as added by the Affordable Care Act, provides that, for discharges occurring in FYs 2011 and 2012, the Secretary shall determine the applicable percentage increase using a continuous linear sliding scale ranging from an additional 25 percent payment adjustment for hospitals with 200 or fewer Medicare discharges to a 0 percent additional payment adjustment for hospitals with more than 1,600 Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275), we revised our regulations at 42 CFR 412.101 to reflect the changes to the payment adjustment for low-volume hospitals provided for by the provisions of the Affordable Care Act. We also clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year; that is, it is not based on a one-time qualification. Furthermore, we established a procedure for a hospital to request low-volume hospital status.

Specifically, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 and 50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume payment adjustment in FYs 2011 and 2012, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. We also defined, at § 412.101(a), the term "road miles" to mean "miles" as defined at § 412.92(c)(i). This change in the qualifying criteria from 25 to 15 road miles is applicable only for FYs 2011 and 2012, but the definition of "road miles" continues to apply even after the distance requirement reverts to 25 road miles beginning in FY 2013.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50239 and 50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume adjustment in FYs 2011 and 2012, a hospital must have fewer than 1,600 "Medicare discharges" during the fiscal year based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS. We also revised the regulations to specify at § 412.101(a) that the term "Medicare discharges" means a "discharge of inpatients entitled to Medicare Part A, including discharges associated with individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare and also discharges of individuals enrolled in a MA organization under Medicare Part C."

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241), we adopted a continuous linear sliding scale equation to determine the low-volume payment adjustment for FYs 2011 and 2012 for eligible low-volume hospitals with Medicare discharges of *more than 200* and *less than 1,600* (that is, from 201 to 1,599 Medicare discharges). Consistent with the statute, for FYs 2011 and 2012 for eligible low-volume hospitals with *200 or fewer* Medicare discharges, we established a low-volume payment adjustment of 25 percent.

Under the regulations at § 412.101(c)(2), for FYs 2011 and 2012, the low-volume adjustment is determined as follows:

- Low-volume hospitals with *200 or fewer* Medicare discharges will receive a low-volume adjustment of an additional 25 percent for each discharge.
- Low-volume hospitals with Medicare discharges of *more than 200* and *fewer than 1,600* will receive for each discharge a low-volume adjustment of an additional percent calculated using the formula: [(4/14) − (Medicare discharges/5600)]. For additional information on the mathematical interpretation of this formula, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241).

While we revised the qualifying criteria and the payment adjustment for low-volume hospitals for FYs 2011 and 2012, consistent with the amendments made by the Affordable Care Act, we also noted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240), that we did not modify the process for requesting and obtaining the low-volume hospital payment adjustment. In general, in order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its fiscal intermediary or MAC sufficient evidence to document that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment and, if so, the applicable add-on percentage. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria.

3. Proposed Discharge Data Source to Identify Qualifying Low-Volume Hospitals and Calculate the Payment Adjustment (Percentage Increase) for FY 2012

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, since the discharge determination is made based on the hospital's number of total discharges, the hospital's most recently submitted cost report is used to determine if the hospital meets the criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). For FYs 2011 and 2012, the hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(ii)). As also described above, the applicable low-volume percentage increase is determined using a continuous linear sliding scale equation that results in a low-volume adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a 0 percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241), we established that, for FY 2011, the low-volume payment adjustment would be determined using Medicare discharge data for FY 2009 from the March 2010 update of the MedPAR files, as these were the most recent available data. We also stated that we expected to use Medicare claims data from FY 2010 to determine the low-volume payment adjustment for FY 2012, as these would be the most recent available data at that time.

In this proposed rule, we are proposing that, for FY 2012, qualifying low-volume hospitals and their payment adjustment would be determined using Medicare discharge data from the most recent update of the FY 2010 MedPAR file, that is, the December 2010 update, as these data are the most recent data available. Furthermore, we are proposing that if more recent FY 2010 Medicare discharge data are available (such as data from the March 2011 update of the MedPAR files), we would use such data in the final rule. Table 14, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the "subsection (d)" hospitals with fewer than 1,600 Medicare discharges based on the December 2010 update of the FY 2010 MedPAR files and their proposed FY 2012 low-volume payment adjustment. Eligibility for the proposed low-volume payment adjustment for FY 2012 is also dependent upon meeting (if the hospital is qualifying for the low-volume payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011) the mileage criteria specified at § 412.101(b)(2)(ii).

We note that the list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion; that is, the hospital also must be located more than 15 road miles from any other IPPS hospital in order to qualify for a low-volume hospital payment adjustment in FY 2012.

In order to receive a low-volume hospital adjustment payment under § 412.101, a hospital must notify and provide documentation to its fiscal intermediary or MAC that it meets the mileage criterion. The use of a Web-based mapping tool, such as MapQuest, as part of documenting that the hospital meets the mileage criterion for low-volume hospitals, is acceptable. The fiscal intermediary or MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the fiscal intermediary or MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. The fiscal intermediary or MAC will refer to the hospital's Medicare discharge data determined by CMS (as proposed for FY 2012 as shown in Table 14, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet), to determine whether or not the hospital meets the discharge criterion, and the amount of the payment adjustment, once it is determined that both the mileage and discharge criteria are met. The Medicare discharge data shown in Table 14, as well as the Medicare discharge data for all "subsection (d)" hospitals with claims in the December 2010 update of the FY 2010 MedPAR files, also will be available on the CMS Web site for hospitals to check their Medicare discharges to help them to decide whether or not to apply for low-volume hospital status.

Similar to the policy we established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20574 through 20575), we are proposing that, for FY 2012, a hospital make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2011, so that the applicable low-volume percentage add-on would be applied to payments for its discharges beginning on or after October 1, 2011. For FY 2012, we are proposing that a hospital which qualified for the low-volume payment adjustment in FY 2011 may continue to receive a low-volume payment adjustment in FY 2012, without reapplying, if it continues to meet the Medicare discharge criterion, based on the latest available FY 2010 MedPAR data (as proposed above) and the distance criterion. However, the hospital would be required to verify in writing to its fiscal intermediary or MAC that it continues to be more than 15 miles from any other "subsection (d)" hospital no later than September 30, 2011. Further, similar to the policy we established for FY 2011 (Transmittal 2060, Change Request 7134; October 1, 2010), we are proposing that, for requests for low-volume hospital status for FY 2012 received after September 1, 2011, if the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC would apply the applicable low-volume adjustment in determining payments to the hospital's FY 2012 discharges prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

*F. Indirect Medical Education (IME) Adjustment (§ 412.105)*

1. Background

Section 1886(d)(5)(B) of the Act provides for an additional payment amount under the IPPS for hospitals that have residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105.

Public Law 105–33 (BBA 1987) established a limit on the number of allopathic and osteopathic residents that a hospital may include in its full-time equivalent (FTE) resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit on the FTE resident count for IME purposes is effective for discharges occurring on or after October 1, 1997. Changes to the policies regarding counting residents for both IME and direct GME payment purposes as a result of the implementation of sections 5503 through 5506 of the Affordable Care Act were issued in a final rule published in the **Federal Register** on November 24, 2010 (75 FR 72133).

2. IME Adjustment Factor for FY 2012

The IME adjustment to the MS–DRG payment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated by using a hospital's ratio of residents to beds, which is represented as *r,* and a formula multiplier, which is represented as *c,* in the following equation: $c \times [\{1 + r\}^{.405} - 1]$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Public Law 108–173 modified the formula multiplier *(c)* to be used in the calculation of the IME adjustment. Prior to the enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. In the FY 2005 IPPS final rule, we announced the schedule of formula multipliers to be used in the calculation of the IME adjustment and incorporated the schedule in our regulations at § 412.105(d)(3)(viii) through (d)(3)(xii). Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2012, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2012 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

*G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)*

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the "Pickle method."

The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction." The Medicare fraction (also known as the "SSI fraction" or "SSI ratio") is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan) and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan). The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to "days" apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

In section IV.G.2. of this preamble, we are combining our discussion of proposed changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) and for counting patient days for purposes of the DSH payment adjustment at § 412.106(a)(1)(ii).

2. Proposed Policy Change Relating to the Exclusion of Hospice Beds and Patient Days From the Medicare DSH Calculation

a. Background

As discussed in the FY 2004 IPPS final rule (68 FR 45415 through 45420), when determining a hospital's Medicare DSH payment, our policy is to include patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost report. Under this policy, CMS uses the level of care generally provided in such a unit or ward as a proxy for determining the level of care provided to a particular

patient on a particular day within that unit. As stated in the FY 2004 IPPS final rule, our policy is "not intended to focus on the level or type of care provided to individual patients in a unit, but rather on the level and type of care provided in the unit as a whole." (68 FR 45417) In the FY 2005 IPPS final rule, we amended this policy to specifically exclude observation and swing days from the patient day count. In this proposed rule, we are proposing to establish an additional exclusion with respect to counting bed days and patient days for patients receiving hospice services in an inpatient setting of a hospital.

b. Hospice Inpatient Services

Section 1861(dd)(1) of the Act defines hospice care to include a limited set of "items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director." Among those items and services specified under section 1861(dd)(1)(G) of the Act is "short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days." Based on these statutory definitions of hospice care, the Secretary, through regulation at § 418.302, has grouped hospice care services into four categories for payment purposes. Two of these payment categories describe hospice services in an inpatient setting: inpatient respite care day and general inpatient care day.

Section 418.302(b)(3) of the regulations defines an inpatient respite care day as "a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite." Section 40.2.2 of Chapter 9 of the Medicare Benefit Policy Manual (*https://www.cms.gov/manuals/Downloads/bp102c09.pdf*) further describes an inpatient respite care day as a short-term inpatient day provided only when necessary to relieve family members or other caregivers caring for the individual at home. Under the Act, inpatient respite care is limited to 5 consecutive days for a given stay. Similarly, the regulations at § 418.302(b)(4) describe a general inpatient care day as "a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings."

Section 40.1.5 of Chapter 9 of the Medicare Benefit Policy Manual provides that general inpatient care is appropriate when care for pain control or acute or chronic symptom management cannot feasibly be provided in another setting. This section of the Medicare Benefit Policy Manual further states that such care is "not equivalent to a hospital level of care." That hospice care is not hospital level care is further supported by the provision at § 418.202(e), which provides that general inpatient care and inpatient respite care hospice services can be "provided in a participating hospice inpatient unit, or a participating hospital or [skilled nursing facility], that additionally meets the standards in § 418.202(a) and (e) regarding staffing and patient areas * * * [and] must conform to the [hospice provider's] written plan of care."

Furthermore, hospice services provided in an inpatient hospital setting are not payable under the IPPS. Rather, at this time, these services are payable under two of the four prospectively determined all-inclusive categories of care under the hospice payment system. In the FY 2004 IPPS final rule (68 FR 45418), we stated that we believed it "reasonable to interpret the phrase 'hospital's patient days,' to mean only the hospital's inpatient days at a level of care that would be covered under the IPPS as a means to determine an IPPS payment adjustment." In that rule, we acknowledged that it would be "administratively inefficient and impracticable" to calculate a hospital' inpatient days based on a determination of whether a particular patient in a particular inpatient bed for a particular stay is receiving a level of care that would be covered under the IPPS (68 FR 45418). Accordingly, we adopted a policy under which we use the level of care that is generally provided in particular units or wards as a proxy for determining whether the care provided to a particular patient is of a type that would be covered under the IPPS. However, we have recognized exceptions to this policy for certain categories of nonacute care, even if that care is provided in an acute care unit.

Therefore, we are proposing to revise § 412.106(a)(1)(ii) to exclude patient days associated with hospice patients receiving inpatient hospice services in an inpatient hospital setting from the Medicare and Medicaid fractions of the DPP. We also are proposing to amend our cost reporting instructions accordingly. Our proposal to exclude hospice inpatient days is analogous to our decision in the FY 2005 IPPS final rule to exclude observation and swing-bed days from the Medicare and Medicaid fractions of the DPP. In that rule, we stated that our policies to exclude observation days and swing-bed days from the count of patient days "stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not payable under the IPPS * * *" (69 FR 49097). Similarly, our proposal to exclude inpatient hospice days stems from the fact that these days are not acute care services generally payable under the IPPS.

We note that, on rare occasions, patients receiving care under a third payment category, routine home care, may also receive services in an inpatient hospital setting. Unlike inpatient respite care or general inpatient services, routine home care services are not intended to be provided in a hospital setting. For the same reasons stated above, such days should also be excluded from the Medicare and Medicaid fractions of the DPP.

We also are proposing to exclude from the hospital's bed count days associated with hospice patients who receive inpatient hospice services in the hospital for purposes of both the IME payment adjustment and the DSH payment adjustment. The rules for counting hospital beds for the purposes of the IME adjustment are codified in the IME regulations at § 412.105(b), which is cross-referenced in § 412.106(a)(1)(i) for purposes of the DSH payment adjustment. Our bed counting policy is to include bed days available for IPPS-level acute care hospital services. Inpatient hospice services provided in an acute unit or ward are occasional, alternative uses of acute inpatient beds that would otherwise be considered available for IPPS-level acute care hospital services (as long as other criteria for a bed to be considered as an available bed are met under § 412.105(b)). A bed used for inpatient hospice services on a given day is not available to be used for IPPS-level services. Therefore, we are proposing to revise § 412.105(b)(4) to state that such hospice days are excluded from the counts of available beds for purposes of the IME payment adjustment. Because the same rules govern the counting of available beds for purposes of the DSH payment

adjustment under § 412.106(a)(1)(i), hospice days will also be excluded from the count of available beds for purposes of the DSH payment adjustment.

We note that there is a circumstance in which a hospital will provide IPPS-level acute care hospital services to a hospice patient for which it would receive payment under the IPPS. This occurs when a Medicare beneficiary receiving hospice care under his or her hospice benefit requires acute care hospital services to treat a condition unrelated to his or her hospice plan of care. For example, an individual who has elected the hospice benefit could be treated in the inpatient hospital setting for a broken bone that is unrelated to his or her terminal illness. Under these circumstances, the patient is receiving acute care hospital services of the sort payable under the IPPS. As such, consistent with § 412.106(a)(ii), we are not proposing to exclude these patient days from the Medicare and Medicaid fractions of the DPP or from the count of available beds under § 412.105(b)(4) and § 412.106(a)(1)(i).

We further note that hospitals may have hospice units that are separate and distinct from their acute care inpatient units. Under existing regulations at § 412.105(b)(3) and § 412.106(a)(ii)(A), services provided in distinct nonacute inpatient units are excluded from the patient day and bed day count. Our proposal with respect to inpatient hospice services does not change or affect this policy.

In summary, we are proposing to exclude inpatient hospice days from the patient day count in § 412.106(a)(1)(ii) (for DSH) and the bed day count at § 412.105(b) (for IME) and at § 412.106(a)(1)(i) (for DSH).

### *H. Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)*

#### 1. Background

Under the IPPS, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH). MDHs are paid based on the higher of the Federal rate for their hospital inpatient services or a blended rate based in part on the Federal rate and in part on the MDH's hospital-specific rate. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in two of its most recent three settled Medicare cost reporting years). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

Although MDHs are paid under an adjusted payment methodology, they are still IPPS hospitals paid under section 1886(d) of the Act. Like all IPPS hospitals paid under section 1886(d) of the Act, MDHs are paid for their discharges based on the DRG weights calculated under section 1886(d)(4) of the Act.

Through and including FY 2006, under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on the hospital's FY 1982 or FY 1987 costs per discharge, whichever of these hospital-specific rates is higher. Section 5003(b) of Public Law 109–171 (DRA 2005) amended section 1886(d)(5)(G) of the Act to provide that, for discharges occurring on or after October 1, 2006, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever of these hospital-specific rates is highest.

For each cost reporting period, the fiscal intermediary or MAC determines which of the payment options will yield the highest aggregate payment. Interim payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary or MAC makes the determination. However, it may not be possible for the fiscal intermediary or MAC to determine in advance precisely which of the rates will yield the highest aggregate payment by year's end. In many instances, it is not possible to accurately forecast the outlier payments, the amount of the DSH adjustment or the IME adjustment, all of which are applicable only to payments based on the Federal rate and not to payments based on the hospital-specific rate. The fiscal intermediary or MAC makes a final adjustment at the settlement of the cost report after it determines precisely which of the payment rates would yield the highest aggregate payment to the hospital.

If a hospital disagrees with the fiscal intermediary's or the MAC's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the determination in accordance with the procedures set forth in 42 CFR Part 405, Subpart R, which govern provider payment determinations and appeals.

#### 2. Extension of the MDH Program

As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50286 and 50287), section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking "October 1, 2011" and inserting "October 1, 2012". Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. We are not proposing any additional changes to this regulatory text for FY 2012.

### *I. Certified Registered Nurse Anesthetist (CRNA) Services Furnished in Rural Hospitals and CAHs (§ 412.113)*

Section 2312 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) provided for reimbursement to hospitals on a reasonable cost basis for the costs that hospitals incur in connection with the services of certified registered nurse anesthetists (CRNAs). Section 2312(c) provided that pass-through payment of CRNA costs was effective for cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987. Section 9320 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (which established a fee schedule for the services of nurse anesthetists) amended section 2312(c) of Public Law 98–369 by extending the CRNA pass-through provision through cost reporting periods beginning before January 1, 1989. In addition, Public Law 99–509 amended section 1861 of the Act to add a new subsection (bb), which provides that CRNA services include anesthesia services and related care furnished by a CRNA. Section 608 of the Family Support Act of 1988 (Pub. L.

100–485) extended pass-through payments for CRNA services through 1991 and amended section 9320 of Public Law 99–509 by including language referring to eligibility for pass-through payments for CRNA services if the facility is "* * *a hospital located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act)." Reasonable cost-based payment for CRNA services was extended indefinitely by section 6132 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239).

Section 1886(d) of the Act defines "rural" as any area outside an urban area. This definition of "rural" was in effect when Public Law 100–485 was implemented. In 1999, the Balanced Budget Refinement Act (Pub. L. 106–113) amended section 1886(d)(8) of the Act by adding a new subparagraph (E), which permits a hospital physically located in an urban area to apply for reclassification to be treated as rural. In addition, Public Law 106–113 made a corresponding change to section 1820(c)(2)(B)(i) of the Act, which specifies the rural location requirement for CAH designation, by adding the phrase "or is treated as being located in a rural area pursuant to section 1886(d)(8)(E)."

The regulations implementing pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists employed by a hospital or CAH, including CRNAs, are located at § 412.113(c). In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24010), we proposed to revise § 412.113(c)(2)(i)(A) to state that, effective for cost reporting periods beginning on or after October 1, 2010, CAHs and hospitals that have reclassified pursuant to section 1886(d)(8)(E) of the Act and § 412.103 of the regulations also are rural for purposes of section 1886(d) of the Act and, therefore, are eligible to be paid based on reasonable cost for anesthesia services and related care furnished by a qualified nonphysician anesthetist.

After consideration of the public comments, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303), we adopted a policy that would allow otherwise eligible critical access hospitals (CAHs) or hospitals, that have reclassified from urban to rural status under section 1886(d)(8)(E) of the Act and 42 CFR 412.103, to receive reasonable cost payments for anesthesia services and related care furnished by qualified nonphysician anesthetists (also referred to in this section as CRNA pass-through payments), effective for cost reporting periods beginning on or after October 1, 2010. After the issuance of the final rule, we received an inquiry from a public commenter who indicated that CMS had misunderstood its submitted comment on the FY 2011 IPPS/LTCH PPS proposed rule in which the commenter stated that the policy should be effective on the basis of a calendar year, not a cost reporting period, since as a rule a hospital can only begin receiving CRNA pass-through payments at the beginning of a calendar year. Our response to this public comment in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303) indicated that it was unnecessary to modify the effective date in the final rule because "if the provision is effective for cost reporting periods beginning on or after October 1, 2010, it will also be in effect for the calendar year beginning January 1, 2011." While this statement was accurate, it did not take into account that if a hospital's cost reporting period begins on or after January 1, 2011, the hospital would be ineligible to receive CRNA pass-through payments until the beginning of the next calendar year, on January 1, 2012. Under the finalized policy in the FY 2011 IPPS/LTCH PPS final rule, hospitals reclassifying from urban to rural areas with cost reporting periods beginning between October 1, 2010, and December 31, 2010, would be able to first receive CRNA pass-through payments effective January 1, 2011, while hospitals with cost reporting periods beginning on or after January 1, 2011, would not be able to receive CRNA pass-through payments until one year later on January 1, 2012.

In an interim final rule with comment period included in the **Federal Register** on November 24, 2010 (75 FR 72256), we stated that our intention in the FY 2011 IPPS/LTCH PPS final rule was not to make the provision for CRNA pass-through payment for anesthesia services and related care furnished by nonphysician anesthetists effective January 1, 2011, for some hospitals and CAHs and January 1, 2012, for other hospitals and CAHs. We stated our belief that the provision would be more equitable if it had a uniform effective date for all eligible hospitals and CAHs. While we considered changing the effective date to January 1, 2011, for all hospitals and CAHs to begin receiving CRNA pass-through payments under this provision, we noted that our regulations at 42 CFR 412.113(c)(2)(iii) state that the hospital or CAH must demonstrate to its fiscal intermediary prior to the start of the calendar year that it meets the requirements for receiving CRNA pass-through payments. For this reason, we stated our belief that the best option was to adopt an effective date of December 2, 2010, for all hospitals and CAHs, which we provided for in the interim final rule with comment period. With an effective date of December 2, 2010, all hospitals and CAHs regardless of their specific fiscal year beginning date were provided the opportunity to demonstrate prior to January 1, 2011, that they met the requirements for receiving CRNA pass-through payments beginning January 1, 2011. In the interim final rule with comment period, we amended the regulations at § 412.113(c)(2)(i)(A) to provide for an effective date of December 2, 2010, for all eligible hospitals and CAHs to receive CRNA pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists.

We intend to respond to public comments received on the interim final rule with comment period and will adopt our final policy in the FY 2012 IPPS/LTCH PPS final rule.

### *J. Additional Payments for Qualifying Hospitals With Lowest per Enrollee Medicare Spending*

#### 1. Background

Section 1109 of the Affordable Care Act requires additional payments for FYs 2011 and 2012 for "qualifying hospitals." Section 1109(d) defines a "qualifying hospital" as a "subsection (d) hospital * * * that is located in a county that ranks, based upon its ranking in age, sex and race adjusted spending for benefits under parts A and B * * * per enrollee within the lowest quartile of such counties in the United States." Therefore, a "qualifying hospital" is one that meets the following conditions: (1) It is a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act; and (2) it is located in a county that ranks within the lowest quartile of counties based upon its spending for benefits under Medicare Part A and Part B per enrollee adjusted for age, sex, and race. Section 1109(b) of the Affordable Care Act makes available $400 million to qualifying hospitals for FY 2011 and FY 2012. Section 1109(c) of the Affordable Care Act requires the $400 million to be divided among each qualifying hospital in proportion to the ratio of the individual qualifying hospital's FY 2009 IPPS operating hospital payments to the sum of total FY 2009 IPPS operating hospital payments made to all qualifying hospitals.

Section 1109 is one of several provisions in the Affordable Care Act that addresses concerns about how Medicare makes adjustments for geographic differences in the cost of

providing services and geographic variation in the volume and intensity of health care spending. Some other provisions in the Affordable Care Act that relate to concerns about geographic variation in Medicare payments include:

- Section 3102(a), which provides a floor of 1.0 on the physician fee schedule work geographic practice cost index (GPCI) through the end of CY 2010 (later extended by the Medicare and Medicaid Extension Act of 2010 through the end of CY 2011);
- Section 3102(b), as amended by section 1108 of the Affordable Care Act, which requires that only one-half of the relative cost differences in employee wages and office rents be reflected in the practice expense GPCIs in 2010 and 2011;
- Section 10324, which provides for a floor on the wage index and the practice expense GPCI in frontier States (defined as 50 percent or more of the counties in the State having a population density of less than six people per square mile).

These provisions provide temporary adjustments in payments while other initiatives are underway to evaluate geographic adjustment factors that are used in Medicare's payment systems. For instance, section 3101 of the Affordable Care Act requires the Secretary, not later than January 1, 2012, to make appropriate adjustments to the practice expense GPCI considering alternative data sources such as the American Community Survey for the nonphysician employee portion of the GPCI. Section 3137 of the Affordable Care Act requires the Secretary to submit to Congress a report that includes a plan to reform the hospital wage index system under section 1886 of the Act by December 31, 2011. In addition to these provisions, the Secretary has contracted with the Institute of Medicine (IOM) to study the hospital wage index and the physician fee schedule GPCI. The IOM's first report to CMS is due in May 2011 and will provide an evaluation and assessment of:

(1) The empirical validity of the adjustment factors (the hospital wage index and physician fee schedule GPCI);

(2) The methodology used to determine the adjustment factors;

(3) Measures used for the adjustment factors, taking into account—

- Timeliness of data and frequency of revisions to such data;
- Sources of data and the degree to which such data are representative of costs; and
- Operational costs of providers who participate in Medicare.

The report will include recommendations for the Secretary to consider. We are looking forward to receiving IOM's report and acting expeditiously on its recommendations to improve Medicare's payment systems and better adjust for geographic differences in the cost of hospital labor as well as the cost of operating a physician practice.

2. Methodology for Identifying Qualifying Hospitals and Eligible Counties

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 50342), we finalized our methodology for distributing the $400 million to qualifying hospitals located in the lowest quartile of counties in per enrollee Medicare spending. First, we provided our methodology for determining the bottom quartile of counties with the lowest Medicare Part A and Part B spending adjusted by age, sex, and race for the purpose of disbursing the available $400 million. We developed an adjustment model by age, sex, and race, as required under the provisions of section 1109. We then applied this adjustment to the county Medicare Part A and Part B spending data to account for the demographics of the Medicare beneficiaries in those counties. After those adjustments were applied, we determined the Medicare Part A and Part B spending by county per enrollee. As we explained in the final rule, our methodology for determining the Medicare Part A and Part B spending per enrollee by county adjusted for age, sex, and race is similar to the methodology we use to calculate risk adjustment models for Medicare Advantage (MA) ratesetting. For more information on the methodology we used to calculate the county Medicare per enrollee spending rates, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 75 FR 50307).

In addition, in the FY 2011 IPPS/LTCH PPS final rule, we developed a methodology to identify the qualifying hospitals located in each of the eligible counties. As we stated earlier, section 1109 defines a qualifying hospital is a "subsection (d) hospital" (as defined for purposes of section 1886(d) of the Act) that is "located in" an eligible county. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a "hospital located in one of the 50 States or the District of Columbia." Therefore, we excluded Puerto Rico hospitals and CAHs from the provisions of section 1109 because they do not meet the definition of a "subsection (d) hospital."

In the FY 2011 IPPS/LTCH PPS final rule, we identified "qualifying hospitals" based on their Medicare provider number (now referred to as the "CMS certification number" (CCN)) because this number is used by hospitals to identify themselves on their Medicare cost reports. We also provided that, in order to meet the definition of a "qualifying hospital," the hospital, as identified by its CCN, must: (1) Have existed as a subsection (d) hospital as of April 1, 2010; (2) be geographically located in an eligible county; and (3) have received IPPS operating payments (in accordance with section 1886(d)) of the Act) under its CCN in FY 2009. We used the Online Survey, Certification and Reporting (OSCAR) database to determine a hospital's county location associated with that CCN. We also specified that the address listed for a hospital's CCN must be currently located in a qualifying county in order for a hospital to meet the definition of a "qualifying hospital." For more information on how we identified the qualifying hospitals, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50307 and 50308). We note that we are proposing to clarify the application of our definition in section IV.J.4. of this preamble.

3. Determination of Annual Payment Amounts

The third step in the implementation of section 1109 of the Affordable Care Act required that we determine the payment amount that each qualifying hospital would receive. Specifically, section 1109(c) of the Affordable Care Act required that the payment amount for a qualifying hospital be determined "in proportion to the portion of the amount of the aggregate payments under section 1886(d) of the Social Security Act to the hospital for fiscal year 2009 bears to the sum of all such payments to all qualifying hospitals for such fiscal year." As specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50310 through 50312), we determined that a qualifying hospital's payment amount will be based on the proportion of its IPPS operating payments made in FY 2009 under section 1886(d) of the Act relative to the total IPPS operating payments made to all qualifying hospitals in FY 2009 under section 1886(d) of the Act. The FY 2009 IPPS operating payments made under section 1886(d) of the Act includes DRG and wage-adjusted payments made under the IPPS standardized amount with add-on payments for operating DSH, operating IME, operating outliers, and new technology (collectively referred to in this preamble as the IPPS operating payment amount). We used the March 2010 update of the FY 2009 MedPAR

hospital inpatient claims data to determine the IPPS operating payment amounts for each qualifying hospital in order to calculate the proportion of money that each qualifying hospital would receive under this provision. For more information on the methodology we used to calculate the payment determinations, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 30310 through 75 FR 50312).

4. Eligible Counties and Qualifying Hospitals

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50312 through 50342), we published the list of eligible counties, that is, the lowest quartile of counties with Medicare Part A and Part B spending per enrollee adjusted for age, sex, and race, the qualifying hospitals located in those counties, and the qualifying hospitals' payment weighting factors, for purposes of making payments under section 1109 for FY 2011 and FY 2012. We identified 3,142 counties in the United States. Therefore, there are 786 eligible counties (rounded from 785.5 eligible counties). Of those 786 eligible counties, there are only 273 counties in which qualifying hospitals are located, using the methodology that we finalized in the FY 2011 IPPS/LTCH PPS final rule. Using CCNs, we identified 416 IPPS hospitals that are currently located in those eligible counties and that received IPPS operating payments in FY 2009.

In response to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, in the FY 2011 IPPS/LTCH PPS final rule, we corrected the list of eligible counties by replacing two counties on our list of eligible counties (adding Crooks County, OR and Bottineu County, ND). However, we did not identify any qualifying hospitals located in those two eligible counties. Therefore, we provided the public an opportunity to notify CMS by August 30, 2010, if there were any qualifying IPPS hospitals located in either of the two newly added counties. We stated that if we added qualifying hospitals in these counties as a result of accurate notification from the public, we would publish a revised list of qualifying hospitals and their payment weighting factors on the CMS Web site after August 30, 2010. We did not receive any public comments that there were qualifying hospitals located in Crooks County, OR or Bottineu County, ND. Therefore, the list of eligible counties and qualifying hospitals that was finalized in Tables 1 and 2 in the FY 2011 IPPS/LTCH PPS final rule remained valid for distribution of payments under section 1109 for FY 2011 and FY 2012.

In auditing our determination of qualifying hospitals prior to the distribution of payments for FY 2011, we found that the following providers on the list of qualifying hospitals which we finalized in the FY 2011 IPPS/LTCH PPS final rule were not subsection (d) hospitals in FY 2011:

| CMS Certification Number | Provider Name |
|---|---|
| 110231 | Landmark Hospital of Athens LLC |
| 130024 | Bonner General Hospital |
| 130069 | SW Idaho Advanced Care |
| 130070 | Complex Care Hospital of Idaho |
| 160156 | Continuing Care Hospital at St. Luke's |
| 250112 | Calhoun Health Services |
| 260221 | Select Specialty Hospital - Springfield Inc. |
| 270002 | Holy Rosary Healthcare |
| 320088 | Advanced Care of South New Mexico |
| 330010 | Amsterdam Memorial Hospital |
| 500143 | Providence St. Peter Chemical Dependency Center |

Because these providers were not subsection (d) hospitals in FY 2011, the statute precludes them from being qualifying hospitals eligible to receive section 1109 payments for FY 2011. We are proposing to clarify in this proposed rule that, in applying our definition of qualifying hospitals for making payments under section 1109 of the Affordable Care Act, these 11 providers (and other providers that do not meet the statutory definition) are not qualifying hospitals and, therefore, should be removed from the list of qualifying hospitals. Furthermore, we are proposing to clarify that, in order to meet the definition of "qualifying hospital" under section 1109 for FY 2012, a hospital that is on the list of qualifying hospitals in this proposed rule must meet the statutory criteria of a "qualifying hospital" for some portion of FY 2012 (a hospital must be a subsection (d) hospital for some part of FY 2012).

In addition, we note that, prior to the issuance of the FY 2012 final rule and prior to making section 1109 payments for FY 2012, we intend to review providers' status vis-à-vis the statutory definition of qualifying hospital. Accordingly, we note that, in the FY 2012 final rule and again prior to distribution of section 1109 payments for FY 2012, we will update the list of qualifying hospitals and payment weighting factors based on these findings. In addition to the opportunity to submit comments on this proposed rule, we are proposing to provide hospitals an opportunity after the FY 2012 IPPS rulemaking cycle to notify CMS whether any qualifying hospitals removed from the list have been removed in error and to notify CMS if a hospital is on the list of qualifying hospitals and will not be a qualifying hospital (for example, a subsection (d) hospital) for any or all part of FY 2012. The public may submit input on these two topics via e-mail to Nisha Bhat, *nisha.bhat@cms.hhs.gov.* All information, including relevant

documentation, must be received by November 1, 2011.

5. Payment Determinations and Distributions for FY 2011 and FY 2012

Under section 1109(b) of the Affordable Care Act, the total pool of payments available to qualifying hospitals for FY 2011 and FY 2012 is $400 million. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50308 through 50310), we stated that we would distribute $150 million for FY 2011 and $250 million for FY 2012. We stated that we would distribute payments to the qualifying hospitals through an annual one-time payment during each of FY 2011 and FY 2012 through their Medicare contractor (fiscal intermediary or MAC). We instructed qualifying hospitals to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period that the hospitals receive the payments and that hospitals should report these payments on the "Other adjustment" line on Worksheet E, Part A of the Medicare hospital cost report Form 2552. We noted that we require these payments to be reported on the cost report for tracking purposes only and that these additional payments will not be adjusted or settled by the fiscal intermediary or MAC on the cost report.

At the time of the issuance of this FY 2012 proposed rule, we have not yet made the payments to the qualifying hospitals for FY 2011. As we stated in the FY 2011 IPPS/LTCH PPS final rule, we will make the FY 2011 payments during FY 2011 (that is, by September 30, 2011). However, in this proposed rule, we are notifying the public that we intend to change the method we will use to distribute the payment for FY 2011 and FY 2012, in order to ease the reporting burden on hospitals. Rather than making a one-time annual payment to the qualifying hospitals through their Medicare contractor using the Medicare cost report, we plan to make payments to the qualifying hospitals through a one-time annual payment made by one Medicare contractor who would directly pay all of the qualifying hospitals. We will send each qualifying hospital a letter stating the specifics of how the hospital will receive its payments. Because these one-time annual payments would be made through a special process outside of the scope of normal payments by their Medicare contractor, the hospitals' Medicare contractor would no longer need to track the payment amounts made to the hospitals under this provision. We believe this will simplify and expedite the payment process so that one Medicare contractor is responsible for overseeing the distribution of payments. In addition, this simplified process will ease the administrative burden within CMS to track that payments have been properly made to the qualifying hospitals. In addition, the burden to hospitals is reduced because hospitals would no longer have to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period for which the hospitals receive payments in FY 2011 or FY 2012 (as we instructed in the FY 2011 IPPS/LTCH PPS final rule and note above).

In the FY 2011 IPPS/LTCH PPS final rule, we also stated that we would make only one determination of eligible counties and qualifying hospitals for FY 2011 and FY 2012, with the caveat that we would accept additional public input on the limited issue of whether there are any qualifying hospitals in the two newly identified eligible counties. As we stated earlier, we did not receive any public input on qualifying hospitals for the two newly identified eligible counties. However, as we describe above, 11 hospitals that were included on the list of qualifying hospitals do not meet the statutory criteria in section 1109 of the Affordable Care Act. Therefore, we are proposing to revise our list of qualifying hospitals and their payment weighting factors finalized in the FY 2011 IPPS/LTCH PPS final rule to exclude these 11 providers. As explained in the FY 2011 IPPS/LTCH PPS final rule, we finalized in that rule (to the best of our ability) the list of eligible counties and qualifying hospitals once for ease of implementation of the section 1109 provision and to allow hospitals to plan their budgets accordingly. The proposed revision of our determination to exclude these 11 providers will result in changes to the payment weighting factors. We are proposing to update the payment weighting factors accordingly. Therefore, we are proposing to distribute the remaining $250 million in FY 2012 to those qualifying hospitals proposed in this proposed rule based on payment weighting factors proposed in this proposed rule. In addition, in order to distribute the section 1109 payments for FY 2011 in as timely a manner as possible, we intend to make preliminary section 1109 payments for FY 2011 using this proposed list of qualifying providers and payment weighting factors using the payment method described above. If additional hospitals are deleted from the proposed list of qualifying hospitals for FY 2011 because they do not meet the statutory criteria, the payment weighting factors would need additional revision. If this situation occurs, we are proposing to further amend the payment weighting factors for payments to be made in FY 2012 so that each qualifying hospital receives its appropriate share of the total $400 million.

We refer readers to the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/TopOfPage* for the tables listed below. The tables are included collectively as the "Section 1109 Files" for the FY 2012 IPPS/LTCH proposed rule.

- The final list of eligible counties that was published in the FY 2011 IPPS/LTCH PPS final rule. We note that we are not updating this table.
- The proposed list of qualifying hospitals, location, and payment weighting factors (based on the March 2010 update of the FY 2009 MedPAR); based on the clarifications proposed above.
- The distribution of the $400 million for FY 2011 and FY 2012 by State based on the proposed list of qualifying hospitals, location, and payment weighting factors.

We note that the Web address for this Web site is effective as of the date of publication of this proposed rule and that, in the future, these tables may be archived to the Web site at: *http://www.cms.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

*K. Proposed Changes in the Inpatient Hospital Update*

1. FY 2012 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient operating costs by a factor called the "applicable percentage increase." Prior to enactment of the Affordable Care Act, section 1886(b)(3)(B)(i)(XX) of the Act set the applicable percentage increase equal to the rate-of-increase in the hospital market basket for subsection (d) hospitals (hereafter referred to as "IPPS hospitals") in all areas, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that did not provide these data, the update was equal to the market basket percentage increase less an additional 2.0 percentage points. The update for the hospital-specific rates for SCHs and MDHs is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

As discussed below in section IV.K.3. of this preamble, section 1886(b)(3)(B)

of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2012 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is currently based on the first quarter 2011 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing an MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated as described below in section IV.K.3. of this preamble, based on IHS Global Insight, Inc.'s (IGI's) first quarter 2011 forecast.

Consistent with current law, and based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with our rules. For hospitals that do not submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law. Specifically, in accordance with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to add a new paragraph (iv) to § 412.64(d)(1) to set the applicable percentage increase to the FY 2012 operating standardized amount as the percentage increase in the market basket index, subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to a multifactor productivity adjustment and, lastly, subject to the additional reduction of 0.1 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an update to the hospital-specific rates applicable to SCHs and MDHs of 1.5 percent for hospitals that submit quality data or −0.5 percent for hospitals that fail to submit quality data. For FY 2012, the regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e), 412.78(e), and 412.79(d) already contain provisions that set the update factor for SCHs and MDHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make further changes to these five regulatory provisions to reflect the FY 2012 update factor for SCHs and MDHs.

2. FY 2012 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.5 percent. For FY 2012, under the authority of section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, we are proposing to revise the existing regulations at § 412.211(c) to set the update factor for the Puerto Rico-specific operating standardized amount equal to the update factor applied to the national standardized amount for all IPPS hospitals.

3. Productivity Adjustment

Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to require certain adjustments to the "applicable percentage increase" to the operating IPPS. One such change is to require that, in FY 2012 (and in subsequent fiscal years), the applicable percentage increase be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at: *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

The projection of MFP is currently produced by IHS Global Insight, Inc. (IGI), an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from its U.S. macroeconomic models. These models take into account a broad range of factors that influence the total U.S.

economy. IGI forecasts the underlying proxy components such as Gross Domestic Product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology. In Table IV.K.1 below, we identify each of the major MFP component series employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined by IGI and CMS to be the best available proxies for the BLS series.

**TABLE IV.K.1.—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT**

| BLS Series | IGI Series |
|---|---|
| Real value-added output, constant 2005 dollars | Nonhousing, nongovernment, nonfarm real GDP, Billions of chained 2005 dollars – annual rate |
| Private nonfarm business sector labor input; 2005=100.00 | Hours of all persons in private non-farm establishments, 2005=100.00, adjusted for labor composition effects |
| Aggregate capital inputs; 2005=100.00 | Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars |

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and, therefore, suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, we refer readers to the BLS Web site at: *http://www.bls.gov/mfp/mprtech.pdf.*

At the time of the development of this proposed rule, the BLS had published a historical time series of private nonfarm business MFP for 1987 through 2009, with 2009 being a preliminary value. Using this historical MFP series and the IGI forecasted series, the IGI had developed a forecast of MFP for 2010 through 2021, as described below.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the "non-housing, non-government, nonfarm, real GDP," "hours of all persons in private non-farm establishments adjusted for labor composition," and "real effective capital stock" series (ranging from 2010 to 2021) are used to "grow" the levels of the "real value-added output," "private nonfarm business sector labor input," and "aggregate capital input" series published by the BLS. Projections of the "hours of all persons" measure are calculated using the difference between projections of the BLS index of output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval.

Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the "nongovernment total compensation" and "flow of capital services from the total private nonresidential capital stock" series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth are subtracted from total output growth to calculate the "change in the growth rates of multifactor productivity":

*MFP = Total output growth—(labor input growth * labor compensation share) + (capital input growth * capital income share))*

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS' methodology. For benchmarking purposes, the historical growth rates of IGI's proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series and, therefore, validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

As described in section I. of the Addendum to this proposed rule, we are proposing to determine the IPPS market

basket percentage increase for FY 2012, which is used to determine the FY 2012 applicable percentage increase, based on the FY 2006-based IPPS market basket. The FY 2006-based IPPS market basket was finalized and adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43843). Section 3401(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act in part by adding a new clause (xi) which requires that, after determining the applicable percentage increase for a fiscal year, "such percentage increase shall be reduced by the productivity adjustment described in subclause (II)" (which we refer to as the "MFP adjustment"). Section 1886(b)(3)(B)(i)(XX) of the Act establishes the applicable percentage increase for FY 2007 and each subsequent fiscal year as equal to the rate-of-increase (that is, the percentage increase) in the hospital market basket for IPPS hospitals, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and to other statutory adjustments, including the productivity adjustment.

We are proposing that the MFP adjustment be subtracted from the FY 2012 operating applicable percentage increase. We are proposing that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate FY update period. Because the applicable percentage increase is reduced by the MFP adjustment, we believe it is appropriate for the numbers associated with both components of the calculation (the underlying market basket percentage increase used to determine the applicable percentage increase and the productivity adjustment) to line up so that changes in market conditions are aligned. Therefore, for the FY 2012 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2012. We are proposing to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we would round the number up; if the number we are rounding is followed by 0, 1, 2, 3, or 4, we would round the number down).

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to base the FY 2012 market basket update used to determine the applicable percentage increase for the IPPS on the first quarter 2011 forecast of the FY 2006-based IPPS market basket, which is estimated to be 2.8 percent. This percentage increase, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, is then reduced by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated as described above and based on IGI's first quarter 2011 forecast. We are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the final rule. Following application of the productivity adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act, as added and amended by sections 3401 and 10319(a) of the Affordable Care Act (as discussed in section I. of the Addendum to this proposed rule).

*L. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)*

Under existing regulations at § 412.104(a), we provide additional Medicare payments to a hospital for inpatient services provided to Medicare beneficiaries with end-stage renal disease (ESRD) who receive dialysis during a hospital stay if the hospital's ESRD Medicare beneficiary discharges, excluding certain MS–DRGs noted below, where the beneficiary receives dialysis during the inpatient stay, are 10 percent or more of its total Medicare discharges. These additional payments are intended to lessen the impact of the added costs for hospitals that deliver inpatient dialysis services to a high concentration of ESRD Medicare beneficiaries. The regulation provides that discharges classified into MS–DRG 652 (Renal Failure), MS–DRG 682 (Renal Failure with MCC), MS–DRG 683 (Renal Failure with CC), MS–DRG 684 (Renal Failure without CC/MCC), and MS–DRG 685 (Admit for Renal Dialysis) are excluded from the calculation of ESRD Medicare beneficiary discharges for purposes of determining a hospital's eligibility for these additional payments. We excluded these MS–DRGs because they include payment for the cost of inpatient dialysis treatments.

The current Medicare cost reporting instructions in the Provider Reimbursement Manual, Part II (PRM–II), at section 3630.1, require hospitals to enter as the denominator of the calculation on Line 5 "total Medicare discharges as reported on Worksheet S–3, Part I," excluding discharges for the dialysis MS–DRGs. As drafted, this instruction includes only discharges for beneficiaries enrolled in original fee-for-service Medicare in the denominator of the calculation. We are proposing to clarify that our policy is that the term "Medicare discharges" used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A. Discharges associated with individuals entitled to Medicare Part A include discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs). Consistent with this proposed clarification, these discharges would be included in the denominator of the calculation for the purpose of determining eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain discharges classified into MS–DRGs 652, 682, 683, 684, and 685, would be included in the determination of eligibility for the additional payment to hospitals. We intend to revise the instructions under section 3630.1 of the Provider Reimbursement Manual to reflect this clarification.

*M. Proposal for Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes*

1. Background

Currently, certain pension costs may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred. Reasonable cost reimbursement is addressed in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act defines "reasonable cost," in part, as the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Section 1861(v)(1)(A) of the Act does not specifically address the determination of reasonable costs, but

authorizes the Secretary to promulgate regulations and principles to be applied in determining reasonable costs.

We have issued regulations implementing this provision of the Act, including 42 CFR 413.9(a), which provide that the determination of reasonable cost "must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries." In addition, § 413.9(c) requires that the provision for payment of reasonable cost of services is intended to meet the actual costs incurred in providing services. Therefore, in accordance with the statute, the regulations include two principles that help guide the determination of which expenses may be considered allowable reasonable costs that can be paid under Medicare; that is, such costs must be "related" to the care of Medicare beneficiaries, and such costs must actually be "incurred."

Consistent with these provisions, we have issued instructions in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I) for determining and reporting defined benefit pension costs on the cost report for Medicare cost-finding purposes. For Medicare wage index purposes, the cost reporting instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension cost to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) also are typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a "funding target" and "target normal cost" measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA "funding target" and "target normal cost" values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new "funding target" and "target normal cost" basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term basis, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost-finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, these instructions also serve as interim guidance for Medicare cost-finding purposes.

In this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis to be used by all types of plans. Therefore, we are proposing to no longer rely on actuarial computation to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our proposal would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we are proposing separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed below under section IV.M.2. of this preamble) and for purposes of updating the wage index (discussed in section III.D.2. of this preamble). We believe it is necessary to have two distinct proposals in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct proposals would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of our proposal of a new methodology for reporting pension costs for Medicare cost-finding purposes. A full discussion of our proposal for reporting pension costs under the wage index is discussed in section III.D.2. of this preamble.

The proposal below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review."

2. Proposal for Allowable Defined Benefit Pension Plan Cost for Medicare Cost-Finding Purposes

As mentioned above, the defined benefit pension plan costs (hereafter referred to as "pension costs") reported for Medicare payment purposes should reflect the actual costs incurred by an individual provider. We are proposing to retain the policy in the current manual requiring pension costs to be funded in order to be reportable. We believe funding is an appropriate basis because it measures the actual expenditure towards the current period liability for pensions. We also are proposing to continue to limit the current period liability for pension costs

(that is, maximum annual allowable pension costs). However, we are proposing to change the methodology for calculating the limit on the current period liability. We are proposing that this methodology would be effective for cost reporting periods beginning on or after October 1, 2011.

Specifically, we are proposing a limit on the current period liability equal to 150 percent of the three consecutive reporting periods out of the recent reporting which produce the highest average. We believe a threshold of 150 percent is appropriate for the following reasons: First, the proposed threshold should be adequate to allow for typical fluctuations in contributions and for inflation. Second, we believe a threshold is necessary to limit the current period liability in order to ensure that reported pension costs are reasonable and do not reflect excessive or advance funding in any particular year. In addition, the proposed limit would help ensure that pension costs in the current year are reasonable because we expect the limit to capture pension costs which relate exclusively to patient care services furnished in the current cost reporting period. While we are proposing a limit, we recognize there may be situations in which pension costs in excess of the 150-percent limit might be reasonable, such as a funding requirement imposed by a third party, that is, ERISA's minimum funding requirement, statute or collective bargaining agreement. Therefore, we are proposing a process to allow hospitals with contributions in excess of the proposed limit to submit documentation demonstrating that all or a portion of the "excess" costs are reasonable and necessary for a particular cost reporting period.

The proposed 150-percent limit was established based on an analysis of historical contribution data submitted by pension plans subject to ERISA and published by the U.S. Department of Labor (DOL). Based on our analysis of the DOL contribution data, we expect the limit to apply only in a small minority of cases. We believe the use of readily available historical contribution data to establish the limitation will avoid the complexity of a limitation based on technical actuarial measurements. A limit based on the three consecutive reporting periods out of the five most recent reporting periods which produce the highest average will help to ensure that periods when no contributions (or only minimal contributions) are made will not dramatically reduce the limit in subsequent periods.

We believe use of a 5-year period would minimize the administrative burden on providers that would be associated with a longer period. We also believe using the three consecutive reporting periods which produce the highest average will better reflect a typical average pension cost while use of contributions for any three periods, even nonconsecutive, could introduce atypical results. Specifically, using the three highest contributions in the 5-year period may overstate the average contribution. However, because excessive contributions tend to reduce future funding requirements, we believe it would be unusual for excessive contributions to occur in three consecutive periods.

While we are proposing a limit, we believe that providers' pension costs in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period under the proposed review process are likely to be prefunded pension costs attributable to the patient care services for a future cost reporting period. Therefore, similar to the current instruction in section 2142.6(C) of the PRM–I, we are proposing to continue to use a carry forward policy. Specifically, we are proposing that current period contributions in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period under the proposed review process be carried forward and reported in future period(s) as the applicable limit for the future period(s) will allow. Medicare contractors would be required to maintain historical data in order to determine the 150-percent limit and track any carry forward amounts. We anticipate making a worksheet available for this purpose.

We are interested in public comments as to documentation or criteria that would be appropriate for the review process proposed above. We also invite public comments on this proposal and are especially interested in receiving public comments related to our proposal to limit the reportable pension amount.

*N. Rural Community Hospital Demonstration Program*

1. Background

Section 410A(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing "rural community hospitals" to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration program pays rural community hospitals for such services under a cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) of MMA, is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173, in conjunction with paragraphs (2) and (3) of section 410A(a), provided that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration program: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003.)

We originally solicited applicants for the demonstration program in May 2004; 13 hospitals began participation with cost reporting years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and became CAHs. In a notice published in the **Federal Register** on February 6, 2008 (73 FR 6971), we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration program payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, there were 13 hospitals participating in the demonstration program.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the

demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) These actions left 8 hospitals participating in the demonstration program as of November 1, 2010.

In addition, section 410A(c)(2) of Public Law 108–173 required that, "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." This requirement is commonly referred to as "budget neutrality." Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality. Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past seven IPPS final regulations, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FY 2005, FY 2006, FY 2007, FY 2008, FY 2009, FY 2010, FY 2011 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, and 75 FR 50343 respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner. In light of the statute's budget neutrality requirement, we are proposing a methodology to calculate a budget neutrality adjustment factor to the FY 2012 national IPPS rates.

2. Changes to the Demonstration Program Made by the Affordable Care Act

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, which established the rural community hospital demonstration program. Sections 3123 and 10313 of the Affordable Care Act changed the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period that begins on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173, as amended (section 410A(g)(1) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of that Act). Further, the Affordable Care Act requires that, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary shall provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation (section 410A(g)(4)(A) of Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of such Act). In addition, the Affordable Care Act provides that during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20 (section 410A(g)(2) of Pub. L. 108–173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Public Law 108–173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act). Additionally, we note that we indicated in the FY 2011 IPPS final rule (75 FR 50343) that section 410A(g)(4)(b) of Public Law 108–173 as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that Act provides that the amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital [other than services furnished in a psychiatric or rehabilitation unit of the hospital that is a distinct part] is the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period. We want to clarify that we believe that section 410A(g)(4)(B) of Public Law 108–173, as added by section 3123(a) the Affordable Care Act and as further amended by section 10313 of such Act, provides this with respect to a rural community hospital that is participating in the demonstration program under section 410A as of the last day of the initial 5-year period. Specifically, the Affordable Care Act requires that in the case of a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period, the Secretary in calculating payments under subsection (b) shall substitute under paragraph (1)(A) the phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period" for the phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration." The phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration" does not precisely track the language in section 410A(b)(1)(A) of

Public Law 108–173, therefore we cannot delete and replace as described in the Affordable Care Act. However, we believe the language of section 410A(g)(4)(B)(i) of Public Law 108–173 as amended is clear. Namely, a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period shall be paid for its covered inpatient hospital services "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period." (This methodology does not apply to services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part.) For discharges occurring in a subsequent cost reporting period during the demonstration, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply to such hospitals. That is, the payment will be the lesser of reasonable cost or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period beginning on or after the first day of the 5-year extension and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. (We note that in calculating target amounts we utilize the IPPS market basket percentage increase as defined in section 1886(b)(3)(B)(iii), opposed to the applicable percentage increase as defined in section 1886(b)(3)(B)(i) of the Act. We note that section 410A(b)(2)(B) of Public Law 108–173, in pertinent part, provides that target amounts are "increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase (as defined in clause (iii) of such section) for that particular cost reporting period." The phrase "applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase * * *" is ambiguous as there is no applicable percentage increase in the market basket percentage increase. Because the focus of the provision is the amount of the IPPS market basket percentage increase, we believe the provision is addressing the IPPS market basket percentage increase, and not the applicable percentage increase, which includes other adjustments to the market basket percentage increase. Further, because section 410A(b)(2)(B) of Public Law 108–173 is addressing target amounts under the demonstration we believed it was logical to read the statute as providing for an update structure mimicking the update structure for target amounts of reasonable cost-based providers like children's and cancer hospitals, as well as RNCHIs. This rationale applies any time we use the IPPS market basket percentage increase to update target amounts in the demonstration. With respect to hospitals that are newly joining the demonstration, they are paid the reasonable costs of providing covered inpatient hospital services, other than services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, for discharges occurring in the hospital's first cost reporting period beginning on or after the implementation of the demonstration program (section 410A(b)(1)(A) of Pub. L. 108–173). We have determined that each of these new hospitals will begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011. We chose this date because it follows immediately upon the notification of the hospitals of their acceptance to the demonstration and it will allow the hospitals to begin participation in the demonstration as soon as possible. With respect to rural community hospitals newly joining the demonstration, for discharges occurring in a subsequent cost reporting period under the demonstration program, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply. That is, payments will be the lesser amount of reasonable costs or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. In addition, various other technical and conforming changes were made to section 410A of Public Law 108–173 by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that Act.

We published a solicitation for applications for additional participants in the Rural Community Hospital Demonstration Program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density, which are eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. As of this date, we are waiting for these hospitals to respond as to whether they accept the terms and conditions stipulated for their participation in the demonstration; therefore, it is possible that fewer than the total of 19 will participate. We have based cost estimates for the demonstration for this new set of hospitals based on the assumption that all 19 hospitals will elect to participate. If fewer actually make this election, we are proposing to accordingly adjust the demonstration cost estimates in the FY 2012 IPPS/LTCH PPS final rule.

3. Proposed FY 2012 Budget Neutrality Adjustment

In order to ensure that the demonstration is budget neutral as is required by the statute, we are proposing to adjust the national IPPS rates in this proposed rule to account for any added costs attributable to the demonstration program. Specifically, the proposed budget neutrality adjustment would account for: (1) The estimated costs of the demonstration program in FY 2012 for the 8 currently participating hospitals ("pre-expansion participating hospitals"); (2) the estimated costs of the demonstration in FY 2012 for the 19 hospitals newly selected to begin participation in the demonstration program; and (3) the amount by which the costs of the demonstration program, as indicated by settled cost reports for cost reporting periods beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008, exceeded the amount that was identified in the FY 2007 and FY 2008 IPPS final rules as the budget neutrality offsets for FYs 2007 and 2008.

a. Component of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs of the "Pre-Expansion Participating Hospitals"

We note that eight hospitals that were selected for participation in either 2005 or 2008 are currently continuing to participate in the extension period mandated by the Affordable Care Act. We are proposing that the component of the proposed FY 2012 budget neutrality adjustment to the national IPPS rates that accounts for the estimated demonstration program costs in FY 2012 for the eight "pre-expansion participating hospitals" would be calculated by utilizing three separate methodologies: one methodology for the six hospitals that have participated in the demonstration program since its inception and that are continuing to participate in the demonstration program ("originally participating hospitals"); a second methodology for one hospital that is currently participating in the demonstration program and that was among the four hospitals that joined the demonstration program in 2008; and a third methodology for the other hospital that is currently participating in the demonstration program and that was among the four hospitals that joined the demonstration program in 2008. Different methods are used for these three sets of hospitals because the data available to us to estimate the demonstration program costs for each is different. Specifically, we are proposing to use the following hospital cost reports as the data sources used to estimate the costs attributable to the demonstration program under section 410A of Pub. L. 108–173 as amended:

(1) For the six "originally participating hospitals", the estimate of the portion of the proposed budget neutrality adjustment that accounts for the estimated FY 2012 demonstration program costs is based on data from their settled cost reports applicable to the second year of the demonstration—that is, for cost reporting periods ending in FY 2007. We are proposing to use these cost reports because they are the most recent finalized cost reports and, thus, we believe their accounting of costs is the most accurate indicator available to us at this time to estimate FY 2012 demonstration costs.

(2) For one of the two hospitals that joined the demonstration program in 2008, and that are still participating, we are proposing to estimate the FY 2012 demonstration program costs under section 410A of Public Law 108–173 as amended based on data from its as submitted cost report beginning January 1, 2008. Because we do not have final settled cost reports for this hospital for either 2008 or 2009, we are proposing to rely on its "as submitted" cost report for this period to estimate FY 2008 demonstration program costs for that hospital. We are proposing to use the "as submitted cost report" because we believe that as it is among the most recent cost reports, its accounting of costs is the most accurate indicator available to us at this time to estimate costs under the demonstration.

(3) The remaining hospital of the eight "pre-expansion participating hospitals", which began participation in FY 2008, is an Indian Health Service provider. Historically, the hospital has not filed standard Medicare cost reports. To estimate its costs for FY 2012, we are proposing to use its full "as submitted" cost report filed for the period ending September 30, 2009. We are proposing to use this "as submitted" cost report because as among the most recent cost reports we believe it allows us to estimate FY 2012 costs accurately.

We are proposing to use the same general methodology as for the FY 2011 IPPS/LTCH PPS final rule, but providing more detail. The proposed methodology for calculating the estimated FY 2012 demonstration cost for the eight "pre-expansion hospitals" is as follows:

*Step 1:* In order to calculate demonstration costs for each of the six "originally participating hospitals" for the cost reporting period ending in FY 2007, we subtracted the amount it would have otherwise been paid under the applicable payment system(s) for covered inpatient hospital services without the demonstration during such period (as indicated on the settled cost report for this period) from the amount paid to it for such services under the reasonable cost methodology in section 410A(b) of Public Law 108–173 (as indicated on the settled cost report for this period). Steps 1(a) through (c) below are performed to calculate FY 2007 demonstration costs for these six hospitals. (We are proposing to use final settled cost reports ending in FY 2007 to represent FY 2007 demonstration costs for each of these hospitals because a substantial portion of the months included within these cost report years (respective to each hospital) fall within FY 2007, and, therefore we believe that for purposes of this analysis it is appropriate to consider data from these cost reports to represent FY 2007 inpatient costs for the demonstration during that period. In addition, we note that throughout the remainder of the preamble discussion on the budget neutrality adjustment for the rural community hospital demonstration we refer to "covered inpatient hospital services" as that term is defined in section 410A(f)(2) of Public Law 108–173 as amended as "inpatient hospital services." We also note that the phrase "the reasonable cost methodology" means the reasonable cost methodology in section 410A(b) of Public Law 108–173 or the reasonable cost methodology in section 410A(b) of Public Law 108–173, as amended as applicable in the particular situation.

- Step 1(a): First, for each hospital, we subtracted the amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007 (as indicated on the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated on the settled cost report for this period). The result of this difference is each hospital's demonstration costs for its inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under the IPPS as indicated above because this is the payment methodology under which the hospital's beds (excluding swing beds) would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural community hospital demonstration budget neutrality adjustment whenever this is a component of the proposed methodology.)
- Step 1(b): Next, with respect to the hospitals that have swing beds, we subtracted the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds for the cost reporting period ending in FY 2007 (as indicated in the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated in the settled cost report for such period). The result of this difference is each hospital's demonstration costs associated with its swing beds for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act as indicated above because this is the payment methodology under which the hospital's swing beds would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural

community hospital demonstration budget neutrality adjustment whenever this is a component of the proposed methodology.)

• Step 1(c): Next, in order to calculate total estimated FY 2010 demonstration costs for all six hospitals, we added together the differences calculated above in Step 1(a) and Step 1(b) as applicable for each of the six hospitals and then multiplied this sum by the IPPS market basket percentage increases for FYs 2008 through 2010, which were adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for the years 2008 through 2010.

We note that we are proposing to apply the applicable IPPS market basket percentage increases described above to model estimated FY 2010 demonstration costs because we believe that this update factor appropriately indicates the trend of increase in hospital operating costs. Further, this approach is consistent with the agency's use of the IPPS market basket percentage increase to update the rate-of-increase limits (which is a reasonable cost-based methodology) for children's and cancer hospitals as well as RNCHIs. Therefore, we believe it enables us to estimate appropriately demonstration costs that are tied to a reasonable cost-based methodology. Also, this approach is consistent with how we update target amounts under the demonstration under section 410A(b)(2)(B) of Public Law 108–173. The proposed 2-percent annual volume adjustment was stipulated by the CMS Office of the Actuary in 2004, at the outset of the demonstration and is supposed to accurately reflect the tendency of hospitals' volumes to increase. We acknowledge the possibility that volumes for small hospitals may fluctuate, and are incorporating into the estimate of demonstration costs a factor to allow for a potential increase. We note that the rationale provided herein for utilizing an IPPS market basket percentage increase and a 2-percent annual volume adjustment to estimate demonstration costs is applicable throughout the preamble discussion on the rural community hospital budget neutrality adjustment whenever these factors are used in the proposed methodology.

As a side note, as a special feature of the demonstration, we added a supplemental work sheet to the standard hospital cost report which is completed by the fiscal intermediary in the final settlement for these six "originally participating hospitals." This supplemental work sheet includes the calculation of the hospital's first year reasonable costs of inpatient hospital services (excluding those associated with swing beds) as set forth in section 410A of Public Law 108–173, and, in addition, for the hospital's second year cost reports (those cost reports ending in FY 2007), the target amount (that is, the previous year's Medicare reasonable cost amount for inpatient hospital services updated by the IPPS market basket percentage increase as provided in section 410A(b)(2)(B) of Pub. L. 108–173). This supplemental work sheet also includes a calculation of the amount that would otherwise be paid for the hospital's inpatient hospital services under the IPPS, as is ordinarily presented on the standard hospital cost report. For hospitals that have swing beds, this supplemental work sheet also includes the following: the estimated amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the hospital's swing beds; the estimated amount the hospital would be paid under the reasonable cost methodology for the inpatient hospital services provided in its swing beds, and the hospital's target amount for its swing beds.

*Step 2:* In order to calculate estimated FY 2008 demonstration costs for the non-Indian Health Service hospital that began the demonstration program in 2008, we subtracted the estimated amount it would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system(s) (as indicated on the "as submitted" cost report beginning January 1, 2008) from the estimated costs of such services under the reasonable cost methodology (as indicated on the "as submitted" cost report for this period). Steps 2(a) through (c) below are performed to calculate this amount. We note that we are proposing to use the cost report beginning January 1, 2008 to represent FY 2008 demonstration costs for this hospital because it corresponds most precisely to FY 2008 and, therefore, we believe correctly represents FY 2008 inpatient costs for the demonstration for that period.

• Step 2(a): Specifically, we subtracted the estimated amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding swing beds) for the cost reporting period beginning January 1, 2008 (as indicated on the "as submitted" cost report) from the estimated amount to be paid for such services under the reasonable cost methodology (as indicated on the "as submitted" cost report for such period).

• Step 2(b): Next, we subtracted the estimated amount that would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds during the cost reporting period beginning January 1, 2008 (as indicated on the "as submitted" cost report) from the estimated amount to be paid for such services under the reasonable cost methodology as indicated on the "as submitted" cost report for such period.

• Step 2(c): We added together the differences calculated in Steps 2(a) and (b) above to obtain the hospital's total estimated FY 2008 demonstration cost.

• Step 2(d): Then, in order to calculate the hospital's estimated FY 2010 demonstration costs, we took the amount calculated in Step 2(c) above and multiplied it by the IPPS market basket percentage increases for FYs 2009 and 2010 as adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for each of FYs 2009 and 2010.

*Step 3:* In order to calculate the estimated FY 2009 demonstration costs for the Indian Health Service provider, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system (as indicated on the "as submitted" cost report ending September 30, 2009) from the estimated costs for such services under the reasonable cost methodology (as indicated in the "as submitted" cost report for such period). Step 3(a) below is performed to calculate this amount. (We note that we are proposing to use the cost report ending September 30, 2009 to represent FY 2009 demonstration costs for this hospital because it corresponds most precisely to FY 2009 and, therefore, we believe correctly represents FY 2009 inpatient costs for the demonstration for that period.)

• Step 3(a): Specifically, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services under the IPPS in the cost reporting period ending September 30, 2009 without the demonstration (as indicated on the "as submitted" cost report for this period) from the estimated amount to be paid under the reasonable cost methodology for such services (as indicated in the "as submitted" cost report for such period). We note that this provider had no swing beds, therefore, we did not estimate any portion of the costs under section 1888(e)(7) of the Act.

• Step 3(b): Next, in order to calculate the Indian Health Service provider's

estimated FY 2010 demonstration costs, we multiplied the difference calculated in Step 3(a) above by the IPPS market basket percentage increase for FY 2010 adopted in the FY 2010 IPPS/LTCH PPS final rule and the 2-percent annual volume adjustment.

*Step 4:* Then, in order to calculate total estimated FY 2010 demonstration costs for all eight "pre-expansion participating hospitals", we added the estimated FY 2010 demonstration costs calculated in Steps 1(c), 2(d), and 3(b) above.

*Step 5:* Next, in order to calculate total estimated FY 2012 demonstration costs for all eight "pre-expansion hospitals", we multiplied the amount calculated in Step 4 above by the FY 2011 IPPS market basket percentage increase adopted in the FY 2011 IPPS/LTCH PPS final rule and the proposed FY 2012 IPPS market basket percentage increase contained elsewhere in this proposed rule and a 2-percent annual volume adjustment for FYs 2011 and 2012. Thus, we arrived at the total estimated FY 2012 demonstration costs for all eight currently participating hospitals which needs to be offset, which is $21,290,305. If updated data become available for the final rule, we are proposing to use them to estimate the costs of the demonstration program in FY 2012 (including the use of any change in the FY 2012 market basket percentage increase).

b. Portion of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs for Hospitals Newly Selected To Participate in the Demonstration Program

Section 410A(g)(3) of Public Law 108–173, as added by section 3123 of the Affordable Care Act and as further amended by section 10313 of such Act, provides that "[n]otwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section." Consequently, up to 22 additional hospitals may be added to the demonstration program (30 hospitals minus the 8 "pre-expansion participating hospitals"). In order to ensure budget neutrality for the 19 newly selected hospitals, we are proposing to include a component in the proposed budget neutrality adjustment factor to the proposed FY 2012 national IPPS rates to account for the estimated FY 2012 costs of those new hospitals. For this proposed rule, we are proposing to generally use "as submitted" cost reports to estimate demonstration costs because they are the most recent cost reports and, therefore, we believe most accurately reflect the hospital's cost and payment for Medicare inpatient services in the respective year. We note that hospitals were required to submit pages from their most recent cost reports with their applications. For 13 of these hospitals, these cost reports had end dates in FY 2009; for the 6 remaining hospitals, they had end dates in FY 2010. Therefore, in various steps in the proposed methodology below, we begin various estimates with FY 2009 if the hospital submitted a cost report ending in FY 2009, and FY 2010 if the hospital submitted a cost report ending in FY 2010.

We are proposing to use the following methodology in order to estimate FY 2012 demonstration program costs for the 19 newly selected hospitals. This methodology differs from that in the FY 2011 IPPS/LTCH PPS final rule, because, at that time, hospitals had not been selected for participation, and thus we had no data specific to those hospitals that would enter the demonstration as a result of its expansion mandated by the Affordable Care Act.

*Step 1(a):* For each hospital that submitted a cost report ending in FY 2009, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS for such period (as indicated on the "as submitted" cost report for such period) from the estimated amount for reasonable costs for such services (as indicated on the "as submitted" cost report for such period) in order to calculate the difference between the hospital's estimated cost and payment for its inpatient hospital services (excluding those associated with swing beds) during the cost reporting period ending in FY 2009.

*Step 1(b):* For each hospital that submitted a cost report ending in FY 2010, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS (as indicated on the "as submitted" cost report for such period) from the estimated amount for the reasonable cost for such services (as indicated on the "as submitted" cost report for such period) in order to calculate the difference between the hospital's estimated costs and payment for its inpatient hospital services (excluding those associated with swing beds) during such period.

*Step 1(c):* While a portion of the 19 newly selected hospitals that have swing beds reported estimated costs for those beds, some hospitals did not, namely a portion of the hospitals that submitted cost reports ending in FY 2009 with their applications. Therefore, we needed to gap-fill in order to account for this issue. For each of the hospitals with swing beds that submitted cost reports ending in FY 2009, but that did not submit with its application estimated costs associated with those swing beds, we assigned an estimated cost for its swing beds based on an average of the estimated cost-payment difference associated with the swing beds of the newly participating hospitals that reported such data on their applications. We are proposing to assign estimated costs based on the average of the cost-payment difference for those hospitals that submitted these data, because these hospitals represent a sample of hospitals chosen for the demonstration, which we believe can accurately reflect costs and payment. We believe that these amounts, derived from the applications of the hospitals that submitted these data, accurately reflect this sample because they are hospitals of similar size and circumstances. Furthermore, these hospitals, which submitted the data, were chosen from the same set of States as the overall set of the newly selected hospitals. We utilized the methodology in Steps 1(c)(i) through (c)(iii) below to calculate this amount:

- Step 1(c)(i): For each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2009 and estimated costs of those swing beds during such period, we calculated its estimated cost-payment difference between the amount that the hospital estimates that will be paid under section 1888(e)(7) of the Act during such period for those swing beds (that is, the amount that the hospital estimates that will be paid under section 1886(e)(7) for the inpatient hospital services associated with its swing beds for such period from the amount that the hospital estimates that it would be paid for the reasonable costs for such services during such period as those amounts are reported on the hospital's application) by simply taking this amount from the hospital's application.
- Step 1(c)(ii): Then, for each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2010 and the estimated costs of those swing beds during such period, we calculated the difference between the estimate costs and payment for those swing beds for such period by simply taking this amount from the hospital's application. (We note that all hospitals that had

swing beds and that submitted cost reports ending in FY 2010 with their application supplied data on the estimated cost and payment for swing bed services on these cost reports.)

• Step 1(c)(iii): Next, we totaled all of the individual amounts calculated under Steps 1(c)(i) and (c)(ii) above and then divided this amount by the total number of hospitals that provided data on estimated costs on swing beds in their applications. We used the result of this computation as the estimated cost for the swing beds for each of the hospitals that failed to submit estimated costs for those beds with their applications.

• *Step 1(d):* Then, in order to calculate the total costs during the cost reporting period ending in FY 2009 for each hospital that submitted a cost report ending in FY 2009, we did the following: (a) If the hospital had no swing beds, its total estimated costs for such period is the difference calculated under Step 1(a); (b) If the hospital had swing beds, we added the difference calculated under Step 1(a) with the difference calculated under Step 1(c)(i) or Step 1(c)(iii) as applicable.

• *Step 1(e):* Next, in order to calculate total estimated FY 2009 costs for all of the hospitals that submitted cost reports ending in FY 2009 with their applications, we added together all of the total estimated costs that were calculated for each such hospital under Step 1(d) above. We note that we believe that using cost reports ending in FYs 2009 and 2010 best reflect costs and payment in FYs 2009 and 2010 because these cost reports most closely respond to those fiscal years.

• *Step 1(f):* Then, in order to calculate the total estimated FY 2011 costs for the newly selected hospitals that submitted cost reports ending in FY 2009 with their applications, we multiplied the amount calculated in Step 1(e) above by the FYs 2010 and 2011 IPPS market basket percentage increases adopted in the respective IPPS/LTCH PPS final rules as well as a 2-percent annual volume adjustment for each of FYs 2010 and 2011.

• *Step 1(g):* Then, in order to calculate the total estimated FY 2010 costs for each hospital that submitted a cost report ending in FY 2010, we did the following: (a) If the hospital had no swing beds, its total estimated costs is the difference calculated under Step 1(b); (b) If the hospital had swing beds, we added the difference calculated under Step 1(b) with the difference calculated under Step 1(c)(ii).

• *Step 1(h):* Next, in order to calculate the total FY 2010 costs for all of the hospitals that submitted FY 2010 cost reports with their applications, we added together all of the total estimated FY 2010 costs calculated for each such hospital under Step 1(g) above.

• *Step 1(i):* Then, we calculated the total estimated FY 2011 costs for all of the newly selected hospitals that submitted cost reports ending in FY 2010 by multiplying the amount calculated in Step 1(h) above by the FY 2011 IPPS market basket percentage increase adopted in the respective IPPS/LTCH PPS final rule as well as a 2-percent annual volume adjustment for FY 2011.

• *Step 1(j):* Next, in order to calculate total estimated FY 2012 demonstration costs for all of the 19 newly selected hospitals, we added together the amounts calculated in Steps 1(f) and 1(i) above and then multiplied this sum by the proposed IPPS FY 2012 market basket percentage increase proposed elsewhere in this proposed rule and a 2-percent annual volume adjustment for FY 2012. The amount of the estimated FY 2012 demonstration costs for the 19 newly selected hospitals needing to be offset is $31,351,908. If updated data become available for the final rule, we are proposing to use them to estimate the costs of the demonstration program in FY 2012.

c. Portion of the Proposed FY 2012 Budget Neutrality Adjustment To Offset the Amount by Which the Costs of the Demonstration Program in FYs 2007 and 2008 Exceeded the Amount That Was Identified in the FYs 2007 and 2008 IPPS Final Rules as the Budget Neutrality Offset for FYs 2007 and 2008

In addition, in order to ensure that the demonstration program in FYs 2007 and 2008 was budget neutral, we are proposing to incorporate a component into the budget neutrality adjustment factor to the proposed FY 2012 national IPPS rates, which would offset the amount by which the demonstration program costs as indicated by settled cost reports beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008 exceeded the amount that was identified in the FYs 2007 and 2008 IPPS final rules as the budget neutrality offset for FYs 2007 and 2008. Specifically, we are proposing the following methodology. This is the same methodology as used in the FY 2011 IPPS/LTCH PPS final rule, but we are adding detail. In this proposed rule, we are recognizing the possibility that in the year's time between the FY 2011 and FY 2012 final rule that the cost reports for the cost reporting years beginning in FY 2008 for the hospitals then participating in the demonstration may be finalized, that is, settled.

• Step One: Calculate the costs of the demonstration program for each of FYs 2007 and 2008 according to the settled cost reports that began in FYs 2007 or 2008 for the then participating hospitals (which represent the third and fourth years of the demonstration program for each of the then participating hospitals) and then add these two sums together. The costs of the demonstration program for each of FYs 2007 and 2008 is the difference resulting from subtracting the total amount that would otherwise be paid to the then participating hospitals under the applicable payment system(s) (that is, under the IPPS and under section 1888(e)(7) of the Act to the extent the participating hospital had swing beds) without the demonstration from the amount paid to those hospitals under the demonstration payment methodology in section 410A(b) of Public Law 108–173. (We are proposing to use these settled cost reports, which represent the third and fourth years of the demonstration program for each of the then participating hospitals, and, therefore, we believe correctly represent inpatient costs for the demonstration program during each of those 2 years.) These settled cost reports represent the third and fourth years of the demonstration, because the demonstration started with cost report start dates on or after October 1, 2004. Therefore, the first year of the demonstration program is represented by cost reports with a start date between October 1, 2004 and September 30, 2005 (that is, FY 2005; the second year of the demonstration program is represented by cost reports with a start date between October 1, 2005 and September 30, 2006 (FY 2006); the third year of the demonstration program is represented by cost reports with a start date between October 1, 2006 and September 30, 2007 (FY 2007); and the fourth year of the demonstration program is represented by cost reports with a start date between October 1, 2007 and September 30, 2008 (FY 2008).

• Step Two: Subtract the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 ($9,197,870 for FY 2007 and $9,681,893 for FY 2008) from the combined costs of the demonstration program in FYs 2007 and 2008 as calculated in Step one.

• Step Three: The result of Step two is a dollar amount, for which we would calculate a factor that would offset such amounts and would be incorporated into the overall proposed budget neutrality adjustment to the proposed national IPPS rates for FY 2012. This specific component to the overall

proposed budget neutrality adjustment for FY 2012 would account for the difference between the combined costs of the demonstration program in FYs 2007 and 2008 and the amount of the budget neutrality adjustment published in the FYs 2007 and 2008 IPPS/LTCH PPS final rules and, therefore, would ensure that the demonstration program is budget neutral for FYs 2007 and 2008.

Because of delays in the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in each FYs 2007 and 2008 respectively, we are unable to state the costs of the demonstration program corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustment for FYs 2007 and 2008. Therefore, we are not proposing the specific numeric amount representing this offsetting process that would be incorporated into the budget neutrality adjustment applied to the national IPPS rates. We note that we anticipate that they may be available for the FY 2012 IPPS/LTCH PPS final rule. Therefore, the estimated adjustment to the national IPPS rates in this proposed rule cannot include a component to account for these costs. However, to the extent such data is available for the final rule, we are proposing to have the budget neutrality offset to the IPPS rates account for the amount by which the costs corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008 as calculated by the process described above.

For this FY 2012 IPPS/LTCH PPS proposed rule, the estimated amount for which an adjustment to the proposed national IPPS rates is being calculated is the sum of the amounts specified in sections IV.N.3.a. and IV. N.3.b. of this proposed rule, which is $52,642,213 (this estimate does not account for the numeric result of the method in IV.N.3.c.). As explained previously, to the extent the numeric result of the method in IV.N.3.c. is available in the final rule, under our proposal, this amount would be included in the amount which needs to be offset by the budget neutrality adjustment. Sections IV.N.3.a. and IV.N.3.b. of this proposed rule state dollar amounts, which represent estimated costs attributable to the demonstration program for the respective component of the overall estimated calculation of the proposed budget neutrality factor for FY 2012. This estimated amount is based on the specific assumptions identified, as well as from data sources that are used because they represent either the most recently finalized, (that is, settled) or, if "as submitted," recently available cost reports.

*O. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window*

1. Background

Section 1886(a)(4) of the Act includes in the definition of "operating costs of inpatient hospital services" diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary) furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient during the 3 days preceding the date of the patient's admission to a subsection (d) hospital subject to the IPPS. For a non-subsection (d) hospital (psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals), the statutory payment window is 1 day preceding the date of the patient's admission.

Section 102(a)(1) of Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111–192, enacted on June 25, 2010) specifies that the term in section 1886(a)(4) of the Act, "other services related to the admission", includes "all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title [Title XVIII] that are provided by a hospital (or an entity wholly owned or wholly operated by the hospital) to a patient—(A) on the date of the patient's inpatient admission; or (B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission." Public Law 111–192 makes no changes to the existing policy regarding billing for diagnostic services.

Under the 3-day (or 1-day) payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. All outpatient nondiagnostic services provided by the hospital (or an entity wholly owned or wholly operated) on the date of the inpatient admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission are deemed related to the admission and must be billed with the inpatient stay unless the hospital attests to specific nondiagnostic services as being unrelated to the hospital claim.

In an interim final rule with comment period issued in the **Federal Register** on August 16, 2010 (75 FR 50346 through 50349), we discussed and made changes to the Medicare regulations pertaining to the 3-day payment window policy in order to comport with the requirements of section 102 of Public Law 111–192. We refer readers to that interim final rule with comment period for further information about the 3-day payment window policy. We have received public comments on the August 16, 2010 interim final rule with comment period, and we plan to address these public comments as well as any public comments we may receive on the proposals in this proposed rule in the FY 2012 IPPS/LTCH PPS final rule.

2. Condition Code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services)

As we stated in the August 16, 2010 interim final rule with comment period (75 FR 50348), we intend to establish a process for hospitals to attest to nondiagnostic services as being unrelated to the hospital claim when a hospital submits an outpatient claim. As part of the process, hospitals would be required to maintain documentation in the beneficiary's medical record to support their claim that the outpatient nondiagnostic services are unrelated to the beneficiary's inpatient admission.

The National Uniform Billing Committee (NUBC) is a committee established by the American Hospital Association and includes the participation of all the major national provider and payer organizations. The NUBC was formed to develop a single billing form and standard data set that could be used nationwide by institutional providers and payers for handling health care claims. The NUBC has provided a mechanism through the establishment of a condition code for a hospital to attest directly on the outpatient claim to specific nondiagnostic services as being clinically unrelated to an inpatient hospital claim (that is, the preadmission diagnostic services are clinically

distinct or independent from the reason for the beneficiary's inpatient admission). As of April 1, 2011, a hospital must add condition code 51 on claims for separately billed outpatient nondiagnostic services furnished on or after June 25, 2010 (the date of enactment of Pub. L. 111–192) if the hospital wishes to attest to nondiagnostic services as being unrelated to the hospital claim. We issued a manual system revision through Change Request #7142, Transmittal 796, on October 29, 2010, instructing CMS contractors to accept condition code 51 on outpatient claims.

3. Applicability of the Payment Window Policy to Services Furnished at Physicians' Practices

We have received several inquiries regarding the applicability of the payment window to preadmission services furnished at hospital-owned or hospital-operated physicians' clinics or practices. The statutory language under section 1886(a)(4) of the Act is clear that the 3-day (or, where applicable, 1-day) payment window policy applies not only to diagnostic and related nondiagnostic services furnished to patients at hospitals but also at entities that are wholly owned or operated by the admitting hospital. In a 1998 final rule on payment for preadmission services (63 FR 6866), we stated, "A hospital-owned or hospital-operated physician clinic or practice is subject to the payment window provision. The technical portion of preadmission diagnostic services performed by the physician clinic or practice must be included on the inpatient bill and may not be billed separately. A physician's professional service is not subject to the window." Thus, we made clear that the term "entities" under this section of the statute includes physicians' clinics or practices. Although the 1998 rule provides specific guidance regarding billing for preadmission diagnostic services furnished at hospital-owned or hospital-operated physician's practices, we had issued no guidelines regarding billing for preadmission nondiagnostic services provided by a hospital-owned or hospital-operated physician's practice, leaving many to assume that the payment window does not apply to such services.

Prior to the June 25, 2010 enactment of section 102(a)(1) of Public Law 111–192, the payment window policy for preadmission nondiagnostic services was rarely applied because the policy required an exact match between the principal ICD–9 CM diagnosis codes for the outpatient services and the inpatient admission. Because of the exact match policy, very few services furnished in a physician's office or clinic that is wholly owned or operated by the hospital would be subject to the policy. However, the statutory change to the payment window policy made by Public Law 111–192 significantly broadened the definition of nondiagnostic services that are subject to the payment window to include any nondiagnostic service that is clinically related to the reason for a patient's inpatient admission, regardless of whether the inpatient and outpatient diagnoses are the same. This statutory change therefore significantly broadens the application of the payment window policy in hospital-owned or hospital-operated physician offices or clinics (that is, clinics that are not provider-based). We note that, under this change, hospitals and hospital-owned or hospital-operated entities must now attest that preadmission nondiagnostic services are not related to an admission using condition code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services) when they submit a claim during the 3-day (or, where applicable, 1-day) preadmission period.

In response to ongoing requests to clarify the applicability of the payment window policy to preadmission nondiagnostic services provided in hospital-owned or hospital-operated physicians' offices or clinics, we are clarifying in this proposed rule that the 3-day (or, where applicable, 1-day) payment window policy applies to both preadmission diagnostic and nondiagnostic services furnished to a patient at physician's practices that are wholly owned or wholly operated by the admitting hospital. For purposes of the payment window, "wholly owned or operated" literally means that the admitting hospital must be the sole owner or the sole operator of the entity providing the preadmission services in order for the payment window policy to apply. A hospital is considered the sole operator of an entity if the hospital has exclusive responsibility for conducting or overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity (we refer readers to the regulations at 42 CFR 412.2(c)(5)(i) and to discussions and examples of wholly owned or operated scenarios in rules issued in the **Federal Register** on January 12, 1994 (59 FR 1656) and February 11, 1998 (63 FR 6865 through 6867)).

In the circumstance where a clinic that is not provider-based meets the definition of being wholly owned or wholly operated by the hospital and the 3-day (or, if applicable, 1-day) payment window applies to related nondiagnostic preadmission services, the hospital's charge on the inpatient claim would include any overhead costs associated with Medicare's physician fee schedule payment. Therefore, it should follow that Medicare's payment to the physician for the physician fee schedule service should be at the lower facility rate, which does not include overhead, staff, equipment, and supplies required to perform the service in the physician's office (rather than the higher nonfacility rate that does include those overhead costs) to avoid paying for the services twice because they are no longer being paid separately under Part B.

Under 42 CFR 414.22(b)(5)(i), Medicare pays physicians using the nonfacility relative value units when services are provided in a physician's office and bases physician payment on the facility relative value units when the physician provides services in a facility, including hospitals, skilled nursing facilities, community mental health centers, and ambulatory surgical centers. Because a hospital-owned or hospital-operated physician practice or clinic that is not provider-based is a nonfacility setting, we will need to change the regulation to specifically provide for Medicare to pay for a service provided in a nonfacility setting at the facility rate in order to comply with section 102(a) of Pub. L. 111–192. We intend to discuss such a proposal in more detail in a future physician fee schedule proposed rule and address how this statutory provision will be implemented in physicians' offices that are wholly owned or wholly operated by the hospital. In all circumstances, we would expect the hospital to inform the physician offices and clinics where the hospital is the sole owner or sole operator and when an inpatient admission occurs.

*P. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy*

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy, set forth in § 412(f), provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a

graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is double the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus one day.

We established the criteria set forth in § 412.4 for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the DRG's total number of discharges and proportion of short-stay discharges to postacute care exceed the 55th percentile for all DRGs, CMS will apply the postacute care transfer policy to that DRG and to any other MS–DRG that shares the same base DRG. In the preamble to the FY 2006 final rule (70 FR 47419), we stated that "we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific DRG."

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a reduced per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. DRGs that are part of an MS–DRG group must meet DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Proposed Changes to the Postacute Care Transfer MS–DRGs

Based on our annual review of MS–DRGs, we have identified a number of MS–DRGs that should be included on the list of MS–DRGs subject to the postacute care transfer policy. As we discuss in section III.G. of this proposed rule, in response to public comments and based on our analysis of FY 2010 MedPAR claims data, we are proposing to make several changes to MS–DRGs to better capture certain severity of illness levels, to be effective for FY 2012. Specifically, we are proposing to modify the assignment of the autologous bone marrow transplants now assigned to MS–DRG 015 (Autologous Bone Marrow Transplant) to capture the severity levels of "with CC/MCC" and "without CC/MCC." We are proposing to establish two new MS–DRGs (proposed MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with MCC/CC and without MCC/CC, respectively) to replace MS–DRG 015. We also are proposing to establish three new MS–DRGs to capture three severity of illness levels for skin debridement—proposed MS–DRG 570 (Skin Debridement with MCC); proposed MS–DRG 571 (Skin Debridement with CC); and proposed MS–DRG 572 (Skin Debridement without CC/MCC). In addition, we are proposing to move the codes for rechargeable dual array deep brain stimulation (codes 02.93 and 86.98) to MS–DRGs 023 and 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX, with MCC and without MCC, respectively) where similar devices are currently assigned. We are proposing to move two procedure codes that either repair a thoracic aneurysm or place a stent graft (codes 38.45 and 39.73) out of MS–DRG 237 and 238 (Major Cardiovascular Procedures w MCC or Thoracic Aortic Aneurysm Repair, and Major Cardiovascular Procedures with MCC and without MCC, respectively). We are proposing to assign these two codes to MS–DRGs 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC, with CC, and without CC, respectively). We are proposing to add a procedure code for partial gastrectomy (43.89) to MS–DRGs 619, 620, and 621 (O.R. Procedure for Obesity with MCC, with CC, and without CC/MCC, respectively). A discussion of these proposed changes can be found in section II.G. of the preamble of this proposed rule.

In light of these proposed changes to the MS–DRGs, according to the regulations under § 412.4(c), we evaluated these proposed FY 2012 MS–DRGs against the general postacute care transfer policy criteria using the FY 2010 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We note that these proposed changes to the MS–DRGs can result in interactive effects between MS–DRGs and in cases moving from existing MS–DRGs to the new proposed MS–DRGs, and that our review reflects this as well. As a result of our review, we are proposing to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 570, 571, and 572 for FY 2012. (These MS–DRGs are reflected in Table 5, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, and are also listed in the tables at the end of this section.)

In addition, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we have identified the following two existing MS–DRGs that meet the criteria to be subject to the postacute care transfer policy for FY 2012: MS–DRGs 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC) and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS PDX without MCC). We are proposing to add these two MS–DRGs to the list of MS–DRGs that are subject to the postacute care transfer policy for FY 2012. The following table lists the respective criteria for each MS–DRG that we are proposing to add to the postacute transfer policy list.

Further, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we have determined that MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), 230 (Other Cardiothoracic Procedures without CC/MCC), 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes with MCC), and 641 (Miscellaneous

Disorders of Nutrition, Metabolism, Fluids/Electrolytes without MCC) no longer meet the postacute care transfer criteria. Therefore, we are proposing that they be removed from the list of DRGs subjected to the postacute care transfer policy, effective FY 2012. We refer readers to the bolded text in the following table to see which criteria were not met in our analysis for each MS–DRG removed from the postacute care transfer policy list.

BILLING CODE 4120–01–P

**LIST OF MS-DRGs CHANGING POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2012**

| MS-DRG | MS-DRG Title | Total cases | Postacute care transfers (55th percentile: 1,586) | Short-stay postacute care transfers | Percent of short-stay postacute care transfers to all cases (55th percentile: 7.9591%) | Postacute transfer policy status |
|---|---|---|---|---|---|---|
| 023 | CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W MCC OR CHEMO IMPLANT | 4,601 | 2,215 | 370 | 8.04% | YES |
| 024 | CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W/O MCC | 1,726 | **992*** | 161 | 9.33% | YES** |
| 228 | OTHER CARDIOTHORACIC PROCEDURES W MCC | 1,929 | **1,215*** | 450 | 23.33% | NO |
| 229 | OTHER CARDIOTHORACIC PROCEDURES W CC | 2,381 | **1,315*** | 418 | 17.56% | NO |
| 230 | OTHER CARDIOTHORACIC PROCEDURES W/O CC/MCC | 641 | **226*** | 11 | **1.72%*** | NO |
| 570 | SKIN DEBRIDEMENT W MCC | 5,211 | 4,007 | 1577 | 30.26% | YES |
| 571 | SKIN DEBRIDEMENT W CC | 5,574 | 3,851 | 1099 | 19.72% | YES |
| 572 | SKIN DEBRIDEMENT W/O CC/MCC | 2,542 | **1,384*** | 226 | 8.89% | YES** |
| 640 | MISC DISORDERS OF NUTRITION,METABOLISM,FLUIDS/ELECTROLYTES W MCC | 57,197 | 22,571 | 3618 | **6.33%*** | NO |
| 641 | MISC DISORDERS OF NUTRITION,METABOLISM,FLUIDS/ELECTROLYTES W/O MCC | 169,353 | 69,590 | 5167 | **3.05%*** | NO |

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG shall all meet postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

BILLING CODE 4120–01–C

Finally, we have determined that MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC), and 218 (Cardiac Valve & Other Major Cardiothoracic Procedure without CC/MCC) meet the criteria for the special payment methodology. Therefore, we are proposing that they would be subject to the DRG special payment methodology, effective FY 2012.

**LIST OF MS-DRGs CHANGING DRG SPECIAL PAYMENT POLICY STATUS IN FY 2012**

| MS-DRG | MS-DRG Title | Geometric mean length of stay | Average charges of 1-day discharges | 50% of average charges for all cases within MS-DRG | Special pay policy status |
|---|---|---|---|---|---|
| 216 | CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W MCC | 14.2497327 | $164,838 | 125,398 | YES |
| 217 | CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W CC | 9.518336312 | $126,655 | 84,669 | YES |
| 218 | CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W/O CC/MCC | 7.102572558 | $0 | 0 | YES* |

* As described in the policy at 42 CFR 412.4(d)(6)(iv), MS-DRGs that share the same base MS-DRG shall meet DRG special payment policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

*Q. Hospital Services Furnished Under Arrangements*

For purposes of Medicare payment, section 1861(b) of the Act defines "inpatient hospital services" in part as "* * * the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) Bed and board;

(2) Such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients * * *; and

(3) Such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;"

We note that the statute specifies that "routine services," for example, bed, board, nursing and other related services, except those specified at paragraph (3) of section 1861(b) of the Act are to be provided by "the hospital," and not just "a hospital." Similarly, our implementing regulations at 42 CFR 409.12 indicate that Medicare pays for "nursing and related services, use of hospital * * * facilities, and medical social services as * * * inpatient hospital services or inpatient CAH services * * * only if those services are ordinarily furnished by the hospital or CAH." Consistent with the statute, only with regard to other diagnostic or therapeutic services do the regulations at 42 CFR 409.16 state that Medicare will also pay for these services if furnished "by others under arrangements made by the hospital or CAH."

However, it has come to our attention that some providers in the hospital community may have interpreted our instructions under section 2118 (Cost of Services Furnished under Arrangement) of the Provider Reimbursement Manual, Part I (PRM–I), relating to payment for routine services to allow additional services to be provided under arrangements. Some providers have interpreted the provision of the paragraph on "Routine Services" relating to services provided "under arrangement" under section 2118 of the PRM–I to mean that even routine services described in sections 1861(b)(1) and (b)(2) of the Act, which are normally provided to hospital inpatients by the hospital, can be provided by an outside entity under arrangement.

To the extent that our manual provisions could be read to allow hospitals to furnish such "routine services" "under arrangements," we are now proposing a change to limit the services a hospital may provide under arrangement to reflect the statutory definition of "inpatient hospital services" and the implementing regulations. Under our proposed policy, if routine services, that is, services described in sections 1861(b)(1) and (b)(2) of the Act, are provided in the hospital, they are considered as being provided "by the hospital." We believe that this proposal is consistent with the statute because the statutory language specifying that the routine services described in sections 1861(b)(1) and (b)(2) of the Act be provided "by the hospital" suggests that the hospital is required to exercise professional responsibility over the services, including quality controls. In situations

in which certain routine services are provided under arrangements "in the hospital," for example, contracted nursing services, we believe the arrangement generally results in the hospital exercising the same level of control over those services as the hospital does in situations in which the services are provided by the hospital's salaried employees. Therefore, if these services are provided in the hospital to its inpatients, we consider the services as being provided by the hospital. However, if these services are provided outside the hospital, the services are considered as being provided under arrangement, and not by the hospital. That is, consistent with the statute, only therapeutic and diagnostic services can be provided under arrangement. If we finalize this proposed policy, we will change the provisions of section 2118 of the PRM–I accordingly.

## V. Proposed Changes to the IPPS for Capital-Related Costs

### *A. Overview*

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a prospective payment system established by the Secretary." Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.) The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, currently the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

### *B. Exception Payments*

The regulations at § 412.348(f) provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. This policy was originally established for hospitals during the 10-year transition period, but as we discussed in the FY 2003 IPPS final rule (67 FR 50102), we revised the regulations at § 412.312 to specify that payments for extraordinary circumstances are also made for cost reporting periods after the transition period (that is, cost reporting periods beginning on or after October 1, 2001). Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

During the transition period, under §§ 412.348(b) through (e), eligible hospitals could receive regular exception payments. These exception payments guaranteed a hospital a minimum payment percentage of its Medicare allowable capital-related costs depending on the class of the hospital (§ 412.348(c)), but were available only during the 10-year transition period. After the end of the transition period, eligible hospitals can no longer receive this exception payment. However, even after the transition period, eligible hospitals receive additional payments under the special exceptions provisions at § 412.348(g), which guarantees all eligible hospitals a minimum payment of 70 percent of its Medicare allowable capital-related costs provided that special exceptions payments do not exceed 10 percent of total capital IPPS payments. Hospitals eligible for special exceptions payments are required to submit documentation to the fiscal intermediary or MAC indicating the completion date of their project. Special exceptions payments may be made only for the 10 years from the cost reporting year in which the hospital completes its qualifying project, and the hospital must have completed the project no later than the hospital's cost reporting period beginning before October 1, 2001. Thus, an eligible hospital may receive special exceptions payments for up to 10 years beyond the end of the capital IPPS transition period. Under this limitation on the period for special exceptions payments at § 412.348(g)(7) of the regulations, FY 2012 is the final year hospitals can receive special exceptions payments. (For more detailed information regarding the special exceptions policy under § 412.348(g), we refer readers to the FY 2002 IPPS final rule (66 FR 39911 through 39914) and the FY 2003 IPPS final rule (67 FR 50102).)

### *C. New Hospitals*

Under the IPPS for capital-related costs, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under current or previous ownership) for less than 2 years. For example, the following hospitals are not considered new hospitals: (1) A hospital that builds new or replacement facilities at the same or another location, even if coincidental with a change of ownership, a change in management, or a lease arrangement; (2) a hospital that closes and subsequently reopens; (3) a hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years; and (4) a hospital that changes its status from a hospital that is excluded from the IPPS to a hospital that is subject to the capital IPPS. For more detailed information, we refer readers to the FY 1992 IPPS final rule (56 FR 43418). During the 10-year transition period, a new hospital was exempt from the capital IPPS for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Originally, this provision was effective only through the transition period and, therefore, ended with cost reporting periods beginning in FY 2002. Because, as discussed in the FY 2003 IPPS final rule (67 FR 50101), we believe that special protection to new hospitals is also appropriate even after the transition period, we revised the regulations at § 412.304(c)(2) to provide that, for cost reporting periods beginning on or after October 1, 2002, a new hospital (defined under § 412.300(b)) is paid 85 percent of its Medicare allowable capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. (We refer readers to the FY 2003 IPPS final rule (67 FR 50101 through 50102) for a detailed discussion of the special payment provisions for new hospitals under the capital IPPS after the 10-year transition period.)

*D. Hospitals Located in Puerto Rico*

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate.

Prior to FY 1998, hospitals in Puerto Rico were paid a blended capital IPPS rate that consisted of 75 percent of the capital IPPS Puerto Rico specific rate and 25 percent of the capital IPPS Federal rate. However, effective October 1, 1997 (FY 1998), in conjunction with the change to the operating IPPS blend percentage for hospitals located in Puerto Rico required by section 4406 of Public Law 105–33, we revised the methodology for computing capital IPPS payments to hospitals in Puerto Rico to be based on a blend of 50 percent of the capital IPPS Puerto Rico rate and 50 percent of the capital IPPS Federal rate. Similarly, in conjunction with the change in operating IPPS payments to hospitals located in Puerto Rico for FY 2005 required by section 504 of Public Law 108–173, we again revised the methodology for computing capital IPPS payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate effective for discharges occurring on or after October 1, 2004.

*E. Proposed Changes for FY 2012: MS–DRG Documentation and Coding Adjustment*

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize patient severity of illness in Medicare payment rates. Adoption of the MS–DRGs resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 747 MS–DRGs and we are proposing 4 additional MS–DRGs for FY 2012.) By increasing the number of DRGs and more fully taking into account patient severity of illness in Medicare payment rates, the MS–DRGs encourage hospitals to change their documentation and coding of patient diagnoses. In that same final rule with comment period (72 FR 47183), we indicated that we believe the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for changes in documentation and coding. Accordingly, we established adjustments to both the national operating standardized amount and the national capital Federal rate to eliminate the estimated effect of changes in documentation and coding resulting from the adoption of the MS–DRGs that do not reflect real changes in case-mix. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010. However, to comply with section 7(a) of Public Law 110–90, enacted on September 29, 2007, in a final rule published in the **Federal Register** on November 27, 2007 (72 FR 66886 through 66888), we modified the documentation and coding adjustment for FY 2008 to −0.6 percent, and consequently revised the FY 2008 IPPS operating and capital payment rates, factors, and thresholds accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2008 IPPS final rule with comment period (72 FR 48447 and 48733 through 48774), we applied an additional documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts and the national capital Federal rate. The documentation and coding adjustments established in the FY 2009 IPPS final rule, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent. (For additional details on the development and implementation of the documentation and coding adjustments for FY 2008 and FY 2009, we refer readers to section II.D. of this preamble and the following rules published in the **Federal Register**: August 22, 2007 (72 FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72 FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450 and 48773 through 48775).)

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we presented the results of a retrospective evaluation of the FY 2008 data for claims paid through December 2008. We sought public comment on our methodology and analysis and our proposal to apply a prospective adjustment to address the effect of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In addition, we sought public comment on addressing in the FY 2011 rulemaking cycle any effect of documentation and coding changes that do not reflect real changes in case-mix for discharges occurring during FY 2009. However, after consideration of the public comments received on the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, consistent with the application of the documentation and coding adjustment to the operating IPPS standardized amounts, we determined that it would be appropriate to postpone the adoption of any additional documentation and coding adjustments to the capital IPPS rates until a full analysis of FY 2009 case-mix changes could be completed (74 FR 43926 through 43928).

For the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014), we performed a thorough retrospective evaluation of the most recent available claims data, and the results of this evaluation were used by our actuaries to determine any necessary payment adjustments beyond the cumulative −1.5 percent adjustment that has already been applied to the national capital Federal rate to ensure budget neutrality for the implementation of MS–DRGs. Specifically, we performed a retrospective evaluation of the FY 2009 claims data updated through December 2009 using the same analysis methodology as we did for FY 2008 claims in the FY 2010 IPPS/RY 2010 LTCH PPS proposed and final rules. Based on this evaluation, our actuaries determined that the implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. We also noted our intent to update our analysis with FY 2009 data on claims paid through March 2009 (sic) for the FY 2011 IPPS/LTCH PPS final rule. (We note that the March 2009 update date for claims paid data in the proposed rule should have stated March 2010.)

As intended, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we updated our analysis with FY 2009 data on claims paid through March 2010 in that final rule. For the FY 2011 IPPS/LTCH PPS final rule, applying the same analysis methodology

as we did for the proposed rule to an FY 2009 claims data updated through March 2010 verified the 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. The 5.4 percent estimate of the cumulative effect of changes in documentation and coding under the MS–DRG system that did not reflect real changes in case-mix for FYs 2008 and 2009 exceeded the cumulative −1.5 percent prospective documentation and coding adjustment that had already been applied to the national capital Federal rate by 3.9 percentage points (5.4 percent minus 1.5 percent). Therefore, an additional cumulative adjustment of −3.9 percent to the national capital Federal rate would be necessary to eliminate the full effect of the documentation and coding changes due to the adoption of the MS–DRGs on future payments.

Therefore, in that same final rule, under the Secretary's broad authority under section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we implemented an adjustment to the FY 2011 national capital Federal rate of −2.9 percent to account for part of the effect of the estimated changes in documentation and coding changes under the MS–DRG system that occurred in FYs 2008 and 2009 that did not reflect real changes in case-mix. We also established that we will leave the −2.9 percent adjustment in place for subsequent fiscal years to account for the effect of that documentation and coding change in subsequent years. Furthermore, we stated our intention to address the remaining estimated adjustment to the national capital Federal rate of −1.0 percent (that is, the estimated effect of documentation and coding changes under the MS–DRG system of −5.4 percent minus the existing −0.6 percent and −0.9 percent adjustments and the −2.9 percent adjustment for FY 2011) in future rulemaking cycles.

2. Proposed Prospective MS–DRG Documentation and Coding Adjustment to the National Capital Federal Rate for FY 2012 and Subsequent Years

We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate the effect of any documentation and coding changes as a result of the implementation of the MS–DRGs. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 accurately reflected the changes due to documentation and coding that occurred in those years. As noted in section V.A. of this preamble, under section 1886(g) of the Act, the Secretary has broad authority in establishing and implementing the IPPS for acute-care hospital inpatient capital-related costs (that is, the capital IPPS). We have consistently stated since the initial implementation of the MS–DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS–DRG related changes in documentation and coding. Accordingly, we believe that it is appropriate under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, to make adjustments to the national capital Federal rate to eliminate the full effect of the documentation and coding changes resulting from the adoption of the MS–DRGs. We believe that this is appropriate because, in absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS–DRGs results in inappropriately high capital IPPS payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

As discussed above, based on our retrospective evaluation of the FY 2009 claims, our actuaries determined that implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. To date, we have made adjustments to the national capital Federal rate to account for 4.4 percent (that is, −0.6 percent in FY 2008, −0.9 percent in FY 2009, and −2.9 percent in FY 2011) of the estimated 5.4 percent documentation and coding effect. Thus, our current estimate of the remaining adjustment to the national capital Federal rate is −1.0 percent to account for the effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009.

In this proposed rule, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, consistent with the intention we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50357), we are proposing to reduce the national capital Federal rate in FY 2012 by −1.0 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system in FYs 2008 and 2009 that did not reflect real changes in case-mix. Furthermore, consistent with the documentation and coding adjustments we have made in the past, we are proposing to leave this proposed −1.0 percent adjustment in place for subsequent fiscal years to account for the effect in FY 2012 and subsequent years. As explained above, this proposed −1.0 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009 of −5.4 percent minus the existing −0.6 percent, −0.9 percent, and −2.9 percent adjustments.

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

Under § 412.74, Puerto Rico hospitals are currently paid based on 75 percent of the national capital Federal rate and 25 percent of the Puerto Rico-specific capital rate. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50358 through 50359), we discussed the retrospective evaluation of the FY 2009 claims data from the March 2010 update of the MedPAR file of hospitals located in Puerto Rico using the same methodology used to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals. This analysis shows that the change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico was approximately 2.6 percent. (As discussed in that same final rule, the Puerto Rico-specific capital rate was not adjusted for the cumulative effects of documentation and coding changes in FY 2008 or FY 2009.) We also explained that we continue to believe that such an adjustment is appropriate because all hospitals have the same financial incentives for documentation and coding improvements, and the same ability to benefit from the resulting increase in aggregate payments that do not reflect real changes in case-mix.

Given this case-mix increase due to changes in documentation and coding under the MS–DRGs, consistent with the adjustment we made to the FY 2011 national capital Federal rate (discussed above) and consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the

Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of −2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. In addition, consistent with our implementation of other prospective MS–DRG documentation and coding adjustments to the capital Federal rate and operating IPPS standardized amounts, we established that we will leave that −2.6 percent adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case-mix in subsequent years. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in this proposed rule, we are not proposing to make any additional adjustments to the capital Puerto Rico-specific rate for FY 2012 for the effect of documentation and coding that did not reflect real changes in case-mix.

*F. Other Proposed Changes for FY 2012*

The proposed annual update to the capital IPPS national Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2012 is discussed in section III. of the Addendum to this proposed rule.

## VI. Proposed Changes for Hospitals Excluded From the IPPS

*A. Excluded Hospitals*

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals.

Payment to children's hospitals and cancer hospitals that are excluded from the IPPS continues to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2012 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs be the estimated FY 2012 percentage increase in the IPPS operating market basket, estimated to be 2.8 percent. Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the remaining number of providers being paid based on reasonable cost subject to a ceiling (that is, children's hospitals, 11 cancer hospitals, and RNHCIs) is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. For FY 2012, we are proposing to continue to use the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

Therefore, we are proposing to use the revised and rebased FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2012. Based on IHS Global Insight, Inc.'s 2011 first quarter forecast, with historical data through the 2010 fourth quarter, we are estimating that the FY 2012 update to the IPPS operating market basket would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). (We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2012.)

We note that IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR part 412, subparts N, O, and P.) We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this proposed rule for the specific proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

*B. Critical Access Hospital (CAH) Payment for Ambulance Services*

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs) under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and that meet the CAH conditions of participation under 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413. Section 1834(l) of the Act sets forth the payment rules for ambulance services. Generally, payment to ambulance providers and suppliers for ambulance services are made under the ambulance fee schedule. Section 205 of Public Law 106–554 (BIPA) amended section 1834(l) of the Act by adding a paragraph (8) to that section, which provides that the Secretary shall pay the reasonable costs incurred in furnishing ambulance services if such services are furnished by a CAH (as defined in section 1861(mm)(1) of the Act), or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH. The term "provider of ambulance services" includes all Medicare-participating providers that submit claims under Medicare for ambulance services (for example, hospitals, CAHs, skilled nursing facilities (SNFs), and home health agencies (HHAs)). The term "supplier of ambulance services" is defined as an

entity that provides ambulance services and that is independent of any Medicare-participating or non-Medicare-participating provider. Section 205 was effective for services furnished on or after December 21, 2000. Regulations implementing section 1834(l)(8) of the Act are set forth at 42 CFR 413.70(b)(5).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50361), we implemented section 3128(a) of the Affordable Care Act, which amended section 1834(l)(8) of the Act by inserting "101 percent of" before "the reasonable costs." As such, section 3128(a) increased payment for ambulance services furnished by a qualifying CAH or entity owned and operated by a CAH to 101 percent of reasonable costs, effective for cost reporting periods beginning on or after January 1, 2004. We amended the regulations at § 413.70(b)(5)(i) to conform to this statutory change by stating that, effective for cost reporting periods beginning on or after January 1, 2004, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity furnishing those services is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

2. Requirement for CAH Ambulance Within a 35-Mile Location of a CAH or Entity

Section 413.70(b)(5) of the existing regulations states that payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is "the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity". However, the statutory language at section 1834(l)(8) of the Act states that a CAH is eligible to be paid based on 101 percent of reasonable cost for ambulance services furnished by the CAH or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such CAH. Because the statute only requires that there be no other provider or supplier of ambulance services within a 35-mile drive of the CAH and does not address whether there is another provider or supplier of ambulance services within a 35-mile drive of the CAH-owned and operated entity, we believe that the existing regulation is not consistent with the plain reading of the statutory language at section 1834(l)(8) of the Act. In addition, we believe the plain reading of the statutory language at section 1834(l)(8) of the Act does not address the situation where there is no provider or supplier of ambulance services within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity furnishing ambulance services that is more than a 35-mile drive from the CAH, thus creating a "gap" in the statutory language. That is, the statutory language does not address the situation where the entity that is owned and operated by the CAH is located *more* than a 35-mile drive from the CAH.

In order to ensure that the regulations are consistent with the plain language of section 1834(l)(8) of the Act, we are proposing to revise § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 1). Under this proposed change, the CAH-owned and operated entity would be paid 101 percent of reasonable cost for its ambulance services only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. However, if there is a provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 2), the CAH-owned and operated entity would not be paid at 101 percent of reasonable cost, but instead would be paid under the ambulance fee-schedule.

In addition, we are proposing to establish a policy that would address the "gap" in the statutory language, that is, where the CAH-owned and operated entity furnishing ambulance services is more than a 35-mile drive from the CAH, but there is no other provider or supplier of ambulance services located within a 35-mile drive of the CAH. We are proposing to include in the proposed new paragraph (C) of § 413.70(b)(5)(i) a provision which states that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services within a 35-mile drive of the CAH but there is a CAH-owned and operated entity that is more than a 35-mile drive from the CAH, the CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH (Figure 3). Allowing the CAH-owned and operated entity to be paid at 101 percent of reasonable cost if there is no other provider or supplier of ambulance services that is closer to the CAH is consistent with the original purpose of section 1834(l)(8) of the Act, which was intended to help ensure an adequate level of ambulance services in areas served by CAHs. The statute allows for reasonable cost-based payment only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. If there is another provider or supplier of ambulance services located within a 35-mile drive of the CAH, the statute does not allow for payment to the CAH or a CAH-owned and operated entity at 101 percent of reasonable cost because there is an adequate level of ambulance services available. Accordingly, where a CAH-owned and operated entity is located more than a 35-mile drive from the CAH, we are proposing to allow payment at 101 percent of reasonable cost only if there is no other provider or supplier of ambulance services located closer to the CAH. If there is a closer provider or supplier of ambulance services, that closer provider or supplier would also be assuring an adequate level of ambulance services in the area served by the CAH, and there would be no need to pay the CAH-owned and operated entity at 101 percent of reasonable cost in order to ensure access to ambulance services. Therefore, if the CAH-owned and operated entity (located more than a 35-mile drive from the CAH) is not the closest provider or supplier of ambulance services to the CAH (Figure 4), the CAH-owned and operated entity would be reimbursed under the ambulance fee schedule.

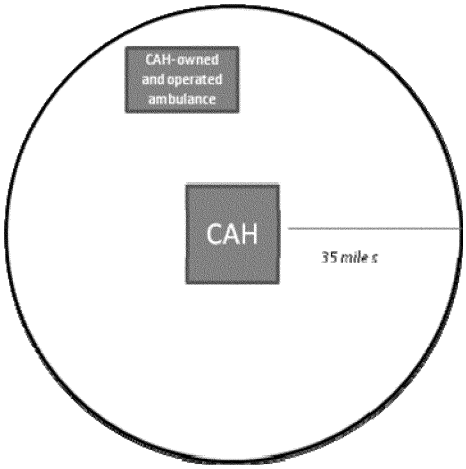



*Figure 1:*
The CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance service because there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH.

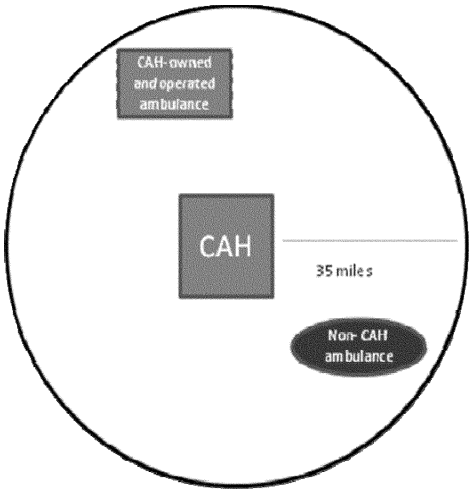



*Figure 2:*
The CAH-owned and operated entity would be paid under the ambulance fee schedule for its ambulance services because the CAH-owned and operated entity is not the only provider or supplier of ambulance services located within a 35-mile drive of the CAH.

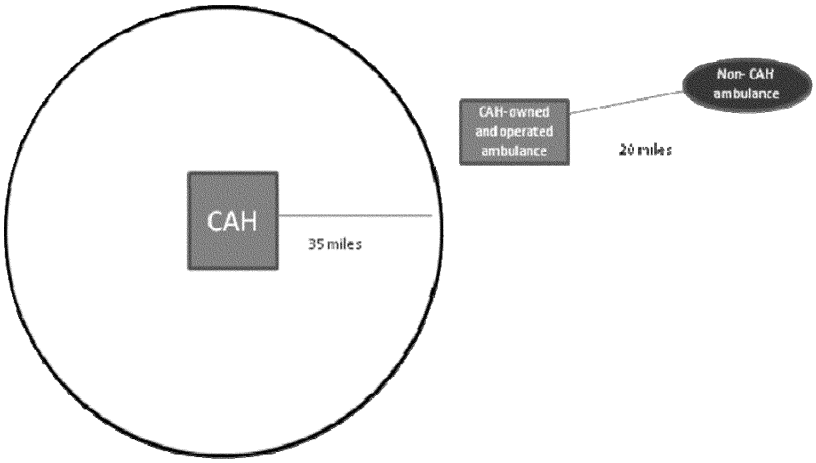


*Figure 3:*

The CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services because even though the CAH-owned and operated entity is more than a 35-mile drive from the CAH, it is the closest provider or supplier of ambulance services to the CAH.

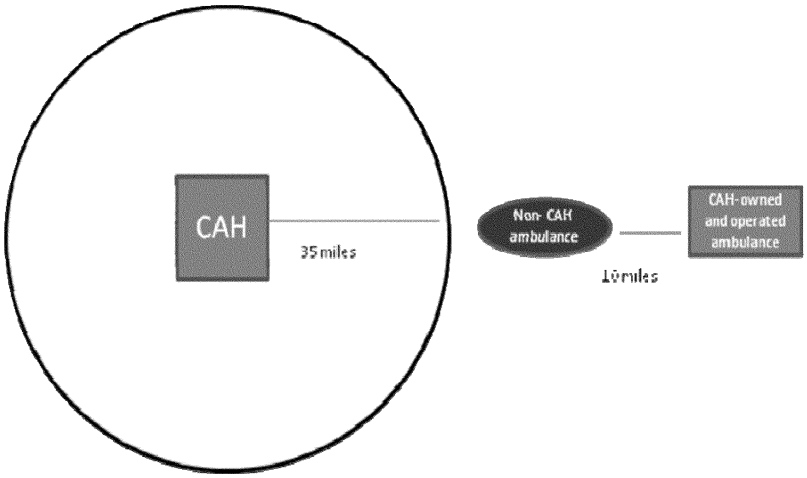



*Figure 4:*

The CAH-owned and operated entity would receive payment under the ambulance fee schedule for its ambulance service because there is another provider or supplier of ambulance services that is closer to the CAH than the CAH-owned and operated entity.

In summary, we are proposing to amend § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. In addition, we are proposing to include in the proposed new § 413.70(b)(5)(i)(C) a provision to state that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity more than a 35-mile drive from the CAH, the CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. We also are making a conforming change to § 413.70(b)(5)(i)(B) to make the effective date of that paragraph consistent with the effective date of the new proposed paragraph (C).

## VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2012

### *A. Background of the LTCH PPS*

#### 1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a "per discharge" system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)

(Pub. L. 97–248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR Part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in section VIII. of this preamble, when we refer to discharges, the intent is to describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period. During this 5-year transition period, a LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts. However, effective for cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR Part 412, Subpart O also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the June 6, 2003 **Federal Register**, we published a final rule that set forth the FY 2004 annual update of the payment rates for the Medicare PPS for inpatient hospital services furnished by LTCHs (68 FR 34122). It also changed the annual period for which the payment rates were to be effective, such that the annual updated rates were effective from July 1 through June 30 instead of from October 1 through September 30. We referred to the July through June time period as a "long-term care hospital rate year" (LTCH PPS rate year). In addition, we changed the publication schedule for the annual update to allow for an effective date of July 1. The payment amounts and factors used to determine the annual update of the LTCH PPS Federal rate are based on a LTCH PPS rate year. In the past, while the LTCH payment rate updates were effective July 1, the annual update of the DRG classifications and relative weights for LTCHs continued to be linked to the annual adjustments of the acute care hospital inpatient DRGs and were effective each October 1.

As discussed in detail in the RY 2009 LTCH PPS final rule (73 FR 26797 through 26798), we again changed the schedule for the annual updates of the LTCH PPS Federal payment rates beginning with RY 2010. We consolidated the rulemaking cycle for the annual update of the LTCH PPS Federal payment rates and description of the methodology and data used to calculate these payment rates with the annual update of the MS–LTC–DRG classifications and associated weighting factors for LTCHs so that the updates to the rates and the relative weights now occur on the same schedule and appear in the same publication. As a result, the updates to the rates and the relative weights are now effective on October 1 (on a Federal fiscal year schedule), and the annual updates to the LTCH PPS Federal rates are no longer published with a July 1 effective date.

Public Law 110–173 (MMSEA), enacted on December 29, 2007, included provisions that have various effects on the LTCH PPS. In addition to amending section 1861 of the Act to add a subsection (ccc) which provided an additional definition of LTCHs, Public Law 110–173 also required the Secretary to submit, no later than 18 months after the date of enactment of the law, a report to Congress on a study of national long-term care hospital facility and patient criteria that included "recommendations for such legislation and administrative actions, including timelines for the implementation of LTCH patient criteria or other actions, as the Secretary determines appropriate." The payment policy provisions under sections 114(c)(1) and (c)(2) of Public Law 110–173 focused on providing 3 years of relief for certain LTCHs from the percentage threshold payment adjustment policy at 42 CFR 412.534 and 412.536. However, because of the original implementation schedule of those sections of the regulations, the payment provisions had varying timeframes of applicability (73 FR 29701 through 29704). In addition, section 114(c)(3) of Public Law 110–173 provided that the Secretary shall not apply, for the 3-year period beginning on the date of enactment of the Act the revision to the short-stay outlier (SSO) policy that was finalized in the RY 2008 LTCH PPS final rule (72 FR 26904 and 26992). In addition, section 114(c)(4) of Public Law 110–173 provided that the Secretary shall not, for the 3-year period beginning on the date of enactment of the Act, make the one-time adjustment to the payment rates provided for in § 412.523(d)(3) or any similar provision (73 FR 26800 through 26804). The statute also provided that the base rate for RY 2008 be the same as the base rate for RY 2007 (the revised base rate, however, does not apply to discharges occurring on or after July 1, 2007, and before April 1, 2008) (73 FR 24875 through 24877). Section 114(d) of Public Law 110–173 established a 3-year moratorium (with specified exceptions) on the establishment and classification of new LTCHs, LTCH satellites, and on the increase in the number of LTCH beds in existing LTCHs or satellite facilities. Finally, section 114(f) of Public Law 110–173 provided for an expanded review of medical necessity for admission and continued stay at LTCHs.

In the RY 2009 LTCH PPS final rule (73 FR 26804 through 26812), we established the applicable Federal rates for RY 2009, consistent with section 1886(m)(2) of the Act as amended by Public Law 110–173. We also revised the regulations at § 412.523(d)(3) to change the methodology for the one-time budget neutrality adjustment and to comply with section 114(c)(4) of Public Law 110–173. Other policy revisions that were necessary as a result of the statutory changes of Public Law 110–173 were addressed in separate interim final rules with comment period (73 FR 24871 and 73 FR 29699). In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43976 through 43990), we addressed all of the public comments received and finalized these two interim final rules with comment period.

Section 4302 of the ARRA, Public Law 111–5, enacted on February 17, 2009, included several amendments to the provisions set forth in section 114 of Public Law 110–173. Specifically, section 4302(a) modified the effective

dates of the provisions of section 114(c) of Public Law 110–173, described above, and added an additional category of LTCHs or satellite facilities that would not be subject to the percentage threshold payment adjustment at § 412.536 for a 3-year period. In addition, section 4302(a)(2)(A) of Public Law 111–5 added "grandfathered" satellites (specified in § 412.22(h)(3)(i) of the regulations) to those "applicable" LTCHs (specified in § 412.534(g) of the regulations) originally granted relief under section 114(c) of Public Law 110–173. We issued instructions to the fiscal intermediaries and MACs interpreting the provisions of section 4302 of Public Law 111–5 (Change Request 6444). In addition, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43990 through 43992), we implemented the provisions of section 4302 of Public Law 111–5 through an interim final rule with comment period. We received one piece of timely correspondence regarding the provisions of section 4302 of Public Law 111–5 that were implemented through the interim final rule with comment period that was included in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. We addressed this public comment and finalized the interim final rule with comment period in section VII.E. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399).

As discussed in the FY 2011 IPPS/LTCH PPS final rule, a number of the provisions of the Affordable Care Act affected the policies, payment rates and factors under the LTCH PPS. Specifically, section 1886(m)(3)(A)(ii) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for each of rate years 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in new section 1886(m)(4) of the Act. Furthermore, section 1886(m)(3)(A)(i) of the Act specifies that, for rate year 2012 and subsequent rate years, any annual update to the standard Federal rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(m)(3)(A)(ii) and sections 1886(m)(4)(A) and (B) of the Act require a 0.25 percentage point reduction for rate year 2010 and a 0.50 percentage point reduction for rate year 2011. Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. Furthermore, section 3401(p) of the Affordable Care Act specifies that the amendments made by section 3401(c) of such Act shall not apply to discharges occurring before April 1, 2010 (75 FR 50387 through 50390). Sections 3106 and 10312 of the Affordable Care Act together provide for a 2-year extension to the payment policies applicable to LTCHs and LTCH satellite facilities set forth in sections 114(c) and (d)(1) of the MMSEA, as amended by the ARRA. Specifically, sections 3106 and 10312 of the Affordable Care Act together result in the phrase "3-year period" being replaced with the phrase "5-year period" each place it appears in sections 114(c) and (d)(1) of MMSEA, as amended by the ARRA. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400), sections 3106 and 10312 of the Affordable Care Act, which amended sections 114(c) and (d)(1) of the MMSEA, as amended by the ARRA, result in the following:

- An additional 2-year delay in the application of the SSO payment adjustment, which would have applied the additional payment option of an "IPPS comparable" payment to LTCHs for certain SSO cases where the covered length of stay is less than or equal to the "IPPS comparable threshold." Therefore, the Secretary will not apply this SSO payment adjustment for the 5-year period beginning on the date of enactment of MMSEA (December 29, 2007).
- An additional 2-year delay in the one-time prospective budget neutrality adjustment to the standard Federal rate (§ 412.523(d)(3)). Thus, the Secretary is precluded from making the one-time adjustment to standard Federal rate until December 29, 2012.
- An increase from 3 years to 5 years to the timeframes set forth in section 114(c) of the MMSEA as amended by the ARRA, thereby extending for an additional 2 years the delay in the application of the 25-percent payment threshold policy for certain LTCHs and LTCH satellite facilities (§§ 412.534 and 412.536), and extending for an additional 2 years, the increased percentage thresholds outlined at section 114(c)(2) of the MMSEA as amended by the ARRA.
- Additional 2-year extensions of the moratorium on the establishment of new LTCHs and LTCH satellite facilities and the moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities as provided by section 114(d) of the MMSEA as amended by the ARRA. In general, section 114(d) of the MMSEA as amended by the ARRA precluded the establishment and classification of new LTCHs or LTCH satellite facilities or additional beds from being added to existing LTCHs or LTCH satellite facilities unless one of the specified exceptions to the particular moratorium was met.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at § 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient length of stay (LOS) of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c), and therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to

the LTCH is the full LTC–DRG payment amount, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services as specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the SSO threshold is exceeded. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services "for which a claim is submitted other than in an electronic form specified by the Secretary." Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial "in such unusual cases as the Secretary finds appropriate" (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR parts 160 and 162, Subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic healthcare transactions according to the applicable transactions and code sets standards.

*B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2012*

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS for LTCHs (that is, a per discharge system with a diagnosis-related group (DRG)-based patient classification system reflecting the differences in patient resources and costs). Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine "the feasibility and the impact of basing payment under such a system [the long-term care hospital (LTCH) PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients, as well as the use of the most recently available hospital discharge data."

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system (that is, the CMS DRGs) that was utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the "long-term care diagnosis-related groups (LTC–DRGs)." Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect "the differences in patient resource use * * *" of LTCH patients (section 123(a)(1) of the BBRA (Pub. L. 106–113)).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development and implementation and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.) We believe the MS–DRGs (and by extension, the MS–LTC–DRGs) represent a substantial improvement over the previous CMS DRGs in their ability to differentiate cases based on severity of illness and resource consumption.

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. As described in section II.G. of this preamble, for FY 2012 we are proposing to delete one MS–DRG and create two new MS–DRGs for a net gain of one MS–DRG. If this proposal is adopted, we would have a total of 751 MS–DRG groupings. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, and as discussed in greater detail below in section VII.B.3.f. of this preamble, we are proposing to continue to use low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 LTCH cases) in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we are proposing to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) We also are proposing to account for adjustments to payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG). Furthermore, we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS–LTC–DRG system that are more severe require greater expenditure of medical care resources and will result in higher average charges

such that, in the severity levels within a base MS–LTC–DRG, the weights should increase monotonically with severity from the lowest to highest severity level. (We discuss nonmonotonicity in greater detail and our proposed methodology to adjust the FY 2011 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights in section VII.B.3.g. (Step 6) of this preamble.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–9–CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKG), or minor surgical procedures (for example, biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS–LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Through FY 2010, the number of secondary or additional diagnoses and the number of surgical procedures considered for MS–DRG assignment was limited to eight and six, respectively. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we established that, for claims submitted on the 5010 format beginning January 1, 2011, we would increase the capacity to process diagnosis and procedure codes up to 25 diagnoses and 25 procedures. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. We refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule for a complete discussion of this change (75 FR 50127).

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). HIPAA Transactions and Code Sets Standards regulations at 45 CFR Parts 160 and 162 require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of Subparts A and I through R of Part 162. Among other requirements, those provisions direct covered entities to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, and the applicable standard medical data code sets for the institutional health care claim or equivalent encounter information transaction (45 CFR 162.1002 and 45 CFR 162.1102). For additional information on the ICD–9–CM Coding System, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples are published in the *Coding Clinic for ICD–9–CM,* a product of the American Hospital Association. (We refer readers to section II.G.13. of this preamble for additional information on the annual revisions to the ICD–9–CM codes.)

With respect to the ICD–9–CM coding system, we have been discussing the conversion to the ICD–10–CM and the ICD–10–PCS coding systems for many years. As is discussed in detail in section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50127) and in section III.G.13 of this proposed rule, the ICD–10 coding systems applicable to hospital inpatient services will be implemented on October 1, 2013. In order for the industry to make the necessary conversions from ICD–9–CM to ICD–10–CM and ICD–10–PCS, we proposed, through the ICD–9–CM Coordination and Maintenance Committee, to consider a moratorium on updates to the ICD–9–CM and ICD–10 coding sets. We refer readers to section II.G.13. of this preamble for additional information on the adoption of the ICD–10–CM and ICD–10–PCS systems.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), individual DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into three, two, or one level, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication and comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare contractors (that is, fiscal intermediaries and MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes

and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2012

As specified by our regulations at § 412.517(a), which requires that the MS–LTC–DRG classifications and relative weights be updated annually and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2011, through September 30, 2012 (FY 2012) consistent with the proposed changes to specific MS–DRG classifications presented in section II.G. of this proposed rule (that is, proposed GROUPER Version 29.0). Therefore, the proposed MS–LTC–DRGs for FY 2012 presented in this proposed rule are the same as the proposed MS–DRGs that would be used under the IPPS for FY 2012. In addition, because the proposed MS–LTC–DRGs for FY 2012 are the same as the proposed MS–DRGs for FY 2012, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed Version 29.0 of the GROUPER discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and proposed changes to the ICD–9–CM coding system, also would be applicable under the LTCH PPS for FY 2012.

3. Development of the Proposed FY 2012 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55984), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case.

Although the adoption of the MS–LTC–DRGs resulted in some modifications of existing procedures for assigning weights in cases of zero volume and/or nonmonotonicity (as discussed in the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550)), the basic methodology for developing the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule continues to be determined in accordance with the general methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2012

Beginning with the FY 2008 update, we established a budget neutrality requirement for the annual update to the MS–LTC–DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the classification and relative weight changes (RY 2008 LTCH PPS final rule (72 FR 26882 through 26884)). Consistent with § 412.517(b), we are proposing to apply a two-step budget neutrality methodology, which is based on the current year MS–LTC–DRG classifications and relative weights. (For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296).) Thus, for this proposed rule, the annual update to the MS–LTC–DRG classifications and relative weights for FY 2012 are based on the FY 2011 MS–LTC–DRG classifications and relative weights established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50627).

c. Data

In this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2012, we are proposing to obtain total charges from FY 2010 Medicare LTCH bill data from the December 2010 update of the FY 2010 MedPAR file, which are the best available data at this time, and to use the proposed Version 29.0 of the GROUPER to classify LTCH cases. We also are proposing that if more recent data become available, we would to use those data and the finalized Version 29.0 of the GROUPER in establishing the FY 2012 MS–LTC–DRG relative weights in the final rule.

Consistent with our historical methodology, we are proposing to exclude the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, as is the case with the IPPS, Medicare Advantage (Part C) claims are now included in the MedPAR files (74 FR 43808). Consistent with IPPS policy, we are proposing to continue to exclude such claims in the calculations for the relative weights under the LTCH PPS that are used to determine payments for fee-for-service Medicare claims. Specifically, we are proposing to remove any claims from the MedPAR files that have a GHO Paid indicator value of "1," which effectively removes Medicare Advantage claims from the relative weight calculations (73 FR 48532). Therefore, in the development of the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, we are proposing to exclude the data of 13 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the FY 2010 MedPAR file, as well as any Medicare Advantage claims.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we are proposing to continue to use a hospital-specific relative value

(HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2012. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, we are proposing to reduce the impact of the variation in charges across providers on any particular proposed MS–LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjust those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, we are proposing to continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described below in section VII.B.3.g. (step 3) of the preamble of this proposed rule) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of DRGs based on volume of cases within specific MS–LTC–DRGs. MS–LTC–DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS–LTC–DRGs (that is, no cases in the given year's claims data were assigned to those MS–LTC–DRGs) are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). In this proposed rule, we are proposing to continue to utilize these same three categories of MS–LTC–DRGs for purposes of determining the proposed MS–LTC–DRG relative weights for FY 2012. (We provide in-depth discussions of our proposed policy regarding weight-setting for proposed low-volume MS–LTC–DRGs in section VII.B.3.f. of the preamble of this proposed rule and for proposed no-volume MS–LTC–DRGs, under Step 5 in section VII.B.3.g. of the preamble of this proposed rule.)

As also noted above, while the LTCH PPS and the IPPS use the same patient classification system, the methodology that is used to set the DRG relative weights for use in each payment system differs because the overall volume of cases in the LTCH PPS is much less than in the IPPS. In general, consistent with our existing methodology, we are proposing to use the following steps to determine the proposed FY 2012 MS–LTC–DRG relative weights: (1) If a proposed MS–LTC–DRG has at least 25 cases, it is assigned its own proposed relative weight; (2) if a proposed MS–LTC–DRG has between 1 and 24 cases, it is assigned to a quintile for which we compute a proposed relative weight for all of the proposed MS–LTC–DRGs assigned to that quintile; and (3) if a proposed MS–LTC–DRG has no cases, it is cross-walked to another proposed MS–LTC–DRG based upon clinical similarities to assign an appropriate proposed relative weight (as described below in detail in Step 5 of section VII.B.3.g. of this preamble). Furthermore, in determining the proposed FY 2012 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology we are proposing, for purposes of determining the proposed FY 2012 MS–LTC–DRG relative weights, to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group those proposed "low-volume MS–LTC–DRGs" (that is, proposed MS–LTC–DRGs that contained between 1 and 24 cases annually) into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS–LTC–DRG to quintiles resulted in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology, we are proposing to make adjustments to the treatment of proposed low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.B.3.g. (Step 6) in this preamble.

In this proposed rule, using LTCH cases from the December 2010 update of the FY 2010 MedPAR file, we identified 277 MS–LTC–DRGs that contained between 1 and 24 cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 55 proposed MS–LTC–DRGs (277/5 = 55 with 2 proposed MS–LTC–DRG as the remainder). We assigned a proposed low-volume MS–LTC–DRG to a specific

low-volume quintile by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Furthermore, because the number of MS–LTC–DRGs with less than 25 cases is not evenly divisible by 5, the average charge of the low-volume quintile was used to determine which of the proposed low-volume quintiles would contain the 2 additional proposed low-volume MS–LTC–DRGs. Specifically, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 55th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The proposed MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 56th proposed low-volume MS–LTC–DRG in the sorted list is closer to the average charge of the 55th proposed low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 57th proposed low-volume MS–LTC–DRG (assigned to Quintile 2), we are proposing to assign it to Quintile 1 (such that Quintile 1 would contain 56 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This process was repeated through the remaining proposed low-volume MS–LTC–DRGs so that 3 of the 5 low-volume quintiles contain 55 proposed MS–LTC–DRGs (Quintiles 2, 3, and 5) and the other 2 low-volume quintiles contain 56 proposed MS–LTC–DRGs (Quintiles 1 and 4). Table 13A, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the composition of the proposed low-volume quantitles for MS–LTC–DRGs for FY 2012.

Accordingly, in order to determine the proposed FY 2012 relative weights for the proposed MS–LTC–DRGs with low volume, we are proposing to use the 5 low-volume quintiles described above. The proposed composition of each of the 5 low-volume quintiles shown in the chart below was used in determining the proposed FY 2012 MS–LTC–DRG relative weights (as shown in Table 11 listed in section VI. of the Addendum to this proposed rule and available via the Internet). We determined a proposed relative weight and (geometric) average length of stay for each of the 5 low-volume quintiles using the methodology that we are proposing to apply to the proposed MS–LTC–DRGs (25 or more cases), as described in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a proposed low volume of LTCH cases will vary in the future. We are proposing to use the best available claims data in the MedPAR file to identify proposed low-volume MS–LTC–DRGs and to calculate the proposed relative weights based on our methodology.

We note that we will continue to monitor the volume (that is, the number of LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the proposed MS–LTC–DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2012 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing, in general, to determine the FY 2012 MS–LTC–DRG relative weights based on our existing methodology. For additional information on the original development of this methodology, and modifications to it since the adoption of the MS–LTC–DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).

In summary, for FY 2012, to determine the proposed FY 2012 MS–LTC–DRG relative weights, we are proposing to group LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintile (as described above). After grouping the cases to the appropriate MS–LTC–DRG (or low-volume quintile), we are proposing to calculate the proposed FY 2012 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (as discussed in greater detail below). Next, we are proposing to adjust the number of cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (step 3 below). After removing statistical outliers (step 1 below) and cases with a length of stay of less than 8 days (step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate proposed "relative adjusted weights" for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the proposed FY 2012 MS–LTC–DRG relative weights. We note that, as we stated in section VII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the FY 2010 MedPAR file.

*Step 1*—Remove statistical outliers.

The first step in the calculation of the proposed FY 2012 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each proposed MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the proposed MS–LTC–DRGs. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

*Step 2*—Remove cases with a length of stay of 7 days or less.

The proposed MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2012 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short-stays. Therefore, consistent with our historical relative weight methodology, in determining the proposed FY 2012 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less. (For additional information on this step of the relative weight methodology,

we refer readers to 67 FR 55989 and 74 FR 43959.)

*Step 3*—Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the proposed FY 2012 MS–LTC–DRG relative weights, consistent with our historical relative weight methodology, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the proposed MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the proposed MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the proposed MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2012 MS–LTC–DRG relative weights would lower the proposed FY 2012 MS–LTC–DRG relative weight for affected proposed MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a proposed MS–LTC–DRG. This would result in an "underpayment" for non-SSO cases and an "overpayment" for SSO cases. Therefore, we are proposing to adjust for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

*Step 4*—Calculate the proposed FY 2012 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2012 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we are proposing to calculate a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH case (after removing the statistical outliers (see Step 1)) and LTCH cases with a length of stay of 7 days or less (see Step 2) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce a proposed adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS–LTC–DRG, we are proposing to calculate the proposed FY 2012 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed MS–LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) is calculated by dividing the sum of all the LTCH's proposed MS–LTC–DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values above were multiplied by these hospital-specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

*Step 5*—Determine a proposed FY 2012 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2012 relative weight for each proposed MS–LTC–DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the December 2010 update of the FY 2010 MedPAR file for this proposed rule). Using these data, we identified a number of proposed MS–LTC–DRGs for which there were no LTCH cases in the database, such that no patients who would have been classified to those proposed MS–LTC–DRGs were treated in LTCHs during FY 2010 and, therefore, no charge data were available for these proposed MS–LTC–DRGs. Thus, in the process of determining the proposed MS–LTC–DRG relative weights, we were unable to calculate proposed relative weights for the proposed MS–LTC–DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of "transplant" MS–LTC–DRGs and "error" MS–LTC–DRGs, as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

In general, we are proposing to determine proposed FY 2012 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the FY 2010 MedPAR file used in this proposed rule (that is, proposed "no-volume" MS–LTC–DRGs) by cross-walking each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG with a calculated proposed relative weight (determined in accordance with the proposed methodology described above). Then, the proposed "no-volume" MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 751 proposed MS–LTC–DRGs for FY 2012, we identified 237 proposed MS–LTC–DRGs for which there were no LTCH cases in the database (including the 8 "transplant" proposed MS–LTC–DRGs and 2 "error" proposed MS–LTC–DRGs). As stated above, we are proposing to assign relative weights for each of the 237 proposed no-volume MS–LTC–DRGs (with the exception of the 8 "transplant" proposed MS–LTC–DRGs and the 2 "error" proposed MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 514 (751—237= 514) proposed MS–LTC–DRGs for which we were able to determine proposed relative weights based on FY 2010 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the proposed "cross-walked" MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we crosswalk one of the 237 proposed "no volume" MS–LTC–DRGs for purposes of determining a proposed relative weight.) Then, we assigned the proposed no-volume MS–LTC–DRG the proposed relative weight of the proposed cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this proposed rule, we are proposing to crosswalk the proposed no-volume MS–LTC–DRG to a proposed MS–LTC–DRG for which there were LTCH cases in the FY 2010 MedPAR file, and to which it is similar clinically

in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable proposed MS–LTC–DRG to which a proposed no-volume MS–LTC–DRG was cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2012. (For more detail on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the proposed no-volume MS–LTC–DRGs in FY 2012, the proposed relative weights assigned based on the proposed cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the proposed cross-walked MS–LTC–DRG as the proposed relative weight for the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2012. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which was calculated using the proposed methodology described in Steps 1 through 4 above, was assigned to the proposed no-volume MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume MS–LTC–DRG is cross-walked had 24 or less cases and, therefore, was designated to one of the low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable low-volume quintile to the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2012. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS–LTC–DRG results, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the proposed no-volume MS–LTC–DRGs and the proposed MS–LTC–DRG to which it is cross-walked (that is, the proposed cross-walked MS–LTC–DRG) for FY 2012 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the FY 2012 MS–LTC–DRGs with no LTCH cases, we are providing the following example, which refers to the proposed no-volume MS–LTC–DRGs crosswalk information for FY 2012 provided in Table 13B.

*Example:* There were no cases in the FY 2010 MedPAR file used for this proposed rule for MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 70 (Nonspecific Cebrovascular Disorders with MCC) was similar clinically and based on resource use to MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight of MS–LTC–DRG 70 of 0.8062 for FY 2012 to MS–LTC–DRG 61 (Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available vie the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume of LTCH cases based on the system will vary in the future. We are proposing to use the most recent available claims data in the MedPAR file to identify proposed no-volume MS–LTC–DRGs and to determine the proposed relative weights in this proposed rule.

Furthermore, for FY 2012, consistent with our historical relative weight methodology, we are proposing to establish proposed MS–LTC–DRG relative weights of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (proposed MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (proposed MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (proposed MS–LTC–DRG 5); Liver Transplant without MCC (proposed MS–LTC–DRG 6); Lung Transplant (proposed MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (proposed MS–LTC–DRG 8); Pancreas Transplant (proposed MS–LTC–DRG 10); and Kidney Transplant (proposed MS–LTC–DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these proposed eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

*Step 6*—Adjust the proposed FY 2012 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as "without CC/MCC." When data do not support the creation of three severity levels, the base DRG is subdivided into either two levels or the base DRG is not subdivided. The two-level subdivisions could consist of the DRG with CC/MCC and the DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the DRG with MCC and the DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the "without CC/MCC" MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the "with CC/MCC" MS–LTC–DRG (in the case of a two-level split) or both the "with CC" and the "with MCC" MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, proposed relative weights should increase by severity, from lowest to highest. If the proposed relative weights decrease as severity decreased (that is, if within a base proposed MS–LTC–DRG, a proposed MS–LTC–DRG with CC has a higher proposed relative weight than one with MCC, or the proposed MS–LTC–DRG without CC/MCC has a higher proposed relative weight than either of the others), they are nonmonotonic. We

continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, consistent with our historical methodology we are proposing to combine proposed MS–LTC–DRG severity levels within a base proposed MS–LTC–DRG for the purpose of computing a proposed relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in sectin VI. of the Addendum to this proposed rule and is available via the Internet.

*Step 7*— Calculate the proposed FY 2012 budget neutrality factor.

As we established in the RY 2008 LTCH PPS final rule (72 FR 26882), under the broad authority conferred upon the Secretary to develop the LTCH PPS under section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554, beginning with the MS–LTC–DRG update for FY 2008, the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes (§ 412.517(b) in conjunction with § 412.503). (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in accordance with § 412.503). Under the budget neutrality requirement at § 412.517(b), for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2012 based on the most recent available LTCH data, and to apply a budget neutrality adjustment in determining the proposed FY 2012 MS–LTC–DRG relative weights.

To ensure budget neutrality in the proposed update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing for FY 2012 to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced by changes in the composition of case types or the changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the proposed normalization factor for FY 2012 (the first step of our budget neutrality methodology), we are proposing to use the following three steps: (1.a.) We used the most recent available LTCH claims data (FY 2010) and grouped them using the proposed FY 2012 GROUPER (Version 29.0) and the proposed recalibrated FY 2012 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2012 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2010) using the FY 2011 GROUPER (Version 28.0) and FY 2011 MS–LTC–DRG relative weights and calculated the average CMI; and (1.c.) we computed the ratio of these average CMIs by dividing the average CMI for FY 2011 (determined in Step 1.b.) by the proposed average CMI for FY 2012 (determined in step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2012, each proposed recalibrated MS–LTC–DRG relative weight was multiplied by 1.11482 in the first step of the budget neutrality methodology, which produced "normalized relative weights."

In this proposed rule, in the second step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing to determine a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the proposed FY 2012 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2011 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2010 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2011 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2012 MS–LTC–DRGs and relative weights. Furthermore, consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to determine the budget neutrality adjustment factor for FY 2012 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2012 budget neutrality adjustment factor using the following three steps: (2.a.) we simulated estimated total LTCH PPS payments using the proposed normalized relative weights for FY 2012 and proposed GROUPER Version 29.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights shown in Table 11 of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50626); and (2.c.) we calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights (determined in step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2012 GROUPER (Version 29.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2012 (determined in Step 2.a.). In determining the proposed FY 2012 MS–LTC–DRG relative weights, each proposed normalized relative weight was multiplied by a budget neutrality factor of 0.994312 in the second step of the proposed budget neutrality methodology to determine the proposed budget neutral FY 2012 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.11482 and a budget neutrality factor of 0.994312 (computed as described above). Table 11, which is listed in sectin VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used in determining SSO payments under § 412.529) for FY 2012. The proposed FY 2012 MS–LTC–DRG relative weights in Table 11, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, reflect both the proposed normalization factor of 1.11482 and the proposed budget neutrality factor of 0.994312.

*C. Proposed Quality Reporting Program for LTCHs*

1. Background and Statutory Authority

CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information. Such quality reporting programs already exist for various settings such as hospital inpatient services via the Hospital Inpatient Quality Reporting (IQR) Program (formerly called the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program), hospital outpatient services via the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and physicians' and other eligible professionals' services via the Physician Quality Reporting System (formerly called the Physician Quality Reporting Initiative, or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program (ESRD QIP) that links payment to performance.

Section 3004(a) of the Affordable Care Act authorizes an additional quality reporting program for LTCHs, by adding a new paragraph (5) to section 1886(m) of the Act. Section 1886(m)(5)(A)(i) of the Act requires that, for rate year 2014 and each subsequent rate year, the Secretary shall reduce any annual update to the standard Federal rate for discharges occurring during such rate year, by 2 percentage points, for any LTCH that does not comply with quality data submission requirements with respect to an applicable rate year. We note that section 1886(m)(5) of the Act uses the term "rate year." Beginning with the annual update to the LTCH PPS that took effect on October 1, 2009, we consolidated the rulemaking cycle for the annual update of the LTCH PPS Federal payment rates with the annual update of the MS–LTC–DRG classifications and weights so that the annual updates to the rates and factors have an October 1 effective date and occur on the same schedule. To reflect this change to the annual payment rate update cycle, we revised the regulations at § 412.503 to specify that, beginning on or after October 1, 2009, the "LTCH PPS rate year" is defined as October 1 through September 30 (73 FR 26797 through 26798 and 26838). Beginning October 1, 2010, we changed from using the term "rate year" to "fiscal year" under the LTCH PPS in order to conform to the standard definition of the Federal fiscal year (October 1 through September 30). For LTCH PPS purposes, the term "rate year" and the term "fiscal year" both refer to the time period beginning October 1 and ending September 30. For more information regarding this terminology change, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50396 and 50397). For purposes of the discussion below, in order to eliminate any possible confusion that may be caused by using the term "rate year" with respect to the proposed Quality Measurement Reporting Program for LTCHs, we will use the term "fiscal year" rather than "rate year."

As provided at section 1886(m)(5)(A)(ii) of the Act, depending on the amount of annual update for a particular year, a reduction of 2.0 percentage points may result in the annual update being less than 0.0 percent for a fiscal year and may result in payment rates under the LTCH PPS being less than payment rates for the preceding fiscal year. In addition, as set forth at section 1886(m)(5)(B) of the Act, any reduction based on failure to comply with the reporting requirements, as required by section 1886(m)(5)(A) of the Act, shall apply only with respect to the particular fiscal year involved, and any such reduction shall not be taken into account in computing the payment rate for subsequent fiscal years.

Section 1886(m)(5)(C) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, each LTCH shall submit to the Secretary data on quality measures as specified by the Secretary. Such data must be submitted in a form and manner, and at a time, specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We have generally adopted NQF-endorsed measures in our reporting programs.

However, section 1886(m)(5)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act (currently, NQF), the Secretary may specify a measure(s) that is (are) not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under section 1886(m)(5)(D)(iii) of the Act, the Secretary shall publish, by no later than October 1, 2012, measures which shall be applicable with respect to the FY 2014 payment determination.

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making data submitted under the LTCH quality reporting program available to the public. The Secretary must ensure that each LTCH has the opportunity to review the data that are to be made public with respect to that facility prior to such data being made public. The Secretary must also report quality measures that relate to services furnished in LTCHs on the CMS Web site.

2. Proposed Quality Measures for the LTCH Quality Reporting Program for FY 2014

a. Considerations in the Selection of the Proposed Quality Measures

In implementing the LTCH quality reporting program, we believe that the development of a quality reporting program that is successful in promoting the delivery of high quality health care services in LTCHs is of paramount importance. As the statute provides in section 1886(m)(5)(D) of the Act, in establishing the LTCH quality reporting program, we must publish quality measures to be reported with respect to the FY 2014 payment determination no later than October 1, 2012. In an effort

to meet that mandate, we sought to develop a quality reporting program that incorporates overarching health care aims and goals intended to facilitate quality care in a manner that is effective and meaningful, while remaining mindful of reporting burden and feasibility of data collection by LTCHs, in order to reduce and avoid duplicative reporting efforts when possible. We seek to efficiently collect information on valid, reliable, and relevant measures of quality and to share this information with the public, as provided at section 1886(m)(5)(E) of the Act.

Several provisions of the Affordable Care Act, taken together, call on the Secretary to establish a national strategy to provide a comprehensive plan and priorities to improve the delivery of health care services, patient health outcomes, and population health through a transparent, collaborative process. This strategy, the National Quality Strategy, was released by the Secretary (available on the Web site at: *http://www.healthcare.gov/center/reports/quality03212011a.html#es)*. We have used the priorities of the National Quality Strategy to guide identification of the proposed quality measures for LTCHs under section 1886(m)(5) of the Act.

We also applied the following additional considerations and criteria in selecting the proposed quality measures for LTCHs: whether a measure is included in, or facilitates alignment with, other Medicare and Medicaid programs; whether a measure addresses HHS priorities, such as prevention, care of chronic illness, high prevalence conditions, patient safety, patient and caregiver engagement, and care coordination; and whether a measure is evidence-based and may drive quality improvement as well as has a low probability of causing unintended adverse consequences, such as reduced LTCH admissions of higher risk patients.

Furthermore, at the Listening Session held on November 15, 2010, for the Affordable Care Act section 3004 quality reporting programs, we sought input, and invited comments and suggestions, regarding quality reporting, quality measurement recommendation, prioritization, and feasibility, and did the same through the use of a Special Open Door Forum held on December 16, 2010, for the Affordable Care Act section 3004 quality reporting programs. Transcripts for both the Listening Session and the Open Door Forum can be found on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.*

In addition, we invited suggestions and input regarding the section 3004 quality reporting programs to be sent to us using the CMS Web site mail box *LTCH-IRF-Hospice-Quality-ReportingComments@cms.hhs.gov* found at *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.* We also received suggestions and input from a LTCH technical expert panel (TEP), convened by the CMS measure development contractor on January 31, 2011, that reviewed and prioritized the quality measures identified by a LTCH environmental scan led by a CMS measures development contractor, RTI International, specifically for the LTCH quality reporting program. Specifically, this TEP reviewed measures found in the environmental scan and rated them for importance, scientific soundness, usability, and feasibility.

In sum, in selecting the proposed quality measures discussed below, with applicability for FY 2014 and subsequent years, our goal is to achieve several objectives. First, the proposed measures should relate to the general aims of better care for the individual, better population health, and lower cost through better quality. Second, the proposed measures should promote improved quality specifically to the priorities that are of most relevance to LTCHs. These include patient safety, such as avoiding healthcare-associated infections (HAIs) and adverse events, better coordination of care, and person-centered and family-centered care. Third, the proposed measures should address improved quality for the primary role of LTCHs, which is to furnish extended medical care to individuals with clinically complex problems, such as multiple acute or chronic conditions, that need hospital-level care for relatively extended periods of greater than 25 days.

b. Proposed LTCH Quality Measures for FY 2014 Payment Determination

We are proposing that, for the FY 2014 payment determination, LTCHs submit data on three quality measures: (1) Urinary Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened

HAIs are a topic area widely acknowledged by the HHS Action Plan to Prevent HAIs, the Institute of Medicine (IOM), the National Priorities Partnership, and others as a high impact priority requiring measurement and improvement. Better care is one of the aims found in the National Quality Strategy, and patient safety is one of the priorities. Mitigating HAIs is essential in the improvement of patient safety, and, therefore, patient care. HAIs are among the leading causes of death in the United States and, therefore, are serious reportable events. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[50] HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. Therefore, two of the three quality measures proposed are HAI measures.

Other HAIs included in the HHS Action Plan to Prevent HAIs were under consideration for the LTCH quality reporting program beginning October 1, 2012. However, the TEP convened by the measure development contractor recommended the two proposed infection events, urinary catheter-associated urinary tract infection and central line catheter-associated bloodstream infection (each an episode of an infection, such as CAUTI or CLABSI) as highly pertinent, and important for data collection as well as most ready and currently feasible for implementation in the LTCH setting. HAI quality measures are important for quality reporting, and we intend to propose additional HAI measures included in the HHS HAI Action Plan to Prevent HAIs through future rulemaking. These potential HAI quality measures are listed in our discussion of possible measures under consideration for future years. At this time, we are proposing the selection of the CLABSI and CAUTI events as the two initial HAI quality measures for the LTCH quality measure reporting program.

(1) Proposed FY 2014 LTCH Measure #1: Urinary Catheter-Associated Urinary Tract Infections (CAUTI)

The first measure we are proposing for LTCHs for purposes of the FY 2014 payment determination is an application of the NQF-endorsed measure developed by CDC for hospital intensive care units (ICU) entitled (NQF# CAUTI 0138) "Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit Patients" to all LTCH care units. This measure was developed by the CDC to measure the percentage of patients with CAUTIs in the ICU context. At the time we are developing this proposed rule, the measure we are applying, NQF CAUTI #0138, is undergoing measure

[50] McKibben L; Horan T: Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217 through 226.

maintenance review by NQF. This review may result in a change in how the CDC calculates the aggregated data from using a rate for CAUTI, to the use of a Standardized Infection Ratio (SIR) of healthcare associated catheter-associated urinary tract infections. We are proposing to adopt the current measure in this rulemaking cycle. However, we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking.

While it is fast becoming a medical best practice to avoid urinary catheter use whenever possible, this may not always be possible with the LTCH patient population, due to the severity of their primary illnesses as well as comorbidities. Patients who are exposed to indwelling urinary catheters have a significantly higher risk of developing urinary tract infections (UTIs).

UTIs are a common cause of morbidity and mortality. The HHS National Action Plan to Prevent HAIs identified catheter associated urinary tract infections as the leading type of HAI that is largely preventable, and the occurrence of which can be drastically reduced in order to reduce adverse health care related events and avoid excess costs.

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[51] Healthcare-associated UTIs are commonly attributed to catheterization of the urinary tract.

CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI also include discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[2] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections*.[52] The NQF-endorsed CAUTI measure we are proposing is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals. We note that CDC's NHSN is a secure Internet-based surveillance system that currently has data collection forms and data submission and reporting mechanism in place for LTCHs. NHSN is currently used, in part, as one means by which certain State-mandated reporting and surveillance data are collected.

We recognize that the NQF has endorsed this measure for the short term, acute care ICU setting, but believe that this measure is highly relevant to LTCHs, in that urinary catheters are commonly used in the LTCH care setting. As previously noted, NQF CAUTI #0138 is undergoing measure maintenance review by NQF. This review may result in a change in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR). We are proposing to adopt the current measure in this rule making cycle. However, we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. The TEP convened by the CMS measure development contractor on January 31, 2011, identified CAUTI as a high priority quality issue for LTCHs, and there was agreement by this TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term care units (CDC/NHSN Manual, Device-Associated Module, CAUTI Event, which is available on the CDC Web site at: *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf.*

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for urinary catheter-associated urinary tract infections for the LTCH setting. We are unaware of any other measures for catheter-associated urinary tract infections that have been approved by a voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt an application of this NQF-endorsed (in the short-term acute care ICU setting) measure under the Secretary's authority to select non-NQF-endorsed measures. We are proposing to adopt the measure under the exception authority provided in section 1886(m)(5)(D)(ii) of the Act. As previously noted, NQF CAUTI #0138 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR. We are proposing to adopt the current measure in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. We note that we intend to ask NQF to formally extend its endorsement of the CAUTI measure to the LTCH setting.

(2) FY 2014 Measure #2: Central Line Catheter-Associated Bloodstream Infection (CLABSI)

The second measure we are proposing for LTCHs for the FY 2014 payment determination is an application of a CDC-developed NQF-endorsed measure for hospital ICU and high-risk nursery patients; (NQF# CLABSI 0139) "Central Line Catheter-Associated Bloodstream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients." This is a measure of the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections over a specified number of line days. At the time we are developing this proposed rule, the measure we are proposing to apply, NQF CLABSI #0139, is undergoing measure maintenance review by NQF. This review may result in a change in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR of health care associated CLASBIs. We propose to adopt the measure in its current state in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in a future rule cycle.

A central line is a catheter that health care providers often place in a large vein in the neck, chest, or groin to give medication or fluids or to collect blood for medical tests. Many LTCH patients have been discharged from short-term acute care hospital ICUs or ICU step-down units with these central lines already in place. In other situations, a central line IV may be inserted during the patient's stay at the LTCH. Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and

[51] Klevens RM, Edward JR, *et al.* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[52] Wong ES. Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981;2:126–30.

increased cost and risk of mortality.[53] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[54] Furthermore, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. healthcare system, yet these infections are preventable. The CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. Techniques to prevent CLABSI through proper central line management are addressed in CDC's Healthcare Infection Control Practices Advisory Committee Guidelines for the Prevention of Intravascular Catheter Related Infections.[55]

We recognize that NQF endorsement of this measure is limited to ICU and HRN patients in hospital settings, but believe that this measure is also highly relevant in the LTCH setting because intravascular, central venous catheters (also known as a "central line") are used frequently due to the fact that these types of hospitals care for patients with complex medical problems which require LTCH stays and intensive treatment. As previously noted, NQF CLABSI #0139 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR. We are proposing to adopt the current measure in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. The CMS measure development contractor convened a TEP on January 31, 2011, which identified CLASBIs as a high priority quality issue for LTCHs; there was agreement by the TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term hospital care units (CDC/NHSN Manual, Device-Associated Module, CLABSI Event, which is available at the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We reviewed the NQF's consensus-endorsed measures, and were unable to identify any NQF endorsed measures for central line catheter-associated bloodstream infections for the LTCH setting. We are unaware of any other measures for CLABSI that have been approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we are proposing to adopt an application of this NQF-endorsed (for ICU and HRN) measure under the Secretary's authority provided in section 1886(m)(5)(D)(ii) of the Act. As previously noted, NQF CLABSI #0139 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR. We are proposing to adopt the measure in its current state in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. We note that we intend to ask NQF to formally extend its endorsement of the CLABSI measure to all care settings within the LTCH (that is, beyond the LTCH ICU).

(3) FY 2014 Measure #3: Pressure Ulcers

The third measure we are proposing for LTCHs for purposes of the FY 2014 payment determination is an application of a CMS-developed NQF-endorsed measure for short-stay nursing home patients: (NQF NH–012–10) "Percent of Residents with Pressure Ulcers that Are New or Have Worsened." This measure includes the percentage of patients who have one or more stage 2–4 pressure ulcers that are new or worsened from a previous assessment. Consistent in our support of the National Quality Strategy principles, mitigating the occurrence or worsening of pressure ulcers is essential in the improvement of patient safety and, therefore, patient care.

We recognize NQF endorsement of this measure is limited to short-stay nursing home patients, but believe that this measure is highly relevant and a high priority quality issue for the care of LTCH patients. Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the LTCH setting are medically complex, have functional limitations that often are severe, and, therefore, are at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life-threatening infections, which substantially increase the total cost of care. Furthermore, as we noted in the FY 2008 IPPS final rule with comment period (72 FR 42705), in 2006 there were 322,946 reported cases of Medicare patients with a pressure ulcer as a secondary diagnosis—each case had an average charge of $40,381 for a hospital stay, for an annual total cost of 13 billion dollars. The prevalence of pressure ulcers in health care facilities is increasing, with some 2.5 million patients being treated annually for pressure ulcers in acute care facilities.[56] [57] In 2006, there were 503,300 acute hospital stays during which pressure ulcers were noted. This is a 78.9 percent increase from 1993 when there were about 281,300 hospital stays related to pressure ulcers.[58]

The CMS measure development contractor convened a TEP on January 31, 2011, which identified this topic as highly relevant and a high priority quality issue for the care of LTCH patients, and the application of this measure (NQF NH–012–10) as appropriate for LTCHs.

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We

[53] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf,* assessed on Jauary 20, 2011.

[54] Klevens RM, Edward JR, *et al.* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[55] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.* Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR–10:1–26.

[56] Russo CA, Steiner C, Spector W.: *Hospitalizations related to pressure ulcers among adults 18 years and older, 2006* (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf.*

[57] Institute for Healthcare Improvement: Relieve the pressure and reduce harm. May 21, 2007. Available at: *http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethePressureandReduceHarm.htm.*

[58] MacLean DS.: Preventing & managing pressure sores. Caring for the Ages. March 2003;4(3):34–7. Available at: *http://www.amda.com/publications/caring/march2003/policies.cfm.*

reviewed the NQFconsensus-endorsed measures, and we were unable to identify any NQF-endorsed measures for the monitoring of pressure ulcers that are new or worsened, for the LTCH setting. We are unaware of any other measure for the LTCH setting of new or worsened pressure ulcers that are approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we are proposing to adopt an application of this NQF-endorsed (for short-stay nursing home patients) measure for the LTCH quality reporting program under the Secretary's authority set forth at section 1886(m)(5)(D)(ii) of the Act. We also intend to ask NQF to extend its endorsement of the short-stay nursing home pressure ulcer measure specifically to the LTCH setting.

We invite public comment on the proposed quality measures: (1) Urinary Catheter Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Bloodstream Infection (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

3. Possible LTCH Quality Measures Under Consideration for Future Years

As discussed below, we seek to achieve a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement. Therefore, as stated previously, we intend to propose, through future rulemaking, measures included in the HHS Action Plan to Prevent HAIs. We also intend to propose through future rulemaking measures related to ventilator care such as the NQF-endorsed Institute for Healthcare Improvement process measure, NQF #0302, Ventilator Bundle, which is a comprehensive ventilator care-bundle process measure that is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as ventilator-associated pneumonia, and other complications. We also intend to propose additional outcome measures such as those related to acute care rehospitalization. We are aware of the limits related to feasibility in data submission at the present time. For example, there is no feasible means to submit the ventilator bundle process measure at this at this time, and are therefore currently identifying the data elements necessary for this measure using a data subset from the Continuity Assessment Record and Evaluation (CARE) data set as well as a submission mechanism. We also intend to propose, through future rulemaking, additional measures, such as those related to symptom management, physical restraints, medication use, falls, infections, and function, using the data subsets of the CARE data set necessary for measure calculations. We invite public comment and suggestions on the implementation of a standardized assessment instrument for LTCHs that would similarly support the calculation of quality measures. We also invite public comment on the measures and measures topics under consideration for future years set out below. In addition, we invite other suggestions and rationale to support the adoption of measures and topics not listed below.

BILLING CODE 4120–01–P

| Possible Measures and Measure Topics for the LTCH Quality Reporting Program Under Consideration for Future Years | |
|---|---|
| **Overarching Goal:** Safety and Healthcare Acquired Conditions -- HAIs | |
| | HAI reporting for:<br>● Ventilator-associated Pneumonia***<br>● Surgical site infection rate***<br>● Multi-drug resistant organism infection |
| **Overarching Goal:** Safety and Healthcare Acquired Conditions: Avoidable Adverse Events and Serious Reportable Events | |
| | ● Unplanned acute care hospitalizations<br>● Mortality***<br>● Blood Incompatibility**<br>● Foreign object retained after surgery**<br>● Manifestation of poor glycemic control**<br>● Air Embolism**<br>● Falls and trauma**<br>● Venous Thromboembolism*<br>● Injuries secondary to Poly-pharmacy<br>● Injuries related restraint use<br>● Medication errors*<br>● Stage III and IV Pressure Ulcer** |
| **Overarching Goal:** Safety and Improvement Practices for Adverse Event Reduction | |
| | ● Central line bundle***<br>● Ventilator bundle***<br>● Patient Immunization for Influenza***<br>● Patient Immunization for Pneumonia***<br>● Staff immunization*** |
| **Overarching Goal:** Safety -- NQF Endorsed Nursing Sensitive Care Measures | |
| | ● Patient Fall Rate***<br>● Falls with Injury***<br>● Pressure Ulcer Prevalence***<br>● Restraint Prevalence (vest and limb only)***<br>● Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)***Nursing care hours per patient day (RN, LPN, UAP)***<br>● Voluntary turnover for RN, APN, LPN, UAP***<br>● Practice Environment Scale-Nursing Work Index*** |

*Harmonizes with NQF Serious Reportable Events.
**Harmonizes with Hospital-Acquired Conditions –Present on Admission Program for IPPS hospitals.
***Harmonizes with NQF-endorsed measures.

BILLING CODE 4120–01–C

4. Proposed Data Submission Methods and Timelines

a. Proposed Method of Data Submission for HAIs

We are proposing to adopt two proposed HAI quality measures, Central Line Catheter-Associated Blood Stream Infection (CLABSI) Event: CLABSI rate per 1000 central line days, and Urinary Catheter-Associated Urinary Tract Infection (CAUTI) Event: CAUTI rate per 1000 urinary catheter days. We are proposing to use CDC/NHSN for data collection and reporting for these two HAI measures (*http://www.cdc.gov/nhsn/*).

As we noted above, the NHSN is a secure, Internet-based surveillance system. It is maintained by CDC, and can be utilized by all types of healthcare facilities in the United States, including LTCHs, acute care hospitals that collect and report HAIs through the NHSN as part of our Hospital IQR Program, as well as psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to submit their HAI event data, and access their data for the purposes of internal infection-surveillance.

Facilities can also use the NHSN to obtain information on clinical practices known to prevent HAIs, information on the incidence or prevalence of multidrug-resistant organisms within their organizations, and information on other adverse events. Some States use the NHSN as a means of collecting State law-mandated HAI reporting. NHSN collects data via a Web-based tool hosted by the CDC and available at: *http://www.cdc.nhsn.* This reporting service is provided free of charge to healthcare facilities. In addition, CDC may have the ability to receive NHSN measures data from electronic health records (EHRs) in the near future. Currently, the data reporting of these two HAI events is completed through the NHSN. More than 20 States require hospitals to report HAIs using NHSN, and CDC supports more than 4,000 hospitals that are using the NHSN. Over 80 LTCHs currently submit HAI data via the NHSN.

HAI event reporting, and meaningful HAI event surveillance by the LTCH, using the CDC/NHSN requires the submission of HAI events, regardless of payor. We believe delivery of high quality care in the LTCH setting is imperative. Collecting such quality data on all patients in the LTCH setting supports CMS' mission to ensure high quality care for Medicare beneficiaries. This will provide us with the most robust and accurate reflection of quality in the LTCH setting. Therefore, in order to facilitate and ensure that high quality care is delivered to Medicare beneficiaries in the LTCH setting, we are proposing that quality data related to HAIs be collected on all LTCH patients, regardless of payor.

Currently the NHSN has data collection forms and data submission and reporting mechanisms in place that are in use by LTCHs for these CLABSI and CAUTI measures. Details related to the procedures using the NHSN for data submission can be found at: *http://www.cdc.gov/nhsn.* Specifically, details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CLABSI Event: CLABSI rate per 1000 central line days calculated by dividing the number of CLABSI by the number of central line days and multiplying the result by 1000 can be found at *http://www.cdc.gov/nhsn/PatientSafety.html.* Details related to the CLABSI SIR can be found at *http://www.cdc.gov/hai/pdfs/stateplans/SIR_05_25_2010.pdf.* Details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CAUTI Event: CAUTI rate per 1000 urinary catheter days calculated by dividing the number of CAUTIs by the number of catheter days and multiplying the result by 1000 can also be found at *http://www.cdc.gov/nhsn/PatientSafety.html.*

The reporting procedures for these HAI events would not be affected by the use of the SIR instead of the current rate calculation. CDC performs those calculations. Further information related to the use of the SIRs can be found on the Web sites at: *http://www.hhs.gov/ash/initiatives/hai/appendices.html* and *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html.*

b. Proposed Timeline for Data Reporting Related to HAIs

CDC recommends that HAI reporting occur closest in time to the event, and further recommends that reporting occur no later than 30 days following the event. To facilitate HAI surveillance and reporting for these proposed measures for payment determination, we are proposing an additional timeframe for reporting following the initial reporting period. We are proposing a data submission timeframe for NHSN event reporting for these proposed LTCH quality reporting program HAI measures of October 1, 2012 through December 31, 2012 for the determination of FY 2014 annual payment update, and that LTCHs submit their data no later than May 15, 2013.

In order to better align with the current Hospital IQR Program HAI reporting processes (75 FR 20223), we also are proposing that all subsequent LTCH quality reporting cycles will be based on a calendar year cycle (for example, beginning January 1, 2013 through December 31, 2013) for determination of the update to the standard Federal rate for each LTCH in FY 2015 and subsequent years. We are proposing that, beginning in CY 2013, and for all subsequent years, LTCHs would submit HAI event data via the NHSN, for four consecutive quarters of the calendar year. For example, for the FY 2015 annual payment update to the standard Federal rate, LTCHs would submit HAI data collected in the first quarter of CY 2013, the second quarter of CY 2013, the third quarter of CY 2013, and the fourth quarter of CY 2013.

The proposed timelines for submission of quality data on the CLABSIs and CAUTIs for the FY 2015 annual payment update are set out below.

| Proposed Timelines for Submission of Data on the Proposed Central Line Catheter-Associated Bloodstream Infections and Urinary Catheter-Associated Urinary Tract Infections (CAUTI & CLABSI) Measures for the FY 2015 Annual Payment Update | | |
|---|---|---|
| **CY 2013 Infection Event (s)** | **CDC-NHSN collection and quarterly report generation time** | **Proposed final submission deadlines for the LTCH quality reporting program FY 2015 payment determination** |
| Q1 (January-March 2013) | January 31-August 15 | August 15, 2013 |
| Q2 (April-June 2013) | April 30-November 15 | November 15, 2013 |
| Q3 (July-September 2013) | July 31-February 15 | February 15, 2014 |
| Q4 (October-December 2013) | October 31-May 15 | May 15, 2014 |

LTCHs would have until the final submission deadline for the LTCH quality reporting program to submit their quarterly data to the NHSN. After the final submission deadline has occurred for each CY 2013 quarter, CMS will receive a file from the CDC with the aggregated measurement rates of the specific calculations that have been generated by the NHSN for the LTCH quality reporting program and we will use those results for purposes of determining whether the LTCH met the requirements for the LTCH quality reporting program. We invite public comments on the proposed reporting cycle for LTCHs.

In alignment with the Hospital IQR Program, (75 FR 50223), we also are proposing that once quarterly each LTCH will utilize an automated report function that will be made available to submitters in the NHSN, to generate a quarterly report containing individual LTCH-level numerator, denominator, and exclusion counts for these two HAI measures specifically. CDC will create an automated LTCH quality program report function and add it to NHSN's reporting functionalities. While LTCHs may be reporting other data elements to CDC for other reporting programs (that is: State-mandated surveillance programs), the quarterly LTCH quality program report that would be generated within NHSN would only contain those data elements needed to calculate the two measures currently being proposed for the LTCH quality reporting program. We would only receive this aggregated data from CDC.

We also are proposing that any further details regarding data submission and reporting requirements for HAI measures to be reported via NHSN would be posted on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* by no later than January 31, 2012.

Requirements for NHSN participation, measure specifications, and data collection can be found at the Web site at: *http://www.cdc.gov/nhsn/*. LTCHs are encouraged to visit this Web site in order to view the NHSN enrollment and reporting requirements. Training resources are available there. In order to allow adequate time for enrollment in the NHSN, and for training to take place, should these measures be finalized, additional details related to this reporting program's requirements, such as when enrollment is due to occur, will be announced by no later than January 31, 2012, on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/*. In the announcement, we would propose to provide guidance on the specifications, definitions and reporting requirements.

We invite public comments on the proposed HAI NHSN submission requirements, reporting cycle, and reporting timeline for LTCHs.

c. Proposed Method of Data Collection and Submission for the Pressure Ulcer Measure Data

We are proposing that the pressure ulcer data elements necessary to calculate the pressure ulcer measure would be identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0), which is a reporting instrument used in nursing homes The current MDS 3.0 pressure ulcer items evolved as an outgrowth of CMS' work to develop a standardized patient assessment instrument, referred to as the Continuity Assessment Record and Evaluation tool, or CARE. The current MDS 3.0 pressure ulcer items are also currently used in the calculation of the NQF-endorsed nursing home pressure ulcer measure, Percent of Residents With Pressure Ulcers That Are New or Worsened [Short Stay] (NQF NH–012–10). We note that the MDS data elements were supported by the National Pressure Ulcer Advisory Panel (NPUAP).

We believe that to support the standardized collection and calculation of the LTCH pressure ulcer quality measure will require the use of a subset of the standardized CARE instrument, and thus we are proposing the use of a subset of the CARE instrument's assessment items for data collection. We will be using specifically the pressure ulcer data elements necessary to calculate the pressure ulcer measure, and those data items are identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0). The current MDS 3.0 pressure ulcer data items can be found at the CMS Web site at: *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp.*[59] This data assessment subset will allow identical data elements to be collected in LTCHs and in nursing homes.

The CARE assessment instrument, was developed and tested in the post-acute care payment reform demonstration (which included LTCHs) as required by section 5008 of the Deficit Reduction Act (DRA) (Pub. L. 109–171). It is a standardized assessment instrument that can be used across all postacute care sites to measure functional status and other factors during treatment and at discharge from each provider. (For more information, we refer readers to the following Web site: *http://www.pacdemo.rti.org*.) CARE was tested

[59] *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp* (Look for Downloads. Select MDS 3.0 Item Subsets v1.002. Click on MDS 3.0 ALL Items. Scroll down to Section M, Skin Conditions, items M0100–M0900.)

over the last 2 years in 199 providers, of which 28 were LTCHs. Participant feedback suggested most of these items are already collected by LTCHs during their intake process and in monitoring the patients' health status during the stay. Importantly, the CARE items meet Federal interoperable data standards and should be transferable by most data systems. A data collection mechanism for transferring the data to CMS is currently under development, and it is anticipated to be similar to the current systems used to report assessment data for payment and quality monitoring in the other post acute care sites.

We believe that, for the collection of data necessary to calculate this pressure ulcer measure, using a CARE subset of standardized data elements to collect, report, and calculate the proposed pressure ulcer quality measure will drive uniformity across settings which will lead to better quality of care in LTCHs and, ultimately, across the continuum of care settings. We also believe that the use of a standardized method of communication will lead to better informed decision making.

If this proposal is finalized, additional details regarding the data elements needed to calculate this measure, submission requirements and specifications used for these data elements to calculate the proposed pressure ulcer quality measure using a subset of CARE instrument will be published on the CMS Web site at *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* by no later than January 31, 2012.

We are proposing to use standardized assessment data elements for data collection that would support the calculation of quality measures in the LTCHs. Specifically, we are proposing to use a subset of the CARE instrument for the collection of the data elements necessary to calculate the proposed quality measure, the Percent of New or Worsened Pressure Ulcers.

We invite public comment on the use of a subset of CARE items for the purposes of data collection for this proposed measure: Percent of Patients with New or Worsened Pressure Ulcers. We invite public comment on this proposal for the calculation of the proposed quality measure for pressure ulcers.

d. Proposed Timeline for Data Reporting Related to Pressure Ulcers

The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to ensure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients, regardless of payor. Thus, so as to facilitate and ensure this effort, we are proposing that quality data related to pressure ulcers shall be collected on all LTCH patients, regardless of payor, using a subset of the CARE data collection instrument in accordance with the timetable and schedule set forth in section VII.C.4.b. of this preamble. We will provide further details about the data collection instrument on the CMS Web site *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* as these details become available. We invite public comments on the proposed reporting cycle for LTCHs.

5. Public Reporting and Availability of Data Submitted

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs available to the public. Such procedures will ensure that a LTCH has the opportunity to review the data that is to be made public with respect to the LTCH prior to such data being made public. The Secretary will report quality measures that relate to services furnished in LTCHs on the CMS Web site. Currently, the agency is developing plans regarding the implementation of this provision. Procedures for public reporting will be proposed through future rule making. At this time no procedures or timeline has been established for public reporting of data.

*D. Proposed Rebasing and Revising of the Market Basket Used Under the LTCH PPS*

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the "excluded hospital with capital" market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term "market basket" technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket," as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. They are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different than the cost structures of the freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. We remain unable to sufficiently understand the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs. Therefore, we do not believe it is appropriate at this time to propose stand-alone market baskets for IRFs, IPFs, and LTCHs.

We are currently exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We invite public comment on the possibility of using this type of market basket to update LTCH payments in the future.

Under the LTCH PPS for FY 2012, we are proposing to rebase and revise the

FY 2002-based RPL market basket by creating a proposed FY 2008-based RPL market basket as described below. In the following discussion, we provide an overview of the market basket and describe the methodologies we are proposing to use for purposes of determining the operating and capital portions of the proposed FY 2008-based RPL market basket.

2. Overview of the Proposed FY 2008–Based RPL Market Basket

The proposed FY 2008-based RPL market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use FY 2008 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

3. Proposed Rebasing and Revising of the RPL Market Basket

We are inviting public comments on our proposed methodological changes to the RPL market basket. The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. "Rebasing" means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we are proposing to shift the base year cost structure for the RPL market basket from FY 2002 to FY 2008). "Revising" means changing data sources, price proxies, or methods, used to derive the input price index. For FY 2012, we are proposing to rebase and revise the market basket used to update the LTCH PPS.

a. Development of Cost Categories

(1) Medicare Cost Reports

The proposed FY 2008-based RPL market basket consists of several major cost categories derived from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, including wages and salaries, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008. We are proposing to use FY 2008 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for IRFs, IPFs, and LTCHs. However, there is an issue with obtaining data specifically for benefits and contract labor from this set of FY 2008 Medicare cost reports because IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Worksheet S–3, Part II). As a result, only a small number of providers (less than 30 percent) reported data for these categories, and we do not expect these FY 2008 data to improve over time. However, because IRFs, IPFs, and LTCHs were not required to submit data for Worksheet S–3, Part II in previous cost reporting years, we have always had this issue of incomplete Medicare cost report data for benefits and contract labor (including when we finalized the FY 2002-based RPL market basket). Due to the incomplete benefits and contract labor data for IRFs, IPFs, and LTCHs, we are proposing to develop these cost weights using FY 2008 Medicare cost report data for IPPS hospitals (similar to the method that was used for the FY 2002-based RPL market basket). We provide additional detail on this approach later in this section.

Because our goal is to measure cost shares that are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries, we are proposing to limit our selection of Medicare cost reports to those from hospitals that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. We are proposing to use the cost reports of LTCHs and IRFs with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for the hospital. This is the same edit we applied to derive the FY 2002-based RPL market basket and generally includes those LTCHs and IRFs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

We are proposing to use a less stringent measure of Medicare average length of stay for IPFs. For this provider type, and in order to produce a robust sample size, we are proposing to use those facilities' Medicare cost reports whose average length of stay is within 30 or 50 percent (depending on the total facility average length of stay) of the total facility average length of stay. This is the same edit we applied to derive the FY 2002-based RPL market basket.

We applied these length of stay edits to first obtain a set of cost reports for facilities that have a Medicare length of stay within a comparable range of their total facility length of stay. Using this set of Medicare cost reports, we then calculated cost weights for four cost categories and a residual as represented by all other costs directly from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs (found in Table VII.D–1 below). These Medicare cost report cost weights were then supplemented with information obtained from other data sources (explained in more detail

below) to derive the proposed FY 2008-based RPL market basket cost weights.

**TABLE VII.D-1.--MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2008 MEDICARE COST REPORTS**

| Major Cost Categories | Proposed FY 2008-Based RPL Market Basket (Percent) |
|---|---|
| Wages and Salaries | 47.371 |
| Professional Liability Insurance (Malpractice) | 0.764 |
| Pharmaceuticals | 6.514 |
| Capital | 8.392 |
| All other | 36.959 |

(2) Other Data Sources

In addition to the IRF, IPF and LTCH Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, the other data sources we used to develop the proposed FY 2008-based RPL market basket cost weights were the FY 2008 IPPS Medicare cost reports and the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. The FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008.

As noted above, the proposed FY 2008-based RPL cost weights for benefits and contract labor were derived using FY 2008-based IPPS Medicare cost reports. We used these Medicare cost reports to calculate cost weights for "wages and salaries," "benefits," and "contract labor" for IPPS hospitals for FY 2008. For the proposed benefits cost weight for the FY 2008-based RPL market basket, the ratio of the FY 2008 IPPS benefits cost weight to the FY 2008 IPPS wages and salaries cost weight was applied to the RPL wages and salaries cost weight. Similarly, the ratio of the FY 2008 IPPS contract labor cost weight to the FY 2008 IPPS wages and salaries cost weight was applied to the RPL wages and salaries cost weight to derive a contract labor cost weight for the proposed FY 2008-based RPL market basket.

The "All other" cost category is divided into other hospital expenditure category shares using the 2002 BEA Benchmark I–O data following the removal of the portions of the "all other" cost category provided in Table VII.D–1 that are attributable to the benefits and contract labor cost categories. The BEA Benchmark I–O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I–O estimates; however, the 2002 Benchmark I–O data represent a much more comprehensive and complete set of data that are derived from the 2002 Economic Census. For the FY 2002-based RPL market basket, we used the 1997 Benchmark I–O data. We are proposing to use the 2002 Benchmark I–O data in the FY 2008-based RPL market basket. Instead of using the less detailed Annual I–O data, we aged the 2002 Benchmark I–O data forward to 2008. The methodology we used to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year.

The "all other" cost category expenditure shares are determined as being equal to each category's proportion to total "all other" expenditures based on the aged 2002 Benchmark I–O data. For instance, if the cost for telephone services represented 10 percent of the sum of the "all other" Benchmark I–O hospital expenditures, then telephone services would represent 10 percent of the "all other" cost category of the RPL market basket.

b. Final Cost Category Computation

As stated previously, for this FY 2012 rebasing proposal, we are proposing to use the Medicare cost reports for IRFs, IPFs, and LTCHs to derive four major cost categories. The proposed FY 2008-based RPL market basket includes two additional cost categories that were not broken out separately in the FY 2002-based RPL market basket: "Administrative and Business Support Services" and "Financial Services." The inclusion of these two additional cost categories, which are derived using the Benchmark I–O data, is consistent with the addition of these two cost categories to the FY 2006-based IPPS market basket (74 FR 43845). We are proposing to break out both categories so we can better match their respective expenses with more appropriate price proxies. A thorough discussion of our rationale for each of these cost categories is provided below in section VII.D.3.f. of this proposed rule. Also, the proposed FY 2008-based RPL market basket excludes one cost category: "Photographic Supplies." The 2002 Benchmark I–O weight for this category is considerably smaller than the 1997 Benchmark I–O weight, presently accounting for less than one-tenth of one percentage point of the RPL market basket. Therefore, we are proposing to include the photographic supplies costs in the "Chemicals" cost category weight with other similar chemical products.

We are not proposing to change our definition of the labor-related share. However, we are proposing to rename our aggregate cost categories from "labor-intensive" and "nonlabor-intensive" services to "labor-related" and "nonlabor-related" services. This is consistent with the FY 2006-based IPPS market basket (74 FR 43845). As discussed in more detail below and similar to the FY 2002-based RPL market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. In previous regulations, we grouped cost categories that met both of these criteria into labor-intensive services. We believe the

proposed new labels more accurately reflect the concepts that they are intended to convey. We are not proposing to change our definition of the labor-related share because we continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

c. Selection of Price Proxies

After computing the FY 2008 cost weights for the proposed rebased RPL market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies for the operating portion of the proposed FY 2008-based RPL market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

*Producer Price Indexes*—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because these PPIs better reflect the actual price changes encountered by hospitals. For example, we use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we use measure price changes at the final stage of production.

*Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditures were more similar to those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is used as a proxy for contracted food services.

*Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table VII.D–2 below sets forth the proposed FY 2008-based RPL market basket, including cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2002-based RPL market basket cost weights also are listed. For example, "Wages and Salaries" are 49.447 percent of total costs in the proposed FY 2008-based RPL market basket compared to 52.895 percent for the FY 2002-based RPL market basket. "Employee Benefits" are 12.831 percent in the proposed FY 2008-based RPL market basket compared to 12.982 percent for the FY 2002-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the proposed FY 2008-based RPL market basket are 62.278 percent of total costs compared to 65.877 percent for the FY 2002-based RPL market basket.

Following Table VII.D–2 is a summary outlining the choice of the proxies we are proposing to use for the operating portion of the FY 2008-based RPL market basket. The price proxies proposed for the capital portion are described in more detail in the capital methodology section below in section VII.D.3.d. of this proposed rule.

We note that the proxies for the operating portion of the FY 2008-based RPL market basket are the same as those used for the FY 2006-based IPPS operating market basket. Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2006-based IPPS market basket, we refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43843).

BILLING CODE 4120–01–P

**TABLE VII.D-2.--PROPOSED FY 2008-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2002-BASED RPL MARKET BASKET COST WEIGHTS INCLUDED FOR COMPARISON**

| Cost Categories | FY 2002-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Price Proxies |
|---|---|---|---|
| 1. Compensation | 65.877 | 62.278 | -- |
| A. Wages and Salaries[1] | 52.895 | 49.447 | ECI for Wages and Salaries, Civilian Hospital Workers |
| B. Employee Benefits[1] | 12.982 | 12.831 | ECI for Benefits, Civilian Hospital Workers |
| 2. Utilities | 0.656 | 1.578 | -- |
| A. Electricity | 0.351 | 1.125 | PPI for Commercial Electric Power |
| B. Fuel, Oil, and Gasoline | 0.108 | 0.371 | PPI for Petroleum Refineries |
| C. Water and Sewage | 0.197 | 0.082 | CPI-U for Water and Sewerage Maintenance |
| 3. Professional Liability Insurance | 1.161 | 0.764 | CMS Hospital Professional Liability Insurance Premium Index |
| 4. All Other Products and Services | 22.158 | 26.988 | -- |
| A. All Other Products | 13.325 | 15.574 | -- |
| (1.) Pharmaceuticals | 5.103 | 6.514 | PPI for Pharmaceutical Preparations for Human Use(Prescriptions) |
| (2.) Food: Direct Purchases | 0.873 | 2.959 | PPI for Processed Foods and Feeds |
| (3.) Food: Contract Services | 0.620 | 0.392 | CPI-U for Food Away From Home |
| (4.) Chemicals[2] | 1.100 | 1.100 | Blend of Chemical PPIs |
| (5.) Medical Instruments | 1.014 | 1.795 | PPI for Medical, Surgical, and Personal Aid Devices |
| (6.) Photographic Supplies[2] | 0.096 | -- | -- |

| Cost Categories | FY 2002-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Price Proxies |
|---|---|---|---|
| (7.) Rubber and Plastics | 1.052 | 1.131 | PPI for Rubber and Plastic Products |
| (8.) Paper and Printing Products | 1.000 | 1.021 | PPI for Converted Paper and Paperboard Products |
| (9.) Apparel | 0.207 | 0.210 | PPI for Apparel |
| (10.) Machinery and Equipment | 0.297 | 0.106 | PPI for Machinery and Equipment |
| (11.) Miscellaneous Products | 1.963 | 0.346 | PPI for Finished Goods less Food and Energy |
| B. All Other Services | 8.833 | 11.414 | -- |
| (1.) Labor-related Services | 5.111 | 4.681 | -- |
| (a.) Professional Fees: Labor-related[3] | 2.892 | 2.114 | ECI for Compensation for Professional and Related Occupations |
| (b.) Administrative and Business Support Services[4] | n/a | 0.422 | ECI for Compensation for Office and Administrative Services |
| (c.) All Other: Labor-Related Services[5] | 2.219 | 2.145 | ECI for Compensation for Private Service Occupations |
| (2.) Nonlabor-Related Services | 3.722 | 6.733 | -- |
| (a.) Professional Fees: Nonlabor-Related[3] | n/a | 4.211 | ECI for Compensation for Professional and Related Occupations |
| (b.) Financial Services [5] | n/a | 0.853 | ECI for Compensation for Financial Activities |
| (c.) Telephone Services | 0.240 | 0.416 | CPI-U for Telephone Services |
| (d.) Postage | 0.682 | 0.630 | CPI-U for Postage |
| (e.) All Other: Nonlabor-Related Services[6] | 2.800 | 0.623 | CPI-U for All Items less Food and Energy |
| 5. Capital-Related Costs | 10.149 | 8.392 | -- |
| A. Depreciation | 6.187 | 5.519 | -- |

| Cost Categories | FY 2002-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Cost Weights | Proposed FY 2008-Based RPL Market Basket Price Proxies |
|---|---|---|---|
| (1.) Fixed Assets | 4.250 | 3.286 | BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (26 years) |
| (2.) Movable Equipment | 1.937 | 2.233 | PPI for Machinery and Equipment—vintage weighted (11 years). |
| B. Interest Costs | 2.775 | 1.954 | -- |
| (1.) Government/Nonprofit | 2.081 | 0.653 | Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years) |
| (2.) For Profit | 0.694 | 1.301 | Average yield on Moody's Aaa bonds—vintage-weighted (26 years) |
| C. Other Capital-Related Costs | 1.187 | 0.919 | CPI–U for Residential Rent |
| **Total** | 100.000 | 100.000 | -- |

**Note**: Detail may not add to total due to rounding.

[1]Contract Labor is distributed to Wages and Salaries and Employee Benefits based on the share of total compensation that each category represents.

[2]To proxy the Chemicals cost category, we used a blended PPI composed of the PPI for Industrial Gases, the PPI for Other Basic Inorganic Chemical Manufacturing, the PPI for Other Basic Organic Chemical Manufacturing, and the PPI for Soap and Cleaning Compound Manufacturing. For more detail about this proxy, we refer readers to section VII.D.3.c.(10) of the preamble of this proposed rule. In addition, we are proposing to now include expenses related to Photographic Supplies in the Chemicals cost category due to the small cost weight associated with these expenses. We note that, although we would be eliminating the specific cost category, these costs are still accounted for within the RPL market basket.

[3]The "Professional Fees: Labor-related" and "Professional Fees: Nonlabor-related" cost categories were included in one cost category called "Professional Fees" in the FY 2002-based RPL market basket. For more detail about how these new categories were derived, we refer readers to section VII.D.3.f. of the preamble of this proposed rule on the labor-related share.

[4]The Administrative and Business Support Services cost category was contained within the "All Other: Labor-intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Labor-intensive Services" cost category is renamed the "All Other: Labor-related Services" cost category for the proposed FY 2008-based RPL market basket.

[5]The "Financial Services" cost category was contained within the "All Other: Non-labor Intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Non-labor Intensive Services" cost category is renamed the "All Other: Nonlabor-related Services" cost category for the proposed FY 2008-based RPL market basket.

BILLING CODE 4120–01–C

(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(2) Employee Benefits

We are proposing to use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(3) Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542). This same proxy was used in the FY 2002-based RPL market basket.

(4) Fuel, Oil, and Gasoline

For the FY 2002-based RPL market basket, this category only included expenses classified under North American Industry Classification System (NAICS) 21 (Mining). We used the PPI for Commercial Natural Gas (BLS series code WPU0552) as a proxy for this cost category. For the proposed FY 2008-based market basket, we are proposing to add costs to this category that had previously been grouped in other categories. The added costs include petroleum-related expenses under NAICS 324110 (previously captured in the miscellaneous category), as well as petrochemical manufacturing classified under NAICS 325110 (previously captured in the chemicals category). These added costs represent 80 percent of the hospital industry's fuel, oil, and gasoline expenses (or 80 percent of this category). Because the majority of the industry's fuel, oil, and gasoline expenses originate from petroleum refineries (NAICS 324110), we are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) as the proxy for this cost category.

(5) Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(6) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268). This same proxy was used in the FY 2002-based RPL market basket.

(7) Pharmaceuticals

We are proposing to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note that we are not making a change to the PPI that is used to proxy this cost category. Although there was a recent change to the BLS naming convention for this series, this is the same proxy that was used in the FY 2002-based RPL market basket.

(8) Food: Direct Purchases

We are proposing to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(9) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(10) Chemicals

We are proposing to use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519–), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561–). Using the 2002 Benchmark I–O data, we found that these NAICS industries accounted for approximately 90 percent of the hospital industry's chemical expenses.

Therefore, we are proposing to use this blended index because we believe its composition better reflects the composition of the purchasing patterns of hospitals than does the PPI for Industrial Chemicals (BLS series code WPU061), the proxy used in the FY 2002-based RPL market basket. Table VII.D–3 below shows the weights for each of the four PPIs used to create the blended PPI, which we determined using the 2002 Benchmark I–O data.

## TABLE VII.D-3.--BLENDED CHEMICAL PPI WEIGHTS

| Name | Weights (in percent) | NAICS |
|---|---|---|
| PPI for Industrial Gas Manufacturing | 35% | 325120 |
| PPI for Other Basic Inorganic Chemical Manufacturing | 25% | 325180 |
| PPI for Other Basic Organic Chemical Manufacturing | 30% | 325190 |
| PPI for Soap and Cleaning Compound Manufacturing | 10% | 325610 |

(11) Medical Instruments

We are proposing to use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. In the 1997 Benchmark I–O data, approximately half of the expenses classified in this category were for surgical and medical instruments. Therefore, we used the PPI for Surgical and Medical Instruments and Equipment (BLS series code WPU1562) to proxy this category in the FY 2002-based RPL market basket. The 2002 Benchmark I–O data show that surgical and medical instruments now represent only 33 percent of these expenses and

that the largest expense category is surgical appliance and supplies manufacturing (corresponding to BLS series code WPU1563). Due to this reallocation of costs over time, we are proposing to change the price proxy for this cost category to the more aggregated PPI for Medical, Surgical, and Personal Aid Devices.

(12) Photographic Supplies

We are proposing to eliminate the cost category specific to photographic supplies for the proposed FY 2008-based RPL market basket. These costs would now be included in the Chemicals cost category because the costs are presently reported as all other chemical products. Notably, although we would be eliminating the specific cost category, these costs would still be accounted for within the RPL market basket.

(13) Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(14) Paper and Printing Products

We are proposing to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(15) Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(16) Machinery and Equipment

We are proposing to use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(17) Miscellaneous Products

We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category. Using this index would remove the double-counting of food and energy prices, which would already be captured elsewhere in the market basket. This same proxy was used in the FY 2002-based RPL market basket.

(18) Professional Fees: Labor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This same proxy was used in the FY 2002-based RPL market basket.

(19) Administrative and Business Support Services

We are proposing to use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. Previously these costs were included in the All Other: Labor-intensive category (now renamed the All Other: Labor-related Services category), and were proxied by the ECI for Compensation for Service Occupations. We believe that this compensation index better reflects the changing price of labor associated with the provision of administrative services and its incorporation represents a technical improvement to the market basket.

(20) All Other: Labor-Related Services

We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(21) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-related cost category.

(22) Financial Services

We are proposing to use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. Previously these costs were included in the All Other: Nonlabor-intensive category (now renamed the All Other: Nonlabor-related Services category), and were proxied by the CPI for All Items. We believe that this compensation index better reflects the changing price of labor associated with the provision of financial services and its incorporation represents a technical improvement to the market basket.

(23) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(24) Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(25) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. Previously these costs were proxied by the CPI for All Items in the FY 2002-based RPL market basket. We believe that using the CPI for All Items Less Food and Energy would remove the double counting of changes in food and energy prices, as they are already captured elsewhere in the market basket. Consequently, we believe that the incorporation of this proxy would represent a technical improvement to the market basket.

d. Proposed Methodology for Capital Portion of the RPL Market Basket

In the FY 2002-based RPL market basket, we did not have freestanding IRF, freestanding IPF, and LTCH 2002 Medicare cost report data for the capital cost weights, due to a change in the 2002 reporting requirements. Therefore, we used these hospitals' 2001 expenditure data for the capital cost categories of depreciation, interest, and other capital expenses, and aged the data to a 2002 base year using relevant price proxies.

For the proposed FY 2008-based RPL market basket, we are proposing to calculate weights for the proposed RPL market basket capital costs using the same set of FY 2008 Medicare cost reports used to develop the operating share for IRFs, IPFs, and LTCHs. To calculate the proposed total capital cost weight, we first apply the same length of stay edits as applied when calculating the operating cost weights as described above in section VII.D.3.a. of this preamble The resulting proposed capital weight for the FY 2008 base year is 8.392 percent.

Lease expenses are unique in that they are not broken out as a separate cost category in the RPL market basket, but rather are proportionally distributed amongst the cost categories of

Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done in the FY 2002-based RPL market basket, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other Capital-Related Costs category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of depreciation, interest, and other capital not including lease expenses.

Depreciation contains two subcategories: (1) Building and Fixed Equipment; and (2) Movable Equipment. The apportionment between building and fixed equipment and movable equipment was determined using the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. This methodology was also used to compute the apportionment used in the FY 2002-based RPL market basket (71 FR 27815).

The total Interest expense cost category is split between government/nonprofit interest and for-profit interest. The FY 2002-based RPL market basket allocated 75 percent of the total Interest cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 25 percent of the Interest cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (70 FR 47912). This was based on the FY 2002-based IPPS capital input price index (70 FR 23406) due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs. For the proposed FY 2008-based RPL market basket, we are proposing to derive the split using the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. Based on these data, we calculated a proposed 33/67 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses for RPL providers. As stated above, we first apply the average length of stay edits (as described in section VII.D.3.a. of this preamble) prior to calculating this split. Therefore, we are using cost reports that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Using data specific to government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs as well as the application of these length of stay edits are the primary reasons for the difference in this split relative to the FY 2002-based RPL market basket.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital portion of the proposed FY 2008-based RPL market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the proposed FY 2008-based RPL market basket. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The capital portion of the proposed FY 2008-based RPL market basket would reflect the annual price changes associated with capital costs, and would be a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the proposed FY 2008-based RPL market basket would reflect the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital purchases. However, AHA does provide a consistent database back to 1963. We used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2008.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category (building and fixed equipment, movable equipment, and interest) is needed to calculate vintage weights. For the FY 2002-based RPL market basket, due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs, we used 2001 Medicare cost reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment (71 FR 27816). The FY 2002-based RPL market basket was based on an expected average life of building and fixed equipment of 23 years. It used 11 years as the average expected life for moveable equipment. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to freestanding IRFs, freestanding IPFs, and LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2002-based RPL market basket, we are proposing to use the average expected life of building and fixed equipment to be equal to 26 years, and the average expected life of movable equipment to be 11 years. These expected lives are calculated using FY 2008 Medicare cost reports for IPPS hospitals since we are currently unable to obtain robust measures of the expected lives for building and fixed equipment and movable equipment using the Medicare cost reports from freestanding IRFs, freestanding IPFs, and LTCHs.

We also are proposing to use the building and fixed equipment and movable equipment weights derived from FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. Year-end asset costs for building and fixed equipment and movable equipment were determined by

multiplying the annual depreciation amounts by the expected life calculations. We then calculated a time series, back to 1963, of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For the proposed building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's chained price index for nonresidential construction for hospitals and special care facilities. Because building and fixed equipment have an expected life of 26 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 26-year periods. With real building and fixed equipment purchase estimates available from 2008 back to 1963, we averaged twenty 26-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period, and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average building and fixed equipment vintage weights for the FY 2008-based RPL market basket.

For the proposed movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 2002-based RPL market basket. Based on our determination that movable equipment has an expected life of 11 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 11-year period. With real movable equipment purchase estimates available from 2008 back to 1963, thirty-five 11-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation was done for each year in the 11-year period and for each of the thirty-five 11-year periods. We used the average of each year across the thirty-five 11-year periods to determine the average movable equipment vintage weights for the FY 2008-based RPL market basket.

For the proposed interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) were used to capture the value of the debt instrument. Because we have determined that hospital debt instruments have an expected life of 26 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 26-year periods. With nominal total equipment purchase estimates available from 2008 back to 1963, twenty 26-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average interest vintage weights for the FY 2008-based RPL market basket. The vintage weights for the capital portion of the FY 2002-based RPL market basket and the FY 2008-based RPL market basket are presented in Table VII.D–4 below.

BILLING CODE 4120–01–P

**TABLE VII.D-4.--FY 2002 AND FY 2008 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES**

| Year | Building and Fixed Equipment | | Movable Equipment | | Interest | |
|---|---|---|---|---|---|---|
| | FY 2002 23 years | FY 2008 26 years | FY 2002 11 years | FY 2008 11 years | FY 2002 23 years | FY 2008 26 years |
| 1 | 0.021 | 0.021 | 0.065 | 0.071 | 0.010 | 0.010 |
| 2 | 0.022 | 0.023 | 0.071 | 0.075 | 0.012 | 0.012 |
| 3 | 0.025 | 0.025 | 0.077 | 0.080 | 0.014 | 0.014 |
| 4 | 0.027 | 0.027 | 0.082 | 0.083 | 0.016 | 0.016 |
| 5 | 0.029 | 0.028 | 0.086 | 0.085 | 0.019 | 0.018 |
| 6 | 0.031 | 0.030 | 0.091 | 0.089 | 0.023 | 0.020 |
| 7 | 0.033 | 0.031 | 0.095 | 0.092 | 0.026 | 0.021 |
| 8 | 0.035 | 0.033 | 0.100 | 0.098 | 0.029 | 0.024 |
| 9 | 0.038 | 0.035 | 0.106 | 0.103 | 0.033 | 0.026 |
| 10 | 0.040 | 0.037 | 0.112 | 0.109 | 0.036 | 0.029 |
| 11 | 0.042 | 0.039 | 0.117 | 0.116 | 0.039 | 0.033 |
| 12 | 0.045 | 0.041 | -- | -- | 0.043 | 0.035 |
| 13 | 0.047 | 0.042 | -- | -- | 0.048 | 0.038 |
| 14 | 0.049 | 0.043 | -- | -- | 0.053 | 0.041 |
| 15 | 0.051 | 0.044 | -- | -- | 0.056 | 0.043 |
| 16 | 0.053 | 0.045 | -- | -- | 0.059 | 0.046 |
| 17 | 0.056 | 0.046 | -- | -- | 0.062 | 0.049 |
| 18 | 0.057 | 0.047 | -- | -- | 0.064 | 0.052 |
| 19 | 0.058 | 0.047 | -- | -- | 0.066 | 0.053 |
| 20 | 0.060 | 0.045 | -- | -- | 0.070 | 0.053 |
| 21 | 0.060 | 0.045 | -- | -- | 0.071 | 0.055 |
| 22 | 0.061 | 0.045 | -- | -- | 0.074 | 0.056 |
| 23 | 0.061 | 0.046 | -- | -- | 0.076 | 0.060 |
| 24 | -- | 0.046 | -- | -- | -- | 0.063 |
| 25 | -- | 0.045 | -- | -- | -- | 0.064 |
| 26 | -- | 0.046 | -- | -- | -- | 0.068 |
| Total | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 |

Note: Numbers may not add to total due to rounding.

BILLING CODE 4120–01–C

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We are proposing to use the same price proxies for the capital portion of the proposed FY 2008-based RPL market basket that were used in the FY 2002-based RPL market basket with the exception of the Boeckh Construction Index. We replaced the Boeckh Construction Index with BEA's chained price index for nonresidential construction for hospitals and special care facilities. The BEA index represents construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. Although these price indices move similarly over time, we believe that it is more technically appropriate to use an index that is more specific to the hospital industry. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital cost categories are the same as those used for the FY 2006-based Capital Input Price Index (CIPI) as described in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857).

e. Proposed FY 2012 Market Basket Update for LTCHs

For FY 2012 (that is, October 1, 2011 through September 30, 2012), we are proposing to use an estimate of the proposed FY 2008-based RPL market basket update based on the best available data. Consistent with historical practice, we estimate the RPL market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally

recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2011 forecast with history through the 4th quarter of 2010, the projected market basket update for FY 2012 is 2.8 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 2.8 percent for FY 2012. Furthermore, because the proposed FY 2012 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.8 percent), we also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2012 annual update in the final rule. (As discussed in greater detail in section V.A.2. of the Addendum to this proposed rule, we are proposing an annual update of 1.5 percent to the LTCH PPS standard Federal rate for FY 2012 under proposed § 412.523(c)(3)(viii) of the regulations.)

Using the current FY 2002-based RPL market basket and IGI's first quarter 2011 forecast for the market basket components, the FY 2012 market basket update would be 2.8 percent (before taking into account any statutory adjustment). Table VII.D–5 below compares the proposed FY 2008-based RPL market basket and the FY 2002-based RPL market basket percent changes.

**TABLE VII.D-5.--FY 2002-BASED AND PROPOSED FY 2008-BASED RPL MARKET BASKET PERCENT CHANGES; FY 2006 THROUGH FY 2014**

| Fiscal Year (FY) | FY 2002-Based RPL Market Basket Index Percent Change | Proposed FY 2008-Based RPL Market Basket Index Percent Change |
|---|---|---|
| Historical data: | | |
| FY 2006 | 3.9 | 3.7 |
| FY 2007 | 3.4 | 3.4 |
| FY 2008 | 3.8 | 3.7 |
| FY 2009 | 2.5 | 2.7 |
| FY 2010 | 2.3 | 2.2 |
| Average 2006-2010 | 3.2 | 3.1 |
| Forecast: | | |
| FY 2011 | 2.6 | 2.7 |
| FY 2012 | 2.8 | 2.8 |
| FY 2013 | 2.9 | 2.9 |
| FY 2014 | 3.0 | 3.0 |
| Average 2011-2014 | 2.8 | 2.9 |

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. first quarter 2011 forecast.

For FY 2012, the proposed FY 2008-based RPL market basket update (2.8 percent) is the same as the market basket update based on the FY 2002-based RPL market basket. The lower total compensation weight in the proposed FY 2008-based RPL market basket (62.278 percent) relative to the FY 2002-based RPL market basket (65.877 percent), absent other factors, would have resulted in a slightly lower market basket update using the FY 2008-based RPL market basket. However, this impact is partially offset by the larger weight associated with the Professional Fees category. In both market baskets, these expenditures are proxied by the ECI for Compensation for Professional and Related Services. The weight for Professional Fees in the FY 2002-based RPL market basket is 2.892 percent compared to 6.325 percent in the proposed FY 2008-based RPL market basket. The net effect is that the market basket update is the same for FY 2012 based on the current FY 2002-based RPL market basket and the proposed FY 2008-based RPL market basket.

f. Proposed Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share, we are proposing to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits,

Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services (previously referred to in the FY 2002-based RPL market basket as labor-intensive), and a portion of the Capital-Related cost weight.

Consistent with previous rebasings, the All Other: Labor-related Services cost category is mostly comprised of building maintenance and security services (including, but not limited to, commercial and industrial machinery and equipment repair, nonresidential maintenance and repair, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the hospital facility (and, therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

As stated in the RY 2007 LTCH PPS final rule (71 FR 27829), the labor-related share was defined as the sum of the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees, and All Other: Labor-intensive Services), and capital costs of the RPL market basket based on FY 2002 data. Therefore, to determine the labor-related share for the LTCH PPS for FY 2011, we used the FY 2002-based RPL market basket cost weights relative importance to determine the labor-related share for the LTCH PPS.

For the proposed FY 2008-based RPL market basket rebasing, the proposed inclusion of the Administrative and Business Support Services cost category into the labor-related share remains consistent with the current labor-related share because this cost category was previously included in the Labor-intensive cost category. As previously stated, we are proposing to establish a separate Administrative and Business Support Service cost category so that we can use the ECI for Compensation for Office and Administrative Support Services to more precisely proxy these specific expenses.

For the FY 2002-based RPL market basket, we assumed that all nonmedical professional services (including accounting and auditing services, engineering services, legal services, and management and consulting services) were purchased in the local labor market and, therefore, all of their associated fees varied with the local labor market. As a result, we previously included 100 percent of these costs in the labor-related share. In an effort to more accurately determine the share of professional fees that should be included in the labor-related share, we surveyed hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market (the results are discussed below).

We continue to look for ways to refine our market basket approach to more accurately account for the proportion of costs influenced by the local labor market. To that end, we conducted a survey of hospitals to empirically determine the proportion of contracted professional services purchased by the industry that are attributable to local firms and the proportion that are purchased from national firms. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments.

With approval from the Office of Management and Budget (OMB), we contacted a sample of IPPS hospitals and received responses to our survey from 108 hospitals. We believe that these data serve as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they are also institutional providers of health care services. Using data on full-time equivalents (FTEs) to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated post-stratification weights. Based on these weighted results, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We applied each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the methodology that we used to separate the proposed FY 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. In addition to the professional services listed above, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in previous rebasings. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Formerly, all of the expenses within this category were considered to vary with, or be influenced by, the local labor market and were thus included in the labor-related share. Because many hospitals are not located in the same geographic area as their home office, we analyzed data from a variety of sources in order to determine what proportion of these costs should be appropriately included in the labor-related share.

Using data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices), we were able to determine that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following three groups:

- Group 1—Provider and home office are located in different States.
- Group 2—Provider and home office are located in the same State and same city.
- Group 3—Provider and home office are located in the same State and different city.

We found that 63 percent of the providers with home offices were classified into Group 1 (that is, different State) and, thus, these providers were determined to not be located in the same local labor market as their home office. Although there were a very limited number of exceptions (that is, providers located in different States but the same MSA as their home office), the 63 percent estimate was unchanged.

We found that 9 percent of all providers with home offices were classified into Group 2 (that is, same State and same city and, therefore, the same MSA). Consequently, these providers were determined to be located in the same local labor market as their home offices.

We found that 27 percent of all providers with home offices were classified into Group 3 (that is, same State and different city). Using data from the Census Bureau to determine the specific MSA for both the provider

and its home office, we found that 10 percent of all providers with home offices were identified as being in the same State, a different city, but the same MSA.

Pooling these results, we were able to determine that approximately 19 percent of providers with home offices had home offices located within their local labor market (that is, 9 percent of providers with home offices had their home offices in the same State and city (and, thus, the same MSA), and 10 percent of providers with home offices had their home offices in the same State, a different city, but the same MSA). We are proposing to apportion the NAICS 55 expense data by this percentage. Thus, we are proposing to classify 19 percent of these costs into the Professional Fees: Labor-related cost category and the remaining 81 percent into the Professional Fees: Nonlabor-related Services cost category.

Using this proposed method and the IGI forecast for the first quarter 2011 of the proposed FY 2008-based RPL market basket, the proposed LTCH labor-related share for FY 2012 is the sum of the FY 2012 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this proposed rule reflects IGI's first quarter 2011 forecast of the proposed FY 2008-based RPL market basket. Table VII.D–6 below shows the proposed FY 2012 relative importance labor-related share using the proposed FY 2008-based RPL market basket and the FY 2011 relative importance labor-related share using the FY 2002-based RPL market basket.

**TABLE VII.D-6.--COMPARISON OF THE FY 2011 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2002-BASED RPL MARKET BASKET AND THE PROPOSED FY 2012 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE PROPOSED FY 2008-BASED RPL MARKET BASKET**

| | FY 2011 Relative Importance Labor-Related Share[1] | Proposed FY 2012 Relative Importance Labor-Related Share[2] |
|---|---|---|
| Wages and Salaries | 52.449 | 49.066 |
| Employee Benefits | 13.971 | 13.040 |
| Professional Fees: Labor-Related | 2.855 | 2.073 |
| Administrative and Business Support Services | -- | 0.416 |
| All Other: Labor-Related Services | 2.109 | 2.094 |
| Subtotal | 71.384 | 66.689 |
| Labor-Related Portion of Capital Costs (46%) | 3.887 | 3.645 |
| **Total Labor-Related Share** | **75.271** | **70.334** |

[1]Published in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391) and based on the second quarter 2010 IGI forecast.
[2]Based on the first quarter 2011 IGI forecast.

The proposed labor-related share for FY 2012 is the sum of the proposed FY 2012 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2008) and FY 2012. The sum of the proposed relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-related Services) would be 66.689 percent, as shown in Table VII.D–6 above. We are proposing that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2002-based RPL market basket. Because the relative importance for Capital-Related Costs would be 7.923 percent of the proposed FY 2008-based RPL market basket in FY 2012, we are proposing to take 46 percent of 7.923 percent to determine the proposed labor-related share of Capital for FY 2012. The result would be 3.645 percent, which we are proposing to add to 66.689 percent for the operating cost amount to determine the total proposed labor-related share for FY 2012. Thus, the labor-related share that we are proposing to use for LTCH PPS in FY 2012 would be 70.344 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

*E. Proposed Changes to the LTCH Payment Rates and Other Proposed Changes to the FY 2012 LTCH PPS*

1. Overview of Development of the LTCH Payment Rates

The LTCH PPS was effective beginning with a LTCH's first cost reporting period beginning on or after October 1, 2002. Therefore, beginning with their FY 2003 cost reporting period, LTCHs were paid, during a 5-year transition period, a total LTCH prospective payment that was comprised of an increasing proportion of the LTCH PPS Federal rate and a decreasing proportion based on reasonable cost-based principles, unless the hospital made a one-time election to receive payment based on 100 percent of the Federal rate, as specified in § 412.533. New LTCHs (as defined at § 412.23(e)(4)) were paid based on 100 percent of the Federal rate, with no phase-in transition payments.

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal rate for FY 2012, that is, effective for LTCH discharges occurring on or after October 1, 2011 through September 30, 2012.

For further details on the development of the FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS Federal rate, we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); and FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444).

The proposed update to the LTCH PPS standard Federal rate for FY 2012 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2012 are discussed below. In addition, as discussed below in section VII.E.3. of this preamble, beginning in FY 2012, in addition to the proposed update factor, we are proposing to make an adjustment to the standard Federal rate to account for the estimated effect of any proposed changes to the area wage level adjustment on estimated aggregate LTCH PPS payments.

2. Proposed FY 2012 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. With the initial implementation of the LTCH PPS for FY 2003, we established the use of the excluded hospital with capital market basket as the LTCH PPS market basket (67 FR 56016 through 56017). (For further details on the development of the excluded hospital with capital market basket, we refer readers to the RY 2004 LTCH PPS final rule (68 FR 34134 through 34137).) The development of the initial LTCH PPS standard Federal rate for FY 2003, using the excluded hospital with capital market basket, is discussed in further detail in the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56033).

Beginning in RY 2007, we adopted the rehabilitation, psychiatric, long-term care (RPL) hospital market basket based on FY 2002 data as the appropriate market basket of goods and services under the LTCH PPS for discharges occurring on or after July 1, 2006. As discussed in the RY 2007 LTCH PPS final rule (71 FR 27810), based on our research, we did not develop a market basket specific to LTCH services. We were unable to create a separate market basket specifically for LTCHs at that time due to the small number of facilities and the limited amount of data that was reported. (For further details on the development of the FY 2002-based RPL market basket, we refer readers to the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).)

As discussed in greater detail in section VII.D. of this preamble, we are proposing to revise and rebase the market basket used under the LTCH PPS for FY 2012. Specifically, we are proposing to adopt a newly created FY 2008-based RPL market basket (described in section VII.D. of this preamble). Also, in section VII.D. of this preamble, we discuss our continued interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Several provisions of the Affordable Care Act affect the policies and payment rates under the LTCH PPS. Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment" as discussed in section VII.E.2.d. of this preamble) described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as "rate year," consistent with our change in the terminology used under the LTCH PPS from "rate year" to "fiscal year," for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ "fiscal year" rather than "rate year" for 2011 and subsequent years.

c. Proposed Market Basket Under the LTCH PPS for FY 2012

As noted above and as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50389), when we initially created the FY 2002-based RPL market basket, we were unable to create a separate market basket specifically for LTCHs due, in part, to the small number of facilities and the limited data that were provided in the Medicare cost reports. Over the last several years, however, the number of LTCHs submitting valid

Medicare cost report data has increased. Based on this development, as well as our desire to move from one RPL market basket to three stand-alone and provider-specific market baskets (for IRFs, IPFs, and LTCHs, respectively), we have begun to explore the viability of creating these market baskets for future use. However, as we discussed in the RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. Therefore, we do not believe it is appropriate at this time to propose stand-alone market baskets for IRFs, IPFs, and LTCHs, and we believe that it is appropriate to continue to use the RPL market basket for LTCHs, IRFs, and IPFs under their respective PPSs.

We continue to believe that the RPL market basket appropriately reflects the cost structure of LTCHs, for the reasons discussed when we adopted the RPL market basket for use under the LTCH PPS in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817). For the reasons explained above, we are proposing to continue to use the RPL market basket under the LTCH PPS for FY 2012. However, as discussed in greater detail in section VII.D. of this preamble, we are proposing to rebase and revise the FY 2002-based RPL market basket by creating a proposed FY 2008-based RPL market basket. Currently, we are exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We invite public comment on the possibility of using this type of market basket to update LTCH payments in the future.

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to use the proposed FY 2008-based RPL market basket (described in section VII.D. of this preamble) under the LTCH PPS for FY 2012, which we continue to believe appropriately reflects the cost structure of LTCHs.

d. Productivity Adjustment

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 and subsequent years, any annual update to the standard Federal rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

The proposed MFP adjustment that would be applied in determining any annual update to the LTCH PPS standard Federal rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act. As described in section IV.K.3. of this preamble, we are proposing to derive the FY 2012 MFP adjustment applied to the operating IPPS applicable percentage increase using a projection of MFP that is currently produced by IHS Global Insight, Inc. (IGI). For a detailed description of the model currently used by IGI to project MFP, as well as a description of how the proposed MFP adjustment is calculated for FY 2012, we refer readers to section IV.K.3 of this preamble. The current estimate of the proposed MFP adjustment for FY 2012 based on IGI's first quarter 2011 forecast is 1.2 percent. Consistent with the statute, we are proposing to reduce the proposed FY 2012 market basket update of the LTCH PPS standard Federal rate using this same proposed FY 2012 MFP adjustment.

To determine the proposed market basket update for LTCHs for FY 2012, as reduced by the MFP adjustment, consistent with the approach proposed under the IPPS for FY 2012 (discussed in section IV.K.3. of this preamble), we are proposing that the proposed FY 2012 MFP percentage adjustment be subtracted from the proposed FY 2012 market basket update. We are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the final rule. Following application of the productivity adjustment, the proposed adjusted market basket update (that is, the full market basket increase less the MFP adjustment) is then reduced by the "other adjustment" as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. The proposed market basket update for FY 2012, which reflects both the proposed MFP adjustment and the "other adjustment" as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is described in section VII.E.2.e. of this preamble.

e. Proposed Annual Market Basket Update for LTCHs for FY 2012

Consistent with our historical practice, we are proposing to estimate the proposed market basket update based on IGI's forecast using the most recent available data.Based on IGI's first quarter 2011 forecast, the proposed FY 2012 market basket estimate for the LTCH PPS using the proposed FY 2008-based RPL market basket is 2.8 percent. Consistent with our historical practice of using market basket estimates based on the most recent available data, we are proposing that if more recent data are available when we develop the final rule, we would use such data, if appropriate.

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 (and subsequent years), any annual update to the standard Federal rate shall be reduced by the productivity adjustment (referred to as "the MFP adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act. Furthermore, section 1886(m)(3)(A)(ii) of the Act specifies that, for each of RYs 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in section 1886(m)(4) of the Act. Specifically, section 1886(m)(4)(C) of the Act requires a 0.1 percentage point reduction to the annual update to the LTCH PPS standard Federal rate for FY 2012.

In accordance with section 1886(m)(3)(A)(i) of the Act, we are proposing to reduce the proposed FY 2012 full market basket estimate of 2.8 percent (based on the first quarter 2011 forecast of the proposed FY 2008-based RPL market basket) by the proposed FY 2012 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2012, as described in section VII.E.2.d of this preamble) of 1.2 percent (based on IGI's first quarter 2011 forecast). Following application of the productivity adjustment, the proposed adjusted market basket update of 1.6

percent (2.8 percent minus 1.2 percentage points) is then reduced by 0.1 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act.

Therefore, in this proposed rule, we are proposing to establish an annual market basket update under the LTCH PPS for FY 2012 of 1.5 percent (that is, the most recent estimate of the proposed LTCH PPS market basket update at this time of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (viii), which would specify that the standard Federal rate for FY 2012 is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.5 percent. Again, consistent with our historical practice of using the most recent available data, we are proposing that if more recent data are available when we develop the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2012. (We note that in section VII.E.3. of this preamble, for FY 2012, we are proposing to adjust the standard Federal rate by an area wage level budget neutrality factor of 0.99723 in accordance with proposed § 412.523(d)(4).)

3. Proposed Budget Neutrality Adjustment for the Changes to the Area Wage Level Adjustment

As described in section V.B. of the Addendum to this proposed rule, when the LTCH PPS was implemented, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Historically, in general, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. However, there are currently no statutory or regulatory requirements that state that any updates or adjustments to the LTCH PPS area wage level adjustment (that is, the wage index or the labor-related share) be budget neutral, such that estimated aggregate LTCH PPS payments would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), when we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable full LTCH PPS wage index values are used to make payments under the LTCH PPS. As discussed in section VII.D. of this preamble, we are proposing to revise and rebase the market basket used under the LTCH PPS for FY 2012, and we are also proposing to update the labor-related share for FY 2012 based on this proposed market basket. We are taking this opportunity to revisit our approach for annually updating the area wage level adjustment. In order to mitigate estimated yearly fluctuations in estimated aggregate LTCH PPS payments, as have been suggested in the past, we have given further consideration to the issue of establishing a budget neutrality requirement for any changes to the area wage level adjustment. Therefore, in this proposed rule, under the broad authority conferred upon the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, to develop the LTCH PPS, we are proposing that, beginning with the proposed adjustment for area wage levels for FY 2012 (discussed in section V.B. of the Addendum to this proposed rule), any changes to the wage index values or labor-related share would be made in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without such changes to the area wage level adjustment. Accordingly, under § 412.525(c), we are proposing to specify that, beginning in FY 2012, any adjustments or updates made to the area wage level adjustment under this section will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

Under this proposal, we would determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment would be budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Specifically, we are proposing to use the following steps to determine a proposed area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate that would ensure that the proposed FY 2012 update to the wage index values and to the labor-related share are adopted in a budget neutral manner.

- Step 1—We would simulate estimated aggregate LTCH PPS payments using the FY 2011 wage index values as established in Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646) and the FY 2011 labor-related share of 75.271 percent as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391 and 50445).
- Step 2—We would simulate estimated aggregate LTCH PPS payments using the proposed FY 2012 wage index values as shown in Tables 12A and 12B of the Addendum to this proposed rule and the proposed FY 2012 labor-related share of 70.334 percent as discussed in section VII.D.3.f. of this proposed rule.
- Step 3—We would calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2012 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor.
- Step 4—We would then apply the proposed FY 2012 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2012 LTCH PPS standard Federal rate after the application of the proposed FY 2012 annual update (discussed in section V.A.2. of the Addendum to this proposed rule). We are proposing to revise the existing regulations at § 412.523(d) to add a new paragraph (4), which would specify that, beginning in FY 2012, we would adjust the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments. In this proposed rule, we also are proposing to revise existing § 412.525(c) to reflect our current policy of updating the labor-related share annually.

For this proposed rule, using the steps in the proposed methodology described above, we have determined a proposed

FY 2012 area wage level adjustment budget neutrality factor of 0.99723. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2012 LTCH PPS standard Federal rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 0.99723, in accordance with proposed § 412.523(d)(4), and therefore, the proposed FY 2012 LTCH PPS standard Federal rate shown in Table 1E reflects this proposed adjustment.

4. Greater Than 25-Day Average Length of Stay Requirement for LTCHs

Section 1886(d)(1)(B) of the Act lists hospitals that are excluded from the IPPS. Section 1886(d)(1)(B)(iv) of the Act specifies the exclusion from the IPPS for "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." The average length of stay requirement was established as the sole prerequisite for a hospital seeking to be excluded from the IPPS under this provider category. Section 114(a) of the MMSEA of 2007 amended section 1861 of the Act by adding a new subsection (ccc), which further defined LTCHs. Thus, a hospital's classification as an LTCH has depended, in large part, upon whether an acute care hospital met the greater than 25 days average length of stay requirement. Once the hospital was classified as such under this criterion, the ability for the hospital to continue its exclusion from the IPPS and be paid as an LTCH depended, in part, upon its continuing to meet that criterion.

The regulations at 42 CFR 412.23(e)(1) and (e)(2) set forth the requirements a hospital must meet in order to be excluded from the IPPS and be paid as an LTCH. Specifically, § 412.23(e)(1) requires that a hospital must have a provider agreement under 42 CFR Part 489 to participate as a Medicare hospital, and § 412.23(e)(2) provides that a hospital must meet the LTCH average length of stay of greater than 25 days policy. The methodology for calculating the average length of stay is specified at § 412.23(e)(3). A detailed explanation of the procedural features of the average length of stay policy was included in the FY 2003 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 55970 through 55974)).

In this proposed rule, we are proposing to clarify two existing CMS policies related to the greater than 25 days average length of stay requirement policy: (1) the determination of the average length of stay for a hospital seeking exclusion under the IPPS to be paid as an LTCH or an existing LTCH undergoes a change of ownership; and (2) the inclusion of Medicare Advantage days in calculating the average length of stay.

a. Determination of the Average Length of Stay When There is a Change of Ownership

Under § 412.23(e)(3)(iv) of the regulations, we implemented a policy regarding the application of the average length of stay methodology, where a hospital (that is either seeking LTCH status, or is an existing LTCH) has undergone a change of ownership. Specifically, in the event of a change of ownership, the regulation provides:

"If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare."

Section 412.23(e)(3)(iv) institutes a procedure by which the average length of stay of a hospital seeking LTCH status or an existing LTCH is evaluated by its fiscal intermediary or MAC to determine whether or not the facility that is being sold meets the requirements for LTCH status. Because the sale of the facility, in effect, ends the seller's cost reporting period (§ 413.24(f)(1)), and triggers the beginning of the purchaser's first cost reporting period, the period of time that is evaluated is the "at least 5 months of the 6 months immediately preceding the period (including time before the change of ownership" to determine the average length of stay that will result in the hospital that meets the requirements for LTCH status. If the average length of stay data indicates that, for this period of time, the hospital met the required average length of stay of greater than 25 days, then the new owner's hospital will achieve IPPS exclusion and LTCH status. On the other hand, if the data indicate that the hospital does not meet the required average length of stay, the hospital will instead be paid under the IPPS under its new ownership. We understand that there has been some confusion in the provider community regarding the specific applicability of this regulation to a change of ownership of an existing LTCH. Accordingly, in this proposed rule, we are proposing to clarify this policy in regulation text by revising § 412.23(e)(3)(iv) to specifically address the circumstance of a hospital that has not as yet been classified as an LTCH and wishes to be classified as an LTCH based on data from the hospital's discharges occurring both before and after the change of ownership. Moreover, in an effort to provide greater clarity, we are also proposing to establish a separate provision in the regulations (proposed paragraph (e)(3)(v) under § 412.23) to directly address LTCH status where there is a change of ownership of an existing LTCH. The sale of an existing LTCH, which triggers the beginning of a new cost reporting period under the new owner (413.24(f)(1)), is a situation where we believe it is appropriate to review whether the hospital that is being sold has been functioning as an LTCH, that is, has been treating patients for on average length of stay of greater than 25 days, before allowing the new owner to continue to be paid for services provided at the hospital under the LTCH PPS. Therefore, we are proposing that where there has been a change of ownership of an existing LTCH, the hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period beginning with the change of ownership only if for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of stay. We note that, conversely, under this proposed policy, if the hospital fails to meet the required average length of stay criterion, after this evaluation, and if it is an acute-care hospital, it will be paid instead under the IPPS effective with the day of the change of ownership, that is, the start of the new owner's cost reporting period.

Accordingly, we are proposing to clarify our existing policy as described above by (1) revising existing § 412.23(e)(3)(iv), to specifically address LTCH status in instances where a hospital is seeking IPPS exclusion and payment under the LTCH PPS but a change of ownership has occurred, and (2) proposing to establish a new § 412.23(e)(3)(v) to specifically address the issue of LTCH status for existing LTCHs undergoing a change of ownership.

b. Inclusion of Medicare Advantage (MA) Days in the Average Length of Stay Calculation

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans instead

of through the original Medicare plan (Parts A and B). These programs were known as Medicare+Choice or Part C plans (Section 1851 through 1859 of the Act, implemented in 42 CFR part 422). Pursuant to the *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003, the compensation and business practices changed for insurers that offer these plans, and "Medicare+Choice" plans became known as Medicare Advantage (MA) plans.

When CMS implemented the LTCH PPS beginning in FY 2003, we revised the then-existing policy for calculating the average length of stay for LTCHs described at then § 412.23(e)(2)(i). Under the TEFRA payment system, the average length of stay was determined by "* * * dividing the number of total inpatient days * * * by the total discharges for the hospital's most recent complete cost reporting period * * *" However, beginning with FY 2003, under the newly implemented LTCH PPS, the calculation was based on "dividing the total number of covered and noncovered days of stay of Medicare inpatients * * * by the total Medicare discharges for the hospital's most recent complete cost reporting period" (§ 412.23(e)(3)(i)). The rationale for this change, as noted in the preamble to the FY 2003 LTCH PPS final rule, is that "LTCHs exist as a provider type in order to treat Medicare patients requiring complex long-term hospital-level care. We believe that a hospital's right to qualify for payments under the prospective payment system for LTCHs should result from the actual provision of clinically appropriate care to Medicare LTCH patients * * *" (67 FR 55971).

Although the policy since the start of the LTCH PPS has been for all LTCH patients being paid for by Medicare to be included in the average length of stay calculation, until recently, we were unable to include data for Medicare Advantage (MA) patients in our calculations because our database did not capture discharge data on claims paid by an MA plan. (In contrast, patients who still had private insurance as their primary health coverage and for whom Medicare was a secondary payer, were included in the calculations because the portion of their claims covered by Medicare was paid by Part A and was therefore included in our database.)

On July 20, 2007, we issued Change Request 5647 that required the submission by hospitals (IPPS, IRFs, and LTCHs) of "information only" (not for payment) bills for their MA patients to their fiscal intermediaries or MACs beginning with FY 2007. The stated goal of capturing these MA data was that the data were needed for disproportionate share payments (DSH) under the IPPS, low-income patient (LIP) payments under the IRF PPS, and for short-stay outlier (SSO) payments under the LTCH PPS. An additional one-time notification, Change Request 6821, issued on June 7, 2010, reiterated the requirements of Change Request 5647 for the reporting of MA days for DHS and LIP data and also noted "[i]n addition, this data is used for other purposes such as determining LTCH short stay outlier payments and evaluating the greater than 25 days length of stay requirement of Medicare patients for LTCHs."

Although the inclusion of MA days in the average length of stay calculation has been CMS' policy under the LTCH PPS because, at the outset of the LTCH PPS, we specified that the average length of stay calculation was based on "all covered" and on "all covered days of stay of Medicare patients" (§ 412.23(e)(2)). We acknowledge that, in practice, MA days were not included due to limitations in our ability to capture the data. We have been informed by some members of the provider community that it was not their understanding that MA data should be included in determining a LTCH's average length of stay, and that, in some cases, the inclusion of these data could substantially lower their average length of stay, thus threatening their status as LTCHs. Therefore, we are proposing to clarify our existing policy at 42 CFR 412.23(e)(3) on the calculation of the average length of stay to specify that all data on all Medicare inpatient days, including MA days, shall be included in the average length of stay calculation.

*F. Proposed Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(2) of Public Law 110–173*

Under section 114(d) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), Congress established one moratorium on the establishment or classification of new LTCHs and LTCH satellite facilities and a second moratorium on the increase in the number of LTCH beds in "existing hospitals and satellite facilities." This section 114(d) provision was amended by section 4302(b) of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) and implemented in interim final rules issued in the **Federal Register** on May 22, 2008, and August 27, 2009 (73 FR 29704 through 29707 and 74 FR 43990 through 43992, respectively), and finalized in the FY 2010 and FY 2011 IPPS/LTCH PPS final rules (74 FR 43985 through 43990 and 75 FR 50397 through 50399, respectively). With the passage of the Affordable Care Act on March 23, 2010, these moratoria were extended under sections 3016 and 10312 for an additional 2 years, through December 29, 2012, and implemented in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50400).

Specific exceptions to each moratorium are included in the statute and permit both the continued establishment or classification of an LTCH or LTCH satellite facility and an increase in LTCH beds at a statutorily defined "existing" hospital or satellite facility, respectively. Under section 114(d)(2) of the MMSEA, as of December 29, 2007, the preclusion on the establishment or classification of a new LTCH or LTCH satellite facility would not apply if the circumstance met one of the following three exceptions:

- The LTCH began its qualifying period for payment as a LTCH under 42 CFR 412.23(e) on or before the date of enactment of the MMSEA (section 114(d)(2)(A)).
- The LTCH has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for a LTCH and had expended before December 29, 2007, at least 10 percent of the estimated cost of the project or, if less, $2.5 million (section 114(d)(2)(B)).
- The LTCH has obtained an approved certificate of need (CON) in a State where one is required on or before December 29, 2007 (section 114(d)(2)(C)).

Section 114(d)(3) of the MMSEA, as originally enacted, provided an exception to the moratorium on increase in beds at an existing LTCH or LTCH satellite facility, if an existing LTCH or satellite facility is located in a State where there is only one other LTCH; and the LTCH or satellite facility requests an increase in beds following the closure or decrease in the number of beds of another LTCH in the State. Section 4302(b) of the ARRA amended this MMSEA provision to specify an additional exception to the moratorium on the increase in bed number if the hospital or facility obtained a certificate of need for an increase in beds that is in a State for which such certificate of need is required and that was issued on or after April 1, 2005, and before December 29, 2007.

In implementing these two moratorium provisions, we required that each hospital or entity submit details of its individual circumstance for evaluation by CMS regional offices and contractors in order to determine whether a specific statutory exception was applicable to the particular situation (74 FR 43985 through 43990). We note that, based upon these exceptions (73 FR 29707), CMS records indicate that, as of January 1, 2011, 50 new LTCHs and 8 new LTCH satellites have been established or classified after December 29, 2007, the date MMSEA was enacted. (Data on additional beds developed in existing LTCHs and LTCH satellite facilities under the CON exception provided by section 4302(b) of the ARRA are maintained by States.)

Sections 3106 and 10312 of the Affordable Care Act provided a 2-year extension of both moratoria initially established by section 114(d)(1) of the MMSEA (which provided for an original 3-year application), indicating that Congress continues to believe that it is appropriate to continue to stem the increase in the number of LTCHs and LTCH satellite facilities and LTCH beds.

As noted above, section 114(d)(1)(B) of the MMSEA established a moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities. Section 114(d)(4) of the MMSEA defines "an existing hospital or satellite facility" as a hospital or satellite facility that received payment under the LTCH PPS as of December 29, 2007, the date of enactment of the MMSEA. By definition, LTCHs or satellite facilities that were established or classified as such under an exception at section 114(d)(2) to the moratorium under section 114(d)(1)(A) first received payments under the LTCH PPS after December 29, 2007, and therefore, would not fall under the definition of "an existing hospital or satellite facility" to whom the moratorium on the increase in bed numbers at section 114(d)(1)(B) applies. However, we do not believe that it was Congress' intent to allow this subset of hospitals and satellite facilities established or classified after the enactment of MMSEA unlimited bed growth and expansion. Continued Congressional concern regarding the increase in the number of LTCHs and satellite facilities and LTCH beds is indicated in the 2-year extension of the moratorium provided by sections 3106 and 10312 of the Affordable Care Act.

Section 123 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA of 1999) (Pub. L. 106–113), as amended by section 307 (b) of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), confers upon the Secretary discretion in creating the LTCH PPS as the payment system for LTCHs beginning in FY 2003. Furthermore, the Secretary has authority, under the general rulemaking authority of sections 1102(a) and 1871(a) of the Act, to establish rules and regulations as necessary to administer the Medicare program and for the efficient administration of the Medicare program. Consistent with these authorities, therefore, we are proposing that, effective October 1, 2011, the moratorium established under section 114(d)(1)(B) of the MMSEA, and implemented at 42 CFR 412.23(e)(7) be applied to those LTCHs and LTCH satellite facilities established or classified as such pursuant to the exceptions at section 114(d)(2) to the moratorium specified under section 114(d)(1)(B) of the MMSEA, as implemented at 42 CFR 412.23(e)(6). Specifically, we are proposing to limit the number of beds in these facilities to the number of beds that were certified by Medicare at the LTCH or satellite facility when it was first paid under the LTCH PPS. We are proposing to amend § 412.23 by adding a new paragraph (e)(8) to specify this proposed policy. We believe that this proposed policy captures the essence of the original statutory moratoria—which was to limit growth in the number of LTCHs and LTCH satellite facilities and LTCH beds payable under Medicare—while recognizing the inherent fairness in allowing those projects already underway that represented substantial investment, planning, and State commitment to be completed.

## VIII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2011 "Report to the Congress: Medicare Payment Policy" and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2012 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov.*

## IX. Other Required Information

### *A. Requests for Data From the Public*

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* Data files and the cost for each file, if applicable, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost of the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2008 Medicare cost reports used to create the proposed FY 2012 prospective payment system wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.K. of the preamble of this proposed rule.

| Processing Year | Wage Data Year | PPS Fiscal Year |
|---|---|---|
| 2011 | 2008 | 2012 |
| 2010 | 2007 | 2011 |
| 2009 | 2006 | 2010 |
| 2008 | 2005 | 2009 |
| 2007 | 2004 | 2008 |

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

*Periods Available:* FY 2007 through FY 2012 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2007–2008 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.K. of the preamble of this proposed rule.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

*Period Available:* FY 2012 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

*Period Available:* FY 2012 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

*Periods Available:* FY 2005 through FY 2012 IPPS Update.

5. FY 2012 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Areas (MSAs).

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

*Period Available:* FY 2012 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

*Media:* Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp* and Compact Disc (CD).

*File Cost:* $100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's or the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

*Media:* Internet at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp*

*Period Available:* Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

*Periods Available:* FY 1985 through FY 2012.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. There are two versions of this file as published in the **Federal Register**.

- Notice of proposed rulemaking.
- Final rule.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

*Periods Available:* FY 2005 through 2012 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital impatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking.
- Final rule.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage* and *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*

*Periods Available:* FY 1994 through FY 2012 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are "Before Outliers

Removed" and the AOR is "After Outliers Removed." (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

*Periods Available:* FY 2006 through FY 2012 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

*Media:* Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

*Period Available:* FY 2012 IPPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

Commenters interested in discussing any data used in constructing this proposed rule should contact Nisha Bhat at (410) 786–5320.

*B. Collection of Information Requirements*

1. Legislative Requirement for Solicitation of Comments

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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of this proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2012 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold. We detailed the burden associated with this requirement in the September 7, 2001, IPPS final rule (66 FR 46902). As stated in that final rule, collection of the information for this requirement is conducted on an individual case-by-case basis. We believe the associated burden is thereby exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). Similarly, we also believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. In FYs 2008, 2009, 2010, 2011, and 2012, we received 1, 4, 5, 3, and 3 applications, respectively.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This Program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a "starter set" of 10 quality measures. OMB approved the collection of information associated with the original starter set of quality measures under OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR measures was part of our implementation of section 5001(a) of the DRA. New section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the "starter set" of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures "that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings." The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022. For the FY 2014 and FY 2015 payment updates, we intend to seek OMB approval for a revised information collection request using the same OMB control number (0938–1022). In the revised request, we will add five measures that we adopted in the FY 2011 IPPS/LTCH PPS final rule (four chart-abstracted measures and an HAI measure (Surgical Site Infection (SSI)) to be collected via NSHN for the FY 2014 payment determination. In addition, we are proposing to add two HAI measures (CLIP and CAUTI) also to be collected via NHSN, one structural measure and one claims-based measure that we are proposing in this proposed rule to adopt for the FY 2014 payment determination. We estimate that the proposed changes to our FY 2014 payment determination measure set would increase the collection burden on hospitals by approximately 4,250,175 hours per year. Because the currently approved CDC information collection request for the NHSN (OCN: 0920–0666) does not include all of the respondents associated with the IQR program, we intend to request a separate OMB control number for the NHSN proposal.

With respect to the four new chart-abstracted measures for the FY 2014 payment determination, hospitals would be required to submit data on patients who receive inpatient acute care hospital services. Specifically, with respect to the two EDT measures and two Global Immunization measures, hospitals would need to collect information on patients who receive inpatient acute care hospital services regarding EDT, as well as flu and pneumonia vaccinations information for all inpatients for which hospitals currently collect only for patients

admitted for pneumonia. We estimate that hospitals would incur an additional 3,500,000 burden hours resulting from the addition of these four measures for the FY 2014 payment determination. We estimate that hospitals would submit approximately 3,500,000 cases annually for these 4 measures, and the information needed to calculate these measures requires an average of 1 hour to abstract from medical records for each case.

The HAI measure (Surgical Site Infection (SSI)) that we adopted in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination and the two HAI measures that we are proposing to add for the FY 2014 payment determination (CLIP and CAUTI) are structured to keep additional burden to a minimum because they are to be collected via NHSN. More than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although this will add burden for hospitals, we believe that the additional burden will be lessened because hospitals will already be using NHSN to report the CLABSI measure for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden because many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with these proposals is the time and effort associated with collecting and submitting the additional data. We estimate that hospitals will need about 750,000 additional hours to report Surgical Site Infection (SSI), CLIP, and CAUTI event data and denominator information into the system.

The structural measure we are proposing to add for the FY 2014 payment determination would require hospitals to indicate whether they are participating in a systematic qualified clinical database for registry for General Surgery and, if so, to identify the registry. If this measure is finalized, we estimate that 3,500 hospitals will spend about 5 minutes each to answer this question each year, resulting in an estimated total increase of 175 hours in terms of the total burden to hospitals each year.

We are also proposing to add one new claims-based measure for the FY 2014 payment determination. We do not believe that this proposed claims-based measure, if finalized, will create any additional burden for hospitals because it would be collected and calculated by CMS based on the Medicare FFS claims the hospitals have already submitted to CMS.

We believe that the overall burden on hospitals will be reduced to some extent by the policy we finalized in the FY 2011 IPPS/LTCH PPS final rule to retire two measures (PN–2 and PN–7) beginning with the FY 2014 payment determination. Burden will be further reduced by our proposal in this proposed rule to retire eight additional measures (AMI–1 Aspirin at Arrival, AMI–3 ACE/ARB, AMI–4 Smoking Cessation, AMI–5 Beta-Blocker at Discharge, HF–4 Smoking Cessation, PN–4 Smoking Cessation, PN–5c Antibiotic within 6 Hours of Arrival and SCIP Inf-6 Appropriate Hair Removal) beginning with the FY 2014 payment determination. We estimate that if we finalize these proposals, the burden to hospitals will be reduced by a total of 740,000 hours as a result of retiring these eight measures, including reductions of 170,000 hours for abstracting AMI measures, 220,000 hours for abstracting PN measures, 50,000 hours for abstracting HF measures, and 300,000 hours for abstracting SCIP measures.

We also are proposing to add two new chart-abstracted measure sets to the Hospital IQR Program for FY 2015: Stroke (eight measures) and Venous Thromboembolism (VTE) (six measures). Both measure sets are of great importance to the Medicare population, with stroke affecting about 795,000 people each year (American Stroke Association). Both stroke and VTE measures are currently collected by the Joint Commission for accreditation and certification purposes. Both measure sets use complimentary data elements to our current SCIP, VTE, and AMI measure sets, thus reducing the chart-abstraction burden. The burden associated with this proposal is the time and effort associated with collecting and submitting the additional data. We estimate that each proposed chart abstracted measure set will require about 1 hour to abstract. We anticipate the number of subsection (d) hospitals participating in the Hospital IQR Program to be approximately 3,500. The number of charts to be abstracted by all participating hospitals is estimated to be 180,000 per year for the proposed Stroke measure set, and 6,000,000 per year for the proposed VTE measure set. In total, our proposal to add Stroke and VTE measures is estimated to increase the burden to hospitals by 6,180,000 hours per year.

We also are proposing to add three new HAI measures to be collected via NHSN to the Hospital IQR Program for FY 2015: (1) Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia measure; (2) C. *Difficile* SIR measure; and (3) Healthcare Personnel Influenza vaccination measure. The information needed for these measures would be collected via NHSN, and, therefore, is structured to keep additional burden to a minimum because more than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although this will add burden to hospitals, the initial setup and acclimation to the NHSN system will have already occurred with the adoption of the CLABSI measure for all hospital IQR for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden since many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with this section is the time and effort associated with collecting and submitting the additional data. With respect to the new HAI proposed measures for the FY 2015 payment determination, we estimate that an additional 1,500,000 burden hours per year (500,000 hours per measure) would be incurred by hospitals to report data on these measures.

We estimate that our proposed changes to our FY 2015 Hospital IQR Program measure set will increase the collection burden to hospitals by approximately 6,780,000 hours per year.

We have stated our intention to explore mechanisms for data submission using electronic health records (EHRs) (73 FR 48614; 74 FR 43866, 43892; 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that at a future date, such as FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

4. ICRs for the Occupational Mix Adjustment to the Proposed FY 2012 Index (Hospital Wage Index Occupational Mix Survey)

Section II.D. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2012 wage index. While the preamble does not contain any new ICRs, it is important to note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; however, it is currently approved under OMB control number 0938–0907, with an expiration date of February 28, 2013.

5. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.I.3. of the preamble of this final rule discusses revisions to the wage index based on hospital redesignations. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938–0573, with an expiration date of December 31, 2011.

6. ICRs for the Proposed Quality Reporting Program for LTCHs

In section VII.C. of this preamble, we are proposing three quality reporting measures for LTCHs for FY 2014: (1) Catheter Associated Urinary Tract Infections (CAUTI); (2) Central Line Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

We are proposing to collect the proposed HAI CLABSI and CAUTI quality measures through the use of the CDC/NHSN (*http://www.cdc.gov/nhsn/*). We will require that LTCH facilities report data on each patient in their facility who has been diagnosed with either a catheter associated urinary tract infection or a central line associated bloodstream infection.

The NHSN is a secure, Internet-based surveillance system which is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs. There are currently 435 LTCHs in operation in the United States and, according to CDC, 80 of these LTCHs already submit HAI data to NHSN. For these LTCHs, the burden of complying with the requirements of the proposed quality reporting program will be reduced because of familiarity with the NHSN submission process.

We require IPPS hospitals to report data regarding certain HAIs via NHSN as part of the Hospital IQR Program. We adopted the CLABSI quality measure under the Hospital IQR Program for the FY 2013 payment determination and are proposing to adopt the CAUTI measure for the FY 2014 payment determination. In addition, hospitals in 29 States are already using NHSN, and CDC supports more than 4,000 hospitals that are already using NHSN. Many LTCHs are integrated into or are part of large inpatient hospital systems. We believe that these hospital systems have gained the requisite knowledge and experience with the submission of data about HAIs via NHSN, under the Hospital IQR Program, State law, or voluntarily. Therefore, the transition to reporting HAIs via the NHSN for these LTCHs may be less burdensome.

The burden associated with these proposed quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI and CLABSI to NHSN for LTCHs that are not currently reporting such data. For LTCHs that already submit data regarding these HAIs to NHSN, there should be little, if any, additional burden. For LTCHs who submit data to NHSN for other HAIs, but not CAUTI and CLABSI data, then there may be some burden. However, we believe that this burden will be significantly decreased because these LTCHs are already enrolled in the NHSN system and are already familiar with the NHSN data submission process.

There are currently 435 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH would submit approximately 12 NHSN submissions (6 CAUTI and 6 CLABSI) per month (144 per LTCH annually). This equates to a total of approximately 62,640 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN data base. Based on this estimate, we expect each LTCH would expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN. Therefore, the total estimated annual hourly burden to all LTCHs in the U.S. for reporting to NHSN is 26,100 hours. The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a Registered Nurse of $41.59 and a Medical Billing Clerk/Data Entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH provider would be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN would be $760,676.[60] While the aforementioned requirements are subject to the PRA, we believe the associated burden hours are accounted for in the information collection request currently approved OCN 0920–0666.

With respect to the proposed pressure ulcer measure, we are proposing that we would post the specification for the pressure ulcer measure on our Web site along with the specific data elements necessary to be collected. We expect that the specific data items needed are part of the Continuity Assessment Record & Evaluation (CARE) instrument. We developed the CARE as required by section 5008 of the Deficit Reduction Act of 2005. CARE is a standardized assessment instrument that could be used across all postacute care sites to measure functional status and other factors during treatment and at discharge from each provider.

Because the CMS CARE pressure ulcer data set has not previously been introduced in the LTCH setting, there will be some initial burdens associated with the introduction of this data assessment tool. These initial costs would mainly be incurred in the

[60] Nursing Time—24 hours @ $41.59 per hour = $998.16/$998.16 × 435 LTCHs = $434,200. Admin Time—36 hours @ $20.57 per hour = $740.52/$740.52 × 435 LTCHs = $326,476. TOTAL = $434,200 + $326,476 = $760,676.

training of the facility staff. However, there should be little, if any, additional education required, in regards to the collection of the data, because pressure ulcer assessment should be a vital part of good patient care and daily in-house patient chart documentation.

We are proposing to require that the CARE pressure ulcer assessment be performed on each patient in a LTCH upon admission and again upon discharge. We believe that it is necessary to obtain admission and discharge pressure ulcer assessments on all patients admitted to LTCH facilities in order to obtain full and complete statistical data regarding the quality of care provided by the facility to the patients receiving care in that facility. The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to insure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients regardless of payor, using a subset of the CARE data set. An admission assessment is necessary in order to assess for either the presence or absence of pressure ulcers upon admission. If pressure ulcers are detected upon admission, then they must be properly assessed, staged and documented. Upon discharge, an assessment is needed to determine if any worsening of the pressure ulcers occurred during the LTCH stay. If no pressure ulcers had been noted on the admission assessment, then a discharge pressure ulcer assessment would be necessary in order to assess whether the patient had developed any new pressure ulcers during the LTCH stay.

At this time, CMS has not completed development of the information collection instrument that LTCHs would have to submit to comply with the aforementioned reporting requirements regarding the CARE pressure ulcer assessment. Because the forms are still under development, we cannot assign a complete burden estimate at this time. Once the forms are available, we will publish the required 60-day and 30-day **Federal Register** notices to solicit public comments on the instrument and to announce the submission of the information collection request to OMB for its review and approval.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1518–P, Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

*C. Response to Comments*

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**List of Subjects**

*42 CFR Part 412*

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

*42 CFR Part 413*

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

*42 CFR Part 476*

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as follows:

## PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332).

2. Section 412.23 is amended by—

a. In paragraph (e)(3)(i), removing the cross-reference "paragraph (e)(3)(ii) through (e)(3)(iv) of this section" and adding in its place the cross-reference "paragraphs (e)(3)(ii) through (e)(3)(v) of this section".

b. Revising paragraph (e)(3)(iv).

c. Adding a new paragraph (e)(3)(v).

d. Adding a new paragraph (e)(8).

The revision and additions read as follows:

**§ 412.23 Excluded hospitals: Classifications.**

* * * * *

(e) * * *

(3) * * *

(iv) If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in § 489.18 of this chapter) occurs within the period of at least 5 months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

(v) For periods beginning on or after October 1, 2011, a hospital that is excluded from the prospective payment system as a long-term care hospital that plans to undergo a change of ownership (as described in § 489.18 of this chapter) must notify its fiscal intermediary or MAC within 30 days of the effective date of such change of ownership, as specified in § 424.516(d)(1)(i) of this subchapter. The hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period following the change of ownership only if, for the period of at least 5 months of the 6 months immediately preceding the start of the hospital's next cost reporting period before the change of ownership, the hospital meets the required average length of stay (calculated in accordance with paragraph (e)(3)(i) of this section).

* * * * *

(8) *Application of LTCH moratorium on the increase in beds at section 114(d)(1)(B) of Public Law 110–173 to LTCHs and LTCH satellite facilities established or classified as such under section 114(d)(2) of Public Law 110–173.* Effective for the period beginning October 1, 2011, and ending December 28, 2012, for long-term care hospitals and long-term care hospital satellite facilities established under paragraph (e)(6)((ii) of this section for the period beginning December 29, 2007, and

ending September 30, 2011, the moratorium at paragraph (e)(7) applies and the number of Medicare-certified beds must not be increased beyond the initial number of Medicare-certified beds established under paragraph (e)(6)(ii) of this section.

* * * * *

3. Section 412.64 is amended by adding a new paragraph (d)(1)(iv) to read as follows:

**§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.**

* * * * *

(d) * * *

(1) * * *

(iv) For fiscal year 2012, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage points for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

4. Section 412.105 is amended by revising paragraph (b)(4) to read as follows:

**§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.**

* * * * *

(b) * * *

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, ancillary labor/delivery services, or inpatient hospice services;

* * * * *

5. Section 412.106 is amended by revising paragraph (a)(1)(ii)(B) to read as follows:

**§ 412.106 Special treatment: Hospitals that service a disproportionate share of low income patients.**

(a) * * *

(1) * * *

(ii) * * *

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services;

* * * * *

6. A new § 412.140 is added to Subpart H to read as follows:

**§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.**

(a) *Participation in the Hospital IQR Program.* In order to participate in the Hospital IQR Program, a subsection (d) hospital must—

(1) Register on QualityNet.org, before it begins to report data;

(2) Identify and register a QualityNet Administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CNN).

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which it wishes to participate.

(ii) A hospital that has received a new CCN and would like to participate in the program must submit a completed Notice of Participation Form to CMS no later than 180 days from the date identified as the open date on the approved CMS OSCAR system.

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

(c) *Submission and validation of Hospital IQR Program data.*

(1) *General rule.* Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) *Exception.* Upon request by a hospital, CMS may grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or waiver are available onQualityNet.org.

(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(e) *Reconsiderations and appeals of Hospital IQR Program decisions.*

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

(vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain the following additional information:

(A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and

(B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under Part 405, Subpart R of this chapter.

7. Section 412.211 is amended by adding a new paragraph (c)(4) to read as follows:

**§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.**

* * * * *

(c) * * *

(4) For fiscal year 2012 and subsequent fiscal years, the applicable percentage increase specified in § 412.64(d).

* * * * *

8. Section 412.523 is amended by—

a. Adding a new paragraph (c)(3)(viii).

b. Adding a new paragraph (d)(4).

The additions to read as follows:

**§ 412.523 Methodology for calculating the Federal prospective payment rates.**

* * * * *

(c) * * *

(3) * * *

(viii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2011, and ending September 30, 2012.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2011, and ending September 30, 2012, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.5 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(4) *Changes to the adjustment for area wage levels.* Beginning in FY 2012, CMS adjusts the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments.

* * * * *

9. Section 412.525 is amended by revising paragraph (c) to read as follows:

**§ 412.525 Adjustments to the Federal prospective payment.**

* * * * *

(c) *Adjustments for area wage levels.* (1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in § 412.503) of the hospital compared to the national average level of hospital wages and wage-related costs. The appropriate wage index that is established by CMS is updated annually. The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

(2) Beginning in FY 2012, any adjustments or updates to the area wage level adjustment under this paragraph (c) will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

* * * * *

## PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

10. The authority citation for Part 413 continues to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–133 (113 Stat. 1501A–332).

11. Section 413.70 is amended by—

a. Revising paragraph (b)(5)(i)(B).

b. Adding a new paragraph (b)(5)(i)(C).

The revision and addition read as follows:

**§ 413.70 Payment for services of a CAH.**

* * * * *

(b) * * *

(5) * * *

(i) * * *

(B) Effective for cost reporting periods beginning on or after January 1, 2004 and on or before September 30, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(C) Effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

* * * * *

## PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

12. The authority citation for Part 476 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

13. Section 476.78 is amended by—

a. In paragraph (a), removing the reference "§ 466.71" and adding in its place the reference "§ 476.71".

b. Revising paragraph (b).

The revision reads as follows:

**§ 476.78 Responsibilities of health care facilities.**

* * * * *

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers must—

(i) Photocopy and deliver to the QIO all required information within 30 calendar days of a request;

(ii) Deliver all required medical information to the QIO within 21 calendar days from the date of the request in those situations where a potential "serious reportable event" has been identified or where other circumstances as deemed by the QIO warrant earlier receipt of all required medical information. For purposes of this paragraph, a serious reportable event is defined as a preventable, serious, and unambiguous adverse event that should never occur.

(3) Providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Providers must assure, in accordance with the provisions of their agreements with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Providers must agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a provider, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Hospitals must agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance)

Dated: April 7, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: April 15, 2011.

**Kathleen Sebelius,**

*Secretary.*

**Note:** The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

## Addendum—Proposed Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2011

### I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2012 for acute care hospitals. We also are setting forth the proposed rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2012. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are proposing the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2011.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that will be applicable to Medicare LTCHs for FY 2012.

In general, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically have been paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Pub. L. 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking "October 1, 2011" and inserting "October 1, 2012". Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2012. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2012. In section IV. of this Addendum, we are setting forth our proposed changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2012. In section V. of this Addendum, we are proposing to make changes in the determination of the standard Federal rate for LTCHs under the LTCH PPS for FY 2012. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet.

### II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2012

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal

years is set forth at § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth at §§ 412.211 and 412.212. Below we discuss the factors used for determining the proposed prospective payment rates for FY 2012.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts and Puerto Rico-specific standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act.
- Proposed updates of 1.5 percent for all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the proposed update is −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage point).
- A proposed update of 1.5 percent to the Puerto Rico-specific standardized amount (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY 2011 budget neutrality factor and applying a revised factor.
- An adjustment to ensure the effects of the rural community hospital demonstration required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration for an additional 5 years are budget neutral, as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment in light of the court's decision in *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)).
- An adjustment to remove the FY 2011 outlier offset and apply an offset for FY 2012, as provided for in section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble to this proposed rule, an adjustment to meet the requirements of sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 to adjust the standardized amounts to offset the estimated amount of the increase in aggregate payments (including interest) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009.

Beginning in FY 2008, we applied the budget neutrality adjustment for the rural floor to the hospital wage indices rather than the standardized amount. As we did for FY 2011, for FY 2012, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment on the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2012 wage index for the rural floor. We note that, as proposed in section III.F.2 of the preamble of this proposed rule, we are not proposing to extend the imputed floor as this policy is set to expire with the FY 2011 wage index. Thus, the imputed floor is not reflected in the proposed FY 2012 wage index.

### *A. Calculation of the Adjusted Standardized Amount*

#### 1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary estimates, from time-to-time, the proportion of hospitals' costs that are attributable to wages and wage-related costs. In general, the standardized amount is divided into labor-related and nonlabor-related amounts; only the proportion considered to be the labor-related amount is adjusted by the wage index. Section 1886(d)(3)(E) of the Act requires that 62 percent of the standardized amount be adjusted by the wage index, unless doing so would result in lower payments to a hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II) of the Act extends this provision to the labor-related share for hospitals located in Puerto Rico.)

For FY 2012, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011, for the national standardized amounts and 62.1 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are applying the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2012, all Puerto Rico hospitals have a wage index less than 1.0. Therefore, the national labor-related share will always be 62 percent because the wage index for all Puerto Rico hospitals is less than 1.0.

For hospitals located in Puerto Rico, we are applying a labor-related share of 62.1 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto-Rico specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Table 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet.

#### 2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the FY 2012 national and Puerto Rico standardized amounts

irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. As discussed in section IV.K.3. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2012 applicable percentage increase (which is based on the first quarter 2011 forecast of the FY 2006-based IPPS market basket) by the multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2011 forecast. In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2012 by the estimated market basket percentage increase less 0.1 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services. Based on IGI's 2011 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2012 is 2.8 percent. Thus, for FY 2012, the proposed update to the average standardized amount is 1.5 percent for hospitals in all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii), the estimated update to the operating standardized amount is −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the IQR program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage point). The proposed standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and available via the Internet reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.5 percent.

Although the update factors for FY 2012 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2012 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2012 standardized amount to remove the effects of the FY 2011 geographic reclassifications and outlier payments before applying the FY 2012 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2012 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

Consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total "operating DRG payments," which does not include IME and DSH payments. In order to account for these Medicare Advantage IME payments in determining the budget neutrality adjustments for this final rule, we identified Medicare Advantage claims from IPPS teaching hospitals in the MedPAR data. Consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we first searched the MedPAR file for all claims with an IME payment greater than zero. We then filtered these claims for a subset of claims with a GHO Paid indicator with a value of "1" or if the IME payment field was equal to the DRG payment field. The GHO Paid indicator with a value of "1" in the MedPAR file indicates that the claim was paid by a Medicare Advantage plan (other than the IPPS IME payment specified at § 412.105(g)). For these Medicare Advantage claims from IPPS teaching hospitals, we computed a transfer-adjusted CMI by provider based on the FY 2011 MS–DRG GROUPER Version 28.0 assignment and relative weights. We also computed a transfer-adjusted CMI for these Medicare Advantage claims from IPPS teaching hospitals based on the proposed FY 2012 MS–DRG GROUPER Version 29.0 assignments and relative weights. These transfer-adjusted CMIs (and corresponding case counts) were used to calculate an IME teaching add-on payment in accordance with § 412.105(g). The total Medicare Advantage IME payment amount was then added to the total Federal payment amount for each provider (where applicable) in order to account for the Medicare Advantage IME payment in determining the budget neutrality adjustments. We note that we did not include Medicare Advantage IME claims when estimating outlier payments for providers because Medicare Advantage claims are not eligible for outlier payments under the IPPS.

Additionally, consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we examined the MedPAR and removed pharmacy charges for antihemophilic blood factor (which are paid separately under the IPPS) with an indicator of "3" for blood clotting with a revenue code of "0636"from the covered charge field for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

a. Proposed Recalibration of DRG Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II. of the preamble of this proposed rule, we normalized the recalibrated DRG weights by an adjustment factor so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals

because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with indices less than or equal to 1.0 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2012, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.C. of the preamble of this proposed rule.

For FY 2012, to comply with the requirement that DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2010 discharge data to simulate payments and compared aggregate payments using the FY 2011 labor-related share percentages, the FY 2011 relative weights, and the FY 2011 pre-reclassified wage data to aggregate payments using the FY 2011 labor-related share percentages, the proposed FY 2012 relative weights, and the FY 2011 pre-reclassified wage data. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.998419. As discussed in section IV. of this Addendum, we also would apply the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 to the hospital-specific rates that are to be effective for cost reporting periods beginning on or after October 1, 2011.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality, it was necessary to use a three-step process to comply with the requirements that DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. We first determined a proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 by using the same methodology described above to determine the proposed DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates. Secondly, to compute a budget neutrality factor for wage index and labor-related share changes, we used FY 2010 discharge data to simulate payments and compared aggregate payments using proposed FY 2012 relative weights and FY 2011 pre-reclassified wage indices, and applied the FY 2011 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) to aggregate payments using the proposed FY 2012 relative weights and the proposed FY 2012 pre-reclassified wage indices, and applied the proposed labor-related share for FY 2012 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0). In addition, we applied the proposed DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2011 to FY 2012. By applying this methodology, we determined a proposed budget neutrality factor of 1.000113 for changes to the wage index. Finally, we multiplied the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 (derived in the first step) by the proposed budget neutrality factor of 1.000113 for changes to the wage index (derived in the second step) to determine the proposed DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.998532.

b. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account "in applying any budget neutrality adjustment with respect to such index" under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality factor for FY 2012, we used FY 2010 discharge data to simulate payments and compared total IPPS payments with proposed FY 2012 relative weights, FY 2012 labor-related share percentages, and proposed FY 2012 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act to total IPPS payments with proposed FY 2012 relative weights, FY 2012 labor-related share percentages, and proposed FY 2012 wage data after such reclassifications. Based on these simulations, we calculated a proposed adjustment factor of 0.991528 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2012 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2011 budget neutrality adjustment factor. We note that the proposed FY 2012 budget neutrality adjustment reflects proposed FY 2012 wage index reclassifications approved by the MGCRB or the Administrator. We note that, for this proposed rule, as discussed in section III.B. of the preamble to this proposed rule, section 3137(c) of the Affordable Care Act resulted in some additional hospitals receiving reclassifications, or some hospitals receiving reclassifications to a different area. These reclassifications are included in the calculation of reclassification budget neutrality.

c. Proposed Rural Floor Budget Neutrality Adjustment

We make an adjustment to the wage index to ensure that aggregate payments to hospitals after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are not affected. As discussed in section III.F. of the preamble of this proposed rule, consistent with section 3141 of the Affordable Care Act, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

As discussed in section III.F.2. of the preamble of this proposed rule, for the FY 2012 wage index, there are wage data for one new hospital in rural Puerto Rico when previously there were none. Therefore, for FY 2012, we are proposing to calculate a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which will be used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals in Puerto Rico which receive 25 percent of the Puerto Rico-specific standardized amount). Our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion on the computation of the rural Puerto Rico wage index can be found in section III.G. of the preamble of this proposed rule. In past fiscal years, when there was no rural Puerto Rico wage index, we applied the national rural floor budget neutrality wage index factor to the national wage indices used to adjust the labor-related share for the national standardized amount (including the national Puerto Rico wage indexes) but did not apply this factor to the Puerto Rico-specific wage indices. We did not apply the national rural floor budget neutrality wage index factor to

the Puerto Rico-specific wage indices (nor did we compute a Puerto Rico-specific rural floor budget neutrality wage index factor) because there were no rural hospitals in Puerto Rico. As mentioned above, for FY 2012, there is now one rural Puerto Rico hospital and, therefore, it is necessary to compute and propose a Puerto Rico-specific rural floor budget neutrality wage index factor (in addition to the national factor).

To calculate both the national and Puerto Rico-specific rural floor budget neutrality adjustment factors, we used FY 2010 discharge data and proposed FY 2012 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national and Puerto Rico-specific rural floor applied to national and Puerto Rico-specific simulated payments with the national and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.993834 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.989226. The proposed national adjustment was applied to the national wage indices to produce a national rural floor budget neutral wage index and the proposed Puerto Rico-specific adjustment was then applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Adjustment in Light of Court Decision in *Cape Cod* v. *Sebelius*

We are proposing a 1.1 percent adjustment to the standardized amount in recognition of the decision of *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)), (here after referred to as "*Cape Cod*"). However, we emphasize that remand proceedings in that case are not complete and this proposal reflects the timing of the development of this proposed rule and not a final decision as to how the remand will proceed. In *Cape Cod,* the plaintiff hospitals challenged the rural floor budget neutrality adjustments for FY 2007 and FY 2008. In its opinion, the D.C. Circuit Court found that section 4410 of the Balanced Budget Act of 1997 (BBA) Public Law 105–33, which authorized both the rural floor and rural floor budget neutrality, would not permit CMS to ignore prior year errors in calculating rural floor budget neutrality adjustments. The case has now been remanded to CMS for further proceedings consistent with the DC Circuit Court's opinion.

While *Cape Cod* involved only FYs 2007 and 2008, the decision may have implications for FY 2012 payment rates, depending on the ultimate result of the remand proceedings. In light of that opinion and the timing of the rulemaking development process, we are proposing to restore to the FY 2012 standardized amount the offset for the rural floor and imputed floor on the standardized amount over FY 1998 through 2006. By making this proposal for FY 2012, all affected parties will have an opportunity to consider and comment on this proposed adjustment. Given that the court has remanded the case to the Secretary for FYs 2007 and 2008 and those remand proceedings are not yet complete, we may decide to take a different approach in the final rule, depending on public comments or developments in the remand proceedings.

To assess the overall impact of applying the rural floor budget neutrality adjustment to the standardized amount for the years between FY 1998 and FY 2006, we remodeled the recalibration/wage index budget neutrality factor for the years at issue (for which data were available), excluding the effect of the rural floor adjustment. For example, to compute the revised recalibration/wage index budget neutrality factor for FY 2000, we compared the FY 1999 pre-reclassified wage data with no rural floor to FY 2000 pre-reclassified wage data with no rural floor. We then compared the revised factor to the wage/recalibration budget neutrality factor derived under the original modeling logic; that is, where the current year's pre-reclassified wage data had a rural floor applied. The percent change in these two factors was then calculated for each remodeled year.

Remodeled years from FY 1998 to FY 2004 showed an approximate 0.1 percentage point increase between the factors for each year. This increase results in a total 0.7 percentage points, which, based on the court's comments, we believe should be returned to the standardized amount. Beginning with FY 2005 through FY 2006, the number of States for which a floor wage index was available was extended via the imputed floor policy. With additional States receiving increases in payment due to the application of the imputed floor, we estimated the combined effects of the rural and imputed floor to be approximately 0.2 percentage points per year. This resulted in a total of 0.4 percentage points, which we believe should be returned to the standardized amount. Therefore, to remove the effects of the rural floor from the standardized amount for FY 1998 through FY 2006, we are proposing to apply a onetime adjustment of 1.1 percentage points, which would increase the standardized amount (0.7 percentage points plus 0.4 percentage points for a factor of 1.011). We note that, in the FY 2008 IPPS final rule with comment period, we applied a onetime adjustment of 1.002214 to the FY 2008 standardized amount to address a single year transition (from FY 2007 to FY 2008) to a noncumulative system of the rural floor budget neutrality adjustment. This adjustment of 1.002214 to the FY 2008 standardized amount reflected the increase to the rates to remove the effects of the rural floor budget neutrality adjustment from FY 2007. Because this 1.002214 factor remains on the rate, we are not including an adjustment for FY 2007 in our calculation above.

e. Proposed Case-Mix Budget Neutrality Adjustment

(1) Proposed Adjustment to the FY 2012 IPPS Standardized Amount for the Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(A)(vi) of the Act

As stated earlier, beginning in FY 2008, we adopted the MS–DRG patient classification system for the IPPS to better recognize patients' severity of illness in Medicare payment rates. In the FY 2008 IPPS final rule with comment period (73 FR 47175 through 47186), we indicated that we believe the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for changes in documentation and coding. In that final rule, using the Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to maintain budget neutrality by adjusting the national standardized amounts to eliminate the effect of changes in documentation and coding that do not reflect real change in case-mix, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010 (for a total adjustment of −4.8 percent). On September 29, 2007, Public Law 110–90 was enacted. Section 7 of Public Law 110–90 included a provision that reduces the documentation and coding adjustment for the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009. To comply with the provision of section 7(a) of Public Law 110–90, in a final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we changed the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 national standardized amounts (as well as other payment factors and thresholds) accordingly, with these revisions being effective as of October 1, 2007. For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment specified in the FY 2008 IPPS final rule with comment period. As required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent.

In the FY 2010 IPPS proposed and final rules (74 FR 24092 through 24101 and 43768 through 43772), we discussed our analysis of FY 2008 claims data and did not apply any additional documentation and coding adjustments to the average standardized amounts under section 1886(d) of the Act. We refer readers to these rules for a detailed description of our analysis, responses to comments, and final policy respectively. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. Therefore, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110–90 to make an adjustment to the average

standardized amounts in order to eliminate the full effect of the documentation and coding changes on future payments. As we discussed in the FY 2011 IPPS/LTCH PPS final rule, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) were 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

Because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, we consider it imperative that CMS propose a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we are proposing a −3.15 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described below), and after considering other positive payment adjustments to FY 2012 rates proposed elsewhere in this proposed rule, we believe that the proposed −3.15 percent adjustment would allow for a significant reduction in potential unrecoverable overpayments, yet will maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. This proposal recognized that an additional adjustment of −0.75 percent (3.9 minus 3.15) will be required in future rulemaking to complete the statutory requirement under section 7(b)(1)(A) of Public Law 110–90. At this time, we are not proposing a timeline to implement the remainder of this adjustment. We refer the reader to section II.D. of the preamble of this proposed rule for more discussion. In addition, for a complete discussion on our proposed documentation and coding adjustment to the hospital-specific rates, we refer readers to section II.D.2.c. of this Addendum.

(2) Proposed Adjustment to the FY 2012 IPPS Standardized Amount for the Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As indicated in section II.D.4. in the preamble to this proposed rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 for those 2 years respectively by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, as we specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50425), we made an adjustment in FY 2011 to the standardized amount of −2.9 percent, representing half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. As we have previously noted, unlike the prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment or repayment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, but would be removed for subsequent fiscal years once we have offset the increase in aggregate payments for discharges for FY 2008 expenditures and FY 2009 expenditures. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, we are proposing to complete the recoupment adjustment according to the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90 by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized in FY 2011. Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals. We refer the reader to section II.D. of the preamble to this proposed rule for more discussion.

(3) Proposed Adjustment to the FY 2012 Puerto Rico Standardized Amount

As discussed in section II.D.9. of the preamble of this proposed rule, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that for documentation and coding changes that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. In FY 2011, as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), we applied an adjustment of −2.6 percent to the Puerto Rico-specific rate. Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we are proposing no further adjustment in this proposed rule for FY 2012. For a complete discussion on this proposal, we refer readers to section II.D.9. of the preamble of this proposed rule.

f. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.N. of the preamble to this proposed rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Public Law 108–173 requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented."

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration for an additional 5-year period, and allow up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426), in order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration as described in section IV.K. of that final rule. In other words, we applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration, consistent with past practice. We stated that we believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented," but does not identify the range across which aggregate payments must be held equal.

For FY 2012, we are proposing the estimated amount for the adjustment to the national IPPS rates for FY 2012 to be $52,642,213. Accordingly, to account for the estimated costs of the demonstration for the specific time periods as explained in detail in section IV.N. of the preamble of this proposed rule, for FY 2012, we computed a proposed factor of 0.999479 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standardized rate.

We note that because the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in FYs 2007 and 2008, has experienced a delay, for this proposed rule, we are unable to state the costs of the demonstration corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs of the demonstration corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustments for FYs and 2008. As a result, we are unable to propose the specific numeric adjustment representing this offsetting process that would be a component of the budget neutrality adjustment and that would be applied to the national IPPS rates. Therefore, the estimated budget neutrality adjustment to the national IPPS rate in this proposed rule does not include a component to account for these costs. We anticipate that this information may be available for the FY 2012 IPPS/LTCH PPS final rule, at which time, if data from settled cost reports are available, under our proposal, we would incorporate a component into the budget neutrality adjustment to the national IPPS rates to account for the amount by which the demonstration costs corresponding to FY 2007 and FY 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008.

g. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2012 is 80 percent, the same marginal cost factor we have used since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. We note that the statute requires outlier payments to be not less than 5 percent nor more than 6 percent of total "operating DRG payments" (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage.*

(1) Proposed FY 2012 Outlier Fixed-Loss Cost Threshold

For FY 2012, we are proposing to continue to use the same methodology used for FY 2009 (73 FR 48763 through 48766) to calculate the outlier threshold. Similar to the methodology used in the FY 2009 IPPS final rule, for FY 2012, we are proposing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). As we have done in the past, to calculate the proposed FY 2012 outlier threshold, we simulated payments by applying proposed FY 2012 rates and policies using cases from the FY 2010 MedPAR files. Therefore, in order to determine the proposed FY 2012 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2010 to FY 2012.

We are proposing to continue to use a refined methodology that takes into account the lower inflation in hospital charges that are occurring as a result of the outlier final rule (68 FR 34494), which changed our methodology for determining outlier payments by implementing the use of more current CCRs. Our refined methodology uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. As we have done in the past, we established the proposed FY 2012 outlier threshold using hospital CCRs from the December 2010 update to the Provider-Specific File (PSF)—the most recent available data at the time of this proposed rule.

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to derive the methodology described below to develop the CCR adjustment factor. For FY 2012, we are proposing to continue to use the same methodology to calculate the CCR adjustment by using the FY 2010 operating cost per discharge increase in combination with the actual FY 2010 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that the FY 2010 actual (otherwise referred to as "final") operating market basket percentage increase reflects historical data, whereas the published FY 2010 operating market basket update factor was based on IGI's 2009 second quarter forecast with historical data through the first quarter of 2009. We also note that while the FY 2010 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or "final" market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2010 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or "final" capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2012, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2008 to FY 2009 (1.0285) from the cost report and dividing it by the final operating market basket percentage increase from FY 2009 (1.0260). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of operating costs per discharge of 1.0465 divided by the FY 2007 final operating market basket percentage increase of 1.036, the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0506 divided by FY 2008 final operating market basket percentage increase of 1.040). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0076. We multiplied the 3-year average of 1.0076 by the FY 2010 final operating market basket percentage increase of 1.021, which resulted in an operating cost inflation factor of 2.87 percent or 1.028747. We then divided the operating cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 0.985018 to the operating CCRs from the

PSF (calculation performed on unrounded numbers).

As stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average "age" of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2009 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2008 to FY 2009 (1.0508) from the cost report and dividing it by the final capital market basket percentage increase from FY 2009 (1.015). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of capital costs per discharge of 1.0507 divided by the FY 2007 final capital market basket percentage increase of 1.013, the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0811 divided by the FY 2008 final capital market basket percentage increase of 1.015). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0459. We multiplied the 3-year average of 1.0459 by the FY 2010 final capital market basket percentage increase of 1.010, which resulted in a capital cost inflation factor of 5.63 percent or 1.056329. We then divided the capital cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 1.011428 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We are proposing to use the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges. Therefore, we believe it is appropriate to apply the charge factor to both the operating and capital CCRs.

As stated above, for FY 2012, we applied the proposed FY 2012 rates and policies using cases from the FY 2010 MedPAR files in calculating the proposed outlier threshold. As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.F. of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2012, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2012. If we did not take into account this provision, our estimate of total FY 2012 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

For this proposed rule, we are using the FY 2010 claims data to calculate the FY 2012 proposed outlier threshold. Our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs through FY 2010 is 5.4 percent, which is already included within the claims data (FY 2010 MedPAR files) used to calculate the proposed FY 2012 outlier threshold. Furthermore, we currently estimate that there would be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2010 MedPAR claims data, and we do not believe there is any need to inflate FY 2010 claims data for any additional case-mix growth projected to have occurred since FY 2010.

Using this methodology, we are proposing an outlier fixed-loss cost threshold for FY 2012 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $23,375.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2012 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also note that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2012 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.93 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2012 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2012 outlier threshold are as follows:

| | Operating Standardized Amounts | Capital Federal Rate |
|---|---|---|
| National | 0.949000 | 0.940626 |
| Puerto Rico | 0.955896 | 0.929936 |

We are proposing to apply the outlier adjustment factors to the proposed FY 2012 rates after removing the effects of the FY 2011 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.147 or capital CCRs greater than 0.158, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described at § 412.84(i)(3) of our regulations),

we use statewide average CCRs to determine whether a hospital qualifies for outlier payments.[61] Table 8A listed in section VI. of this Addendum (and available only via the Internet) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2011, these statewide average ratios would replace the ratios published in the IPPS final rule for FY 2011 (75 FR 50390–50392). Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the proposed comparable statewide average capital CCRs. Again, the proposed CCRs in Tables 8A and 8B would be used during FY 2012 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. Additionally, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010 which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2010 and FY 2011 Outlier Payments

In the FY 2011 IPPS final rule (75 FR 50431), we stated that, based on available data, we estimated that actual FY 2010 outlier payments would be approximately 4.7 percent of actual total DRG payments. This estimate was computed based on simulations using the FY 2009 MedPAR file (discharge data for FY 2009 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2010 claims, but instead reflected the application of FY 2010 rates and policies to available FY 2009 claims.

Our current estimate, using available FY 2010 claims data, is that actual outlier payments for FY 2010 were approximately 4.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2010, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2010. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2010 are equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2011 will be approximately 4.9 percent of actual total DRG payments, approximately 0.2 percentage points lower than the 5.1 percent we projected when setting the outlier policies for FY 2011. This estimate of 4.9 percent is based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims).

5. Proposed FY 2012 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2012. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 68.8 percent, and Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals (other than those in Puerto Rico) whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increase of 1.5 percent for FY 2012, and a proposed update of −0.5 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The labor-related and nonlabor-related portions of the proposed national average standardized amounts for Puerto Rico hospitals for FY 2011 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the proposed Puerto Rico standardized amounts. The labor-related share applied to the Puerto Rico specific standardized amount is the labor-related share of 62.1 percent, or 62 percent, depending on which provides higher payments to the hospital. (Section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the proposed changes from the FY 2011 national standardized amount. The second column shows the proposed changes from the FY 2011 standardized amounts for hospitals that satisfy the quality data submission requirement and therefore receive the full update of 1.5 percent. The third column shows the proposed changes for hospitals receiving the reduced update of −0.5 percent. The first row of the table shows the proposed updated (through FY 2011) average standardized amount after restoring the FY 2011 offsets for outlier payments, demonstration budget neutrality and the geographic reclassification budget neutrality. The DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, the FY 2011 factor is not removed from this table.

**BILLING CODE 4120–01–P**

[61] These figures represent 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals.

## COMPARISON OF FY 2011 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2012 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

| | Full Update (1.5 percent); Wage index is greater than 1.0000 | Full Update (1.5 percent); Wage index is less than or equal to 1.0000 | Reduced Update (-0.5 percent); Wage index is greater than 1.0000 | Reduced Update (-0.5 percent); Wage index is less than or equal to 1.0000 |
|---|---|---|---|---|
| FY 2011 Base Rate, after removing geographic reclassification budget neutrality, demonstration budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2011 documentation and coding recoupment, and outlier offset (based on the labor-related share percentage for FY 2011) | Labor: $3,947.65 Nonlabor: $1,790.21 | Labor: $3,557.48 Nonlabor: $2,180.39 | Labor: $3,947.65 Nonlabor: $1,790.21 | Labor: $3,557.48 Nonlabor: $2,180.39 |
| Proposed FY 2012 Update Factor | 1.015 | 1.015 | 0.9950 | 0.9950 |
| Proposed Adjustment for Restoring Rural Floor Budget Neutrality | 1.011 | 1.011 | 1.011 | 1.011 |
| Proposed FY 2012 DRG Recalibration and Wage Index Budget Neutrality Factor | 0.998532 | 0.998532 | 0.998532 | 0.998532 |
| Proposed FY 2012 Reclassification Budget Neutrality Factor | 0.991528 | 0.991528 | 0.991528 | 0.991528 |
| Proposed FY 2012 Rural Demonstration Budget Neutrality Factor | 0.999479 | 0.999479 | 0.999479 | 0.999479 |
| Proposed FY 2012 Outlier Factor | 0.949000 | 0.949000 | 0.949000 | 0.949000 |
| Proposed documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90 | 0.9282 | 0.9282 | 0.9282 | 0.9282 |
| Proposed Rate for FY 2012 | Labor: $3,531.06 Nonlabor: $1,601.30 | Labor: $3,182.06 Nonlabor:$1,950.30 | Labor: $3,461.48 Nonlabor: $1,569.75 | Labor: $3,119.36 Nonlabor: $1,911.87 |

BILLING CODE 4120–01–C

*B. Proposed Adjustments for Area Wage Levels and Cost-of-Living*

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2012. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2012 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes the Secretary to make an adjustment to take into account the unique circumstances of

hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. For FY 2011 and in prior fiscal years, we used the most recent updated cost of living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp.* We multiply the nonlabor-related portion of the standardized amount by the applicable adjustment factor.

Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

We do not believe it is appropriate to propose to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we are proposing to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPMs 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We believe using these COLAs will appropriately adjust the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii consistent with section 1886(d)(5)(H) of the Act. We invite public comments on this proposal.

Below is a table of factors obtained from OPM that we are proposing for FY 2012, which are the same as the factors currently in use under the IPPS for FY 2011.

**Table of Cost-of-Living Adjustment Factors: Alaska and Hawaii Hospitals**

| Area | Cost of Living Adjustment Factor |
|---|---|
| Alaska: | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.23 |
| Rest of Alaska | 1.25 |
| Hawaii: | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.18 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: http://www.opm.gov/oca/cola/rates.asp.)

*C. Proposed MS–DRG Relative Weights*

As discussed in section II.H. of the preamble of this proposed rule, we have developed relative weights for each MS–DRG that reflect the resource utilization of cases in each MS–DRG relative to Medicare cases in other MS–DRGs. Table 5 listed in section VI. of this Addendum (and available via the Internet) contains the relative weights that we are proposing to apply to discharges occurring in FY 2012. These factors have been recalibrated as explained in section II. of the preamble of this proposed rule.

*D. Calculation of the Proposed Prospective Payment Rates*

General Formula for Calculation of the Proposed Prospective Payment Rates for FY 2012

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs and MDHs, for FY 2012 equals the Federal rate.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2012 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2012 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

The prospective payment rate for hospitals located in Puerto Rico for FY 2012 equals 25 percent of the Puerto Rico rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

*Step 1*—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data (full update for hospitals submitting quality data; update including a −2.0 percent adjustment for hospitals that did not submit these data).

*Step 2*—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

*Step 3*—For hospitals in Alaska and Hawaii, multiply the nonlabor-related

portion of the standardized amount by the applicable cost-of-living adjustment factor.

*Step 4*—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

*Step 5*—Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS–DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by the formula described in section IV.E. of the preamble of this proposed rule.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

Hospital-specific rates have been determined for each of these hospitals based on the FY 1982 costs per discharge, the FY 1987 costs per discharge, or, for SCHs, the FY 1996 costs per discharge or the FY 2006 costs per discharge, and for MDHs, the FY 2002 cost per discharge. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002, and FY 2006 Hospital-Specific Rates for FY 2012

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs is 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point) for hospitals that submit quality data or −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage points) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.H. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the DRG classifications and the recalibration of the DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, for both SCHs and MDHs, the hospital-specific rate is adjusted by the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419, as discussed in section III. of this Addendum. The resulting rate would be used in determining the payment rate an SCH or MDH will receive for its discharges beginning on or after October 1, 2011.

c. Documentation and Coding Adjustment to the FY 2012 Hospital-Specific Rates for SCHs and MDHs

As discussed in section II.D. of the preamble of this proposed rule, because hospitals (SCHs and MDHs) paid based in whole or in part on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patients' severity of illness. Under section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patients' severity of illness. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426) and in section II.D. of the preamble of this proposed rule, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

As we discuss in section II.D. of the preamble of this proposed rule, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011 we had not made any previous adjustments to the hospital specific rates paid to SCHs and MDHs to account for documentation and coding changes. Consequently, in order to maintain consistency as far as possible with the adjustments applied to IPPS hospitals, we made an adjustment of −2.9 percent in FY 2011 to the hospital-specific rates paid to SCHs and MDHs.

As discussed above, we are proposing a −3.15 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−3.15 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2011). The proposed IPPS documentation and coding adjustment exceeds the remaining −2.5 percent documentation and coding adjustment for hospitals receiving a hospital-specific rate (that is, the entire −5.4 percent adjustment, minus the −2.9 percent adjustment finalized for FY 2011). We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we are proposing a −2.5 percent payment adjustment to the hospital-specific rate. We believe that proposing the entire remaining prospective adjustment of −2.5 percent allows CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG.

d. Proposed Adjustment to Restore Prior Rural Floor Budget Neutrality Offsets

As discussed in section II.A.4.d. of this Addendum, in light of the *Cape Cod* decision, we are proposing to adjust hospital-specific amounts by 0.9 percent to restore to these amounts the offset for the rural floor and imputed floor in prior years. Our rationale and methodology for such adjustment are explained in section II.A.4.d of this Addendum. As with the standardized amount, we are proposing to return 0.7 percentage points for FYs 1998 through 2004, and 0.2 percentage points for FY 2005 to the hospital-specific rates. We note that, in the FY 2006 IPPS final rule (70 FR 47429 and 47430), beginning in FY 2006, we changed our methodology and began applying only the DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates. Because the rural floor budget neutrality adjustment was not applied to the hospital-specific rates in FYs 2006 and 2007, we are not including FY 2006 and FY 2007

in our assessment. Therefore, to remove the effects of the rural floor from the hospital-specific rates for FYs 1998 through 2005, we are proposing to apply a onetime permanent adjustment of 0.9 percent to the hospital-specific rates (that is, a factor of 1.009).

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or after October 1, 2011, and before October 1, 2012

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

*Step 1*—Select the applicable average standardized amount considering the applicable wage index (Table 1C published in section VI. of this Addendum and available via the Internet).

*Step 2*—Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

*Step 3*—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

*Step 4*—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

*Step 5*—Multiply the result in Step 4 by 25 percent.

b. National Rate

The national prospective payment rate is determined as follows:

*Step 1*—Select the applicable average standardized amount.

*Step 2*—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

*Step 3*—Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

*Step 4*—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

*Step 5*—Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico rate and the national rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico. This rate would then be further adjusted if the hospital qualifies for either the IME or DSH adjustment.

## III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2012

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, hospitals were paid during a 10-year transition period (which extended through FY 2001) to change the payment methodology for Medicare acute care hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the proposed capital Federal rate for FY 2012, which would be effective for discharges occurring on or after October 1, 2011.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except "new" hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for (regular and special) exceptions under § 412.348. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

For FYs 1992 through 1995, § 412.352 required that the capital Federal rate also be adjusted by a budget neutrality factor so that aggregate payments for inpatient hospital capital costs were projected to equal 90 percent of the payments that would have been made for capital-related costs on a reasonable cost basis during the respective fiscal year. That provision expired in FY 1996. Section 412.308(b)(2) describes the 7.4 percent reduction to the capital Federal rate that was made in FY 1994, and § 412.308(b)(3) describes the 0.28 percent reduction to the capital Federal rate made in FY 1996 as a result of the revised policy for paying for transfers. In FY 1998, we implemented section 4402 of Public Law 105–33, which required that, for discharges occurring on or after October 1, 1997, the budget neutrality adjustment factor in effect as of September 30, 1995, be applied to the unadjusted capital standard Federal rate and the unadjusted hospital-specific rate. That factor was 0.8432, which was equivalent to a 15.68 percent reduction to the unadjusted capital payment rates. An additional 2.1 percent reduction to the rates was effective from October 1, 1997 through September 30, 2002, making the total reduction 17.78 percent. As we discussed in the FY 2003 IPPS final rule (67 FR 50102) and implemented in § 412.308(b)(6), the 2.1 percent reduction was restored to the unadjusted capital payment rates effective October 1, 2002.

To determine the appropriate budget neutrality adjustment factor and the regular exceptions payment adjustment during the 10-year transition period, we developed a dynamic model of Medicare inpatient capital-related costs; that is, a model that projected changes in Medicare inpatient capital-related costs over time. With the expiration of the budget neutrality provision, the capital cost model was only used to estimate the regular exceptions payment adjustment and other factors during the transition period. As we explained in the FY 2002 IPPS final rule (66 FR 39911), beginning in FY 2002, an adjustment for regular exception payments is no longer necessary because regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001 (see § 412.348(b)). Because payments are no longer made under the regular exception policy effective with cost reporting periods beginning in FY 2002, we discontinued use of the capital cost model. The capital cost model and its application during the transition period are described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099).

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Prior to FY 1998, hospitals located in Puerto Rico were paid a blended operating rate that consisted of 75 percent of the applicable standardized amount specific to Puerto Rico hospitals and 25 percent of the applicable national average standardized amount. Similarly, prior to FY 1998, hospitals located in Puerto Rico were paid a blended capital rate that consisted of 75 percent of the applicable capital Puerto Rico-specific rate and 25 percent of the applicable capital Federal rate. However, effective October 1, 1997, in accordance with section 4406 of Public Law 105–33, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 50 percent of the applicable standardized amount specific to Puerto Rico hospitals and 50 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 1997, we also revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 50 percent of the Puerto Rico capital rate and 50 percent of the national capital Federal rate.

As we discussed in the FY 2005 IPPS final rule (69 FR 49185), section 504 of Public Law

108–173 increased the national portion of the operating IPPS payments for hospitals located in Puerto Rico from 50 percent to 62.5 percent and decreased the Puerto Rico portion of the operating IPPS payments from 50 percent to 37.5 percent for discharges occurring on or after April 1, 2004 through September 30, 2004 (refer to the March 26, 2004 One-Time Notification (Change Request 3158)). In addition, section 504 of Public Law 108–173 provided that the national portion of operating IPPS payments for hospitals located in Puerto Rico is equal to 75 percent and the Puerto Rico-specific portion of operating IPPS payments is equal to 25 percent for discharges occurring on or after October 1, 2004. Consistent with that change in operating IPPS payments to hospitals located in Puerto Rico, for FY 2005 we revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico-specific capital rate and 75 percent of the national capital Federal rate for discharges occurring on or after October 1, 2004 (69 FR 49185).

*A. Determination of Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update*

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2012. In particular, we explain why the proposed FY 2012 capital Federal rate would increase approximately 0.60 percent, compared to the FY 2011 capital Federal rate. As discussed in the impact analysis in Appendix A of this proposed rule, we estimate that capital payments per discharge would increase 1.7 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2012 under that framework is 1.5 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.5 percent increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a 0.0 percent adjustment for the FY 2010 DRG reclassification and recalibration, and a forecast error correction of 0.0 percent. As discussed below in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2012 CIPI projection in that same section of this Addendum. We note, as discussed in section VI.E.1. of the preamble of this proposed rule, we are proposing to apply a −1.0 percent adjustment to the capital rate in FY 2012 to account for the effect of changes in documentation and coding under the MS–DRGs that do not correspond to changes in real increases in patients' severity of illness. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2012.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes ("real" case-mix change);
- Changes in hospital documentation and coding of patient records result in higher weight DRG assignments ("coding effects"); and
- The annual DRG reclassification and recalibration changes may not be budget neutral ("reclassification effect").

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B in the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2012, we are projecting a 1.0 percent total increase in the case-mix index. We estimated that the real case-mix increase would also equal 1.0 percent for FY 2012. The proposed net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2012 is 0.0 percentage points.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2010 DRG reclassification and recalibration as part of our update for FY 2012. To adjust for reclassification and recalibration effects, under our historical methodology, we would run the FY 2010 cases through the FY 2009 GROUPER and through the FY 2010 GROUPER. If the resulting ratio of the case-mix indices did not equate to 1.0, in the update framework for FY 2012, we would propose to make an adjustment to account for the reclassification and recalibration effects in FY 2010. In the update framework for FY 2011 (the FY 2011 IPPS final rule (75 FR 50435)), we did not adjust for reclassification and recalibration effects from FY 2009 because it was accounted for in the documentation and coding adjustment to the capital Federal rates for FY 2011. For FY 2012, we are proposing not to perform an analysis of changes in case-mix in FY 2010 due to the effect of documentation and coding, as this would be most consistent with our approach under the operating IPPS. Therefore, at this time, under our broad authority in section 1886(g) of the Act, we are proposing a 0.0 percent adjustment for reclassification and recalibration in the update framework. We may evaluate the effect of FY 2010 reclassification and recalibration if we perform an analysis of the documentation and coding effect in FY 2010 in future rulemaking.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. A forecast error of −0.2 percentage point was calculated for the proposed FY 2012 update. That is, current historical data indicate that the forecasted FY 2010 CIPI (1.2 percent) used in calculating the FY 2010 update factor was 0.2 percentage point higher than the actual realized price increases (1.0 percent). The two primary contributing factors for the FY 2011 CIPI forecast being slightly higher than the actual FY 2011 increase in the CIPI were that the prices for the nonprofit and government interest cost category grew slower than what had been forecasted, and the prices for the other capital expenses cost category also grew slower than what had been forecasted. Because the estimation of the change in the CIPI is not greater than 0.25 percentage point, we are proposing to make a 0.0 percent adjustment for forecast error in the update for FY 2012.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the

discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove non-cost-effective services. Our intensity measure is based on a 5-year average.

Historically, we calculated case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CIPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

We developed a Medicare-specific intensity measure based on a 5-year average. Past studies of case-mix change by the RAND Corporation (*Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between 1987 and 1988* by G. M. Carter, J. P. Newhouse, and D. A. Relles, R–4098–HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent on total change, but was usually a fairly steady increase of 1.0 to 1.5 percent per year. However, we used 1.4 percent as the upper bound because the RAND study did not take into account that hospitals may have induced doctors to document medical records more completely in order to improve payment.

In accordance with § 412.308(c)(1)(ii), we began updating the capital standard Federal rate in FY 1996 using an update framework that takes into account, among other things, allowable changes in the intensity of hospital services, as noted above. For much of the last decade, we found that the charge data appeared to be skewed as a result of hospitals attempting to maximize outlier payments, while lessening costs, and we established a 0.0 percent adjustment for intensity in each of those years. Therefore, for FY 2011, in an effort to further refine the intensity adjustment and more accurately reflect allowable changes in hospital intensity, we revised our intensity measure to use changes in hospital *costs* per discharge over a 5-year average rather than changes in hospital charges, which had been the basis of the intensity adjustment in prior years. The unique nature of capital—how and when it is purchased, its longevity, and how it is financed—creates a greater degree of variance in capital cost among hospitals than does operating cost. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436), we believe that using changes in capital costs per discharge as the basis for the intensity adjustment in lieu of changes in charges will decrease some of the variability of this adjustment. In this proposed rule, for FY 2012, we are proposing to use an intensity measure that is based on a 5-year adjusted average of cost per discharge, as we did for FY 2011. Therefore, the proposed intensity measure for FY 2012 is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2009. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2009. In the past, when we found intensity to be declining, we believed a zero (rather than negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2012. Therefore, we are proposing to make a 0.0 percent adjustment for intensity in the update for FY 2012.

Above, we described the basis of the components used to develop the proposed 1.5 percent capital update factor under the capital update framework for FY 2012 as shown in the table below.

**Proposed CMS FY 2012 Update Factor to the Capital Federal Rate**

| | |
|---|---|
| Capital Input Price Index | 1.5 |
| Intensity: | 0.0 |
| Case-Mix Adjustment Factors: | |
| Real Across DRG Change | -1.0 |
| Projected Case-Mix Change | 1.0 |
| Subtotal | 1.5 |
| Effect of FY 2010 Reclassification and Recalibration | 0.0 |
| Forecast Error Correction | 0.0 |
| Total Update | 1.5 |

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2011 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2012. (MedPAC's Report to the Congress: Medicare Payment Policy, March 2011, Chapter 3.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2011, we estimated that outlier payments for capital would equal 5.96 percent of inpatient capital-related payments based on the capital Federal rate in FY 2011. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 5.94 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2012. Therefore, we are proposing to apply an outlier adjustment factor of 0.9406 in determining the capital Federal rate. Thus, we estimate that the percentage of capital outlier payments to total capital standard payments for FY 2012 would be slightly lower than the percentage for FY 2011. This slight decrease in estimated capital outlier payments is primarily due to the estimated increase in capital IPPS payments per discharge. That is, because capital payments per discharge are projected to be higher in FY 2012 compared to FY 2011, as shown in Table III. in section VIII. of Appendix A to this proposed rule, fewer cases would qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in

determining the capital Federal rate. The proposed FY 2012 outlier adjustment of 0.9406 is a 0.02 percent change from the FY 2011 outlier adjustment of 0.9404. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2012 is 1.0002 (0.9406/0.9404). Thus, the proposed outlier adjustment would increase the FY 2012 capital Federal rate by 0.02 percent compared with the FY 2011 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to estimate the aggregate payments that would have been made on the basis of the capital Federal rate with and without changes in the DRG classifications and weights and in the GAF to compute the adjustment required to maintain budget neutrality for changes in DRG weights and in the GAF. During the transition period, the capital cost model was also used to estimate the regular exception payment adjustment factor. As we explained in section III.A. of this Addendum, beginning in FY 2002, an adjustment for regular exception payments was no longer necessary. Therefore, we no longer use the capital cost model. Furthermore, as discussed below, special exceptions payments will no longer be made in FY 2012, and an exceptions payment adjustment factor will no longer be necessary, as there are no remaining hospitals eligible to receive special exceptions payments.

To determine the proposed factors for FY 2012, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the FY 2011 GAF to estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the proposed FY 2012 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment of 1.0005 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9902, yielding an adjustment of 0.9906, through FY 2012. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment of 1.0087 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9965, yielding a cumulative adjustment of 1.0052 through FY 2012.

We then compared estimated aggregate capital Federal rate payments based on the FY 2011 DRG relative weights and the proposed FY 2012 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2012 MS–DRG classifications and relative weights and the proposed FY 2012 GAFs. The proposed incremental adjustment for DRG classifications and proposed changes in relative weights is 1.0000 both nationally and for Puerto Rico. The proposed cumulative adjustments for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2012 are 0.9906 nationally and 1.0052 for Puerto Rico. We note that all the values are calculated with unrounded numbers. The following table summarizes the adjustment factors for each fiscal year:

BILLING CODE 4120–01–P

## PROPOSED BUDGET NEUTRALITY ADJUSTMENT FOR DRG RECLASSIFICATIONS AND RECALIBRATION AND THE GEOGRAPHIC ADJUSTMENT FACTORS

| Fiscal Year | National | | | | Puerto Rico | | | |
|---|---|---|---|---|---|---|---|---|
| | Incremental Adjustment | | | Cumulative | Incremental Adjustment | | | Cumulative |
| | Geographic Adjustment Factor | DRG Reclassifications and Recalibration | Combined | | Geographic Adjustment Factor | DRG Reclassifications and Recalibration | Combined | |
| 1992 | — | — | — | 1.00000 | — | — | — | — |
| 1993 | — | — | 0.99800 | 0.99800 | — | — | — | — |
| 1994 | — | — | 1.00531 | 1.00330 | — | — | — | — |
| 1995 | — | — | 0.99980 | 1.00310 | — | — | — | — |
| 1996 | — | — | 0.99940 | 1.00250 | — | — | — | — |
| 1997 | — | — | 0.99873 | 1.00123 | — | — | — | — |
| 1998 | — | — | 0.99892 | 1.00015 | — | — | — | 1.00000 |
| 1999 | 0.99944 | 1.00335 | 1.00279 | 1.00294 | 0.99898 | 1.00335 | 1.00233 | 1.00233 |
| 2000 | 0.99857 | 0.99991 | 0.99848 | 1.00142 | 0.99910 | 0.99991 | 0.99901 | 1.00134 |
| 2001[1] | 0.99782 | 1.00009 | 0.99791 | 0.99933 | 1.00365 | 1.00009 | 1.00374 | 1.00508 |
| 2001[2] | 0.99771[3] | 1.00009[3] | 0.99780[3] | 0.99922 | 1.00365[3] | 1.00009[3] | 1.00374[3] | 1.00508 |
| 2002 | 0.99666[4] | 0.99668[4] | 0.99335[4] | 0.99268 | 0.98991[4] | 0.99668[4] | 0.99662[4] | 0.99164 |
| 2003[5] | 0.99915 | 0.99662 | 0.99577 | 0.98848 | 1.00809 | 0.99662 | 1.00468 | 0.99628 |
| 2003[6] | 0.99896[7] | 0.99662[7] | 0.99558[7] | 0.98830 | 1.00809 | 0.99662 | 1.00468 | 0.99628 |
| 2004[8] | 1.00175[9] | 1.00081[9] | 1.00256[9] | 0.99083 | 1.00028 | 1.00081 | 1.00109 | 0.99736 |
| 2004[10] | 1.00164[9] | 1.00081[9] | 1.00245[9] | 0.99072 | 1.00028 | 1.00081 | 1.00109 | 0.99736 |
| 2005[11] | 0.99967[12] | 1.00094 | 1.00061[12] | 0.99137 | 0.99115 | 1.00094 | 0.99208 | 0.98946 |
| 2005[13] | 0.99946[12] | 1.00094 | 1.00040[12] | 0.99117 | 0.99115 | 1.00094 | 0.99208 | 0.98946 |
| 2006 | 1.00185[14] | 0.99892 | 1.00076[14] | 0.99198 | 1.00762 | 0.99892 | 1.00653 | 0.99592 |
| 2007 | 1.00000 | 0.99858 | 0.99858 | 0.99057 | 1.00234 | 0.99858 | 1.00092 | 0.99683 |
| 2008 | 1.00172 | 0.99792 | 0.99963 | 0.99021 | 1.00079 | 0.99792 | 0.99870 | 0.99554 |
| 2009[15] | 1.00206 | 0.99945 | 1.00150 | 0.99170 | 1.00097 | 0.99945 | 1.00041 | 0.99595 |
| 2010[16] | 0.99989 | 0.99945 | 0.99941 | 0.99112 | 1.00141 | 0.99953 | 1.00094 | 0.99688 |
| 2011[17] | 0.99989 | 0.99914 | 0.99903 | 0.99016 | 1.00050 | 0.99914 | 0.999564 | 0.99652 |
| 2012[18] | 1.00050 | 0.99996 | 1.00046 | 0.99061 | 1.00879 | 0.99996 | 1.00874 | 1.00523 |

[1]Factors effective for the first half of FY 2001 (October 2000 through March 2001).
[2] Factors effective for the second half of FY 2001 (April 2001 through September 2001).
[3]Incremental factors are applied to FY 2000 cumulative factors.
[4]Incremental factors are applied to the cumulative factors for the first half of FY 2001.
[5]Factors effective for the first half of FY 2003 (October 2002 through March 2003).
[6]Factors effective for the second half of FY 2003 (April 2003 through September 2003).
[7]Incremental factors are applied to FY 2002 cumulative factors.
[8]Factors effective for the first half of FY 2004 (October 2003 through March 2004).
[9]Incremental factors are applied to the cumulative factors for the second half of FY 2003.
[10]Factors effective for the second half of FY 2004 (April 2004 through September 2004).
[11]Factors effective for the first quarter of FY 2005 (September 2004 through December 2004).
[12]Incremental factors are applied to average of the cumulative factors for the first half (October 1, 2003 through March 31, 2004) and second half (April 1, 2004 through September 30, 2004) of FY 2004.
[13]Factors effective for the last three quarters of FY 2005 (January 2005 through September 2005).
[14]Incremental factors are applied to average of the cumulative factors for 2005.
[15]Final factors for FY 2009, including the implementation of section 124 of Pub. L. 110-275, which affects wage indices and GAFs for FY 2009.
[16] Final revised factors for FY 2010 which reflect the effect of the provisions of the Affordable Care Act.
[17] Final factors for FY 2011.
[18] Proposed factors for FY 2012.

BILLING CODE 4120–01–C

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are determined separately) for changes in the GAF (including geographic reclassification) and the DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

For FY 2011, we established a GAF/DRG budget neutrality factor of 0.9990 (75 FR 50437). For FY 2012, we are proposing to establish a GAF/DRG budget neutrality factor of 1.0005. The GAF/DRG budget neutrality factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs. The incremental change in the proposed adjustment from FY 2011 to FY 2012 is 1.0005. The proposed cumulative change in the capital Federal rate due to this proposed adjustment is 0.9906 (the product of the incremental factors for FYs 1995 through 2011 and the proposed incremental factor of 1.0005 for FY 2012). (We note that averages of the incremental factors that were in effect during FYs 2005 and 2006, respectively, were used in the calculation of the cumulative adjustment of 0.9906 for FY 2012.)

The proposed factor accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. It also incorporates the effects on the proposed GAFs of FY 2012 geographic reclassification decisions made by the MGCRB compared to FY 2011 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital standard Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital PPS payments. In estimating the proportion of regular exception payments to total capital PPS payments during the transition period, we used the actuarial capital cost model originally developed for determining budget neutrality (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to determine the exceptions payment adjustment factor, which was applied to both the Federal and hospital-specific capital rates.

Since FY 2002, an adjustment for regular exception payments was no longer necessary in determining the capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, in FY 2002 and subsequent fiscal years, no payments are made under the regular exceptions provision (66 FR 39949). Furthermore, there are no longer any remaining hospitals eligible to receive a special exceptions payment under § 412.348(g) because they have reached the limitation on the period for exception payments under § 412.348(g)(7). A hospital qualifying for a special exceptions payment could receive exceptions payments for up to 10 years from the year in which it completed a project that met the applicable criteria under § 412.348(g). However, the project had to be completed no later than the end of the hospital's last cost reporting period beginning before October 1, 2001. Therefore, FY 2012 would be the final year any hospital could have received a special exceptions payment. However, as we indicated above, based on the date the projects were completed, there are no remaining hospitals eligible to receive a special exceptions payment in FY 2012, which negates the need for a special exceptions adjustment for FY 2012. Furthermore, we note that special exceptions adjustments will no longer be made in subsequent years because FY 2012 is the final year payments could have been made to eligible hospitals in accordance with § 412.348(g)(7).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50439), we estimated that total (special) exceptions payments for FY 2011 would equal 0.04 percent of aggregate payments based on the capital Federal rate. Therefore, we applied an exceptions adjustment factor of 0.9996 (1 − 0.0004) to determine the FY 2011 capital Federal rate. As we stated above, because there are no special exceptions payments in FY 2012, we are proposing to no longer apply an exceptions payment adjustment factor to the proposed capital Federal rate for FY 2012. However, the exceptions reduction factors were not built permanently into the capital rates; that is, the factors were not applied cumulatively in determining the capital Federal rate. Therefore, we are proposing to apply a factor of 1.0004 (1/0.9996) in determining the proposed FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor that was applied in determining the FY 2011 capital Federal rate.

5. Proposed Capital Standard Federal Rate for FY 2012

For FY 2011, we established a capital Federal rate of $420.01 (75 FR 50439). We are proposing to establish an update of 1.5 percent in determining the proposed FY 2012 capital Federal rate for all hospitals. However, as discussed in greater detail in section V.E. of the preamble of this proposed rule, under the statutory authority at section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we are proposing to make an additional 1.0 percent reduction to the national capital Federal payment rate in FY 2012 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS–DRGs. Accordingly, we are proposing to apply a cumulative documentation and coding adjustment factor of 0.9479 in determining the proposed FY 2012 capital Federal rate (that is, the existing −0.6 percent adjustment in FY 2008 plus the −0.9 percent adjustment in FY 2009, plus the −2.9 percent adjustment for FY 2011, plus the proposed −1.0 percent adjustment for FY 2012, computed as 1 divided by (1.006 × 1.009 × 1.029 × 1.010). (We note that we did not apply a documentation and coding adjustment to the capital Federal rate in FY 2010 (74 FR 43927).) As a result of the proposed 1.5 percent update and other budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $422.54 for FY 2012. The proposed national capital Federal rate for FY 2012 was calculated as follows:

- The proposed FY 2012 update factor is 1.0150, that is, the proposed update is 1.5 percent.
- The proposed FY 2012 budget neutrality adjustment factor that is applied to the capital standard Federal payment rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 1.0005.
- The proposed FY 2012 outlier adjustment factor is 0.9406.
- The proposed FY 2012 (special) exceptions payment adjustment factor is 1.0000 because we project that there will be no exceptions payments made in FY 2012 as discussed above in section III.A. of this Addendum. However, we are proposing to apply a factor of 1.0004 (1/0.9996) in determining the proposed FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor applied in determining the FY 2011 capital Federal rate.
- The proposed cumulative adjustment factor for FY 2012 applied to the national capital Federal rate for proposed changes in documentation and coding under the MS–DRGs is 0.9479.

Because the proposed capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital standard Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2012 affects the computation of the proposed FY 2012 national capital Federal rate in comparison to the FY 2011 national capital Federal rate. The proposed FY 2012 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2011 capital Federal rate. The proposed GAF/DRG budget neutrality factor of 1.0005 has the effect of

increasing the capital Federal rate by 0.05 percent. The proposed FY 2012 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.02 percent compared to the FY 2011 capital Federal rate. The proposed FY 2012 special exceptions payment adjustment factor to restore the FY 2011 exceptions adjustment factor of 0.9996 has the net effect of increasing the proposed FY 2012 national capital Federal rate by 0.04 percent as compared to the FY 2011 national capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 0.60 percent compared to the FY 2011 national capital Federal rate.

**Comparison of Factors and Adjustments: FY 2011 Capital Federal Rate and Proposed FY 2012 Capital Federal Rate**

| | FY 2011 | Proposed FY 2012 | Change | Percent Change |
|---|---|---|---|---|
| Update Factor[1] | 1.0150 | 1.0150 | 1.0150 | 1.50 |
| GAF/DRG Adjustment Factor[1] | 0.9990 | 1.0005 | 1.0005 | 0.05 |
| Outlier Adjustment Factor[2] | 0.9404 | 0.9406 | 1.0002 | 0.02 |
| Exceptions Adjustment Factor[3] | 0.9996 | 1.0000 | 1.0004 | 0.04 |
| MS-DRG Documentation and Coding Adjustment Factor | 0.9574[4] | 0.9479[5] | 0.9901[6] | -0.99 |
| Capital Federal Rate[7] | $420.01 | $422.54 | 1.0060 | 0.60 |

[1] The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates. Thus, for example, the incremental change from FY 2011 to FY 2012 resulting from the application of the 1.0005 GAF/DRG budget neutrality factor for FY 2012 is a net change of 1.0005.

[2] The outlier reduction factor is not built permanently into the capital rate; that is, the factor is not applied cumulatively in determining the capital rate. Thus, for example, the net change resulting from the application of the FY 2012 outlier adjustment factor is 0.9406/0.9404, or 1.0002.

[3] There are no longer any hospitals eligible to receive special exception adjustments in FY 2012, but since the exceptions payment adjustment is not cumulative, we are restoring the 0.9996 special exceptions adjustment applied to the FY 2011 capital rate.

[4] The documentation and coding adjustment factor includes the -0.6 percent in FY 2008, -0.9 percent in FY 2009, no additional reduction in FY 2010, and the -2.9 percent in FY 2011.

[5] The documentation and coding adjustment factor includes the -0.6 percent in FY 2008, -0.9 percent in FY 2009, no additional reduction in FY 2010, the -2.9 percent in FY 2011, and the proposed -1.0 percent in FY 2012.

[6] The change is measured from the FY 2011 cumulative factor of 0.9574.

[7] Sum of percent change may not sum due to rounding.

6. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, as discussed in section V. of the preamble of this proposed rule, beginning with discharges occurring on or after October 1, 2004, capital payments to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustments for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. The proposed national GAF budget neutrality factor is 1.0088 and the proposed DRG adjustment is 1.0000, for a combined proposed cumulative adjustment of 1.0052 for FY 2012.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico). In FY 1998, we implemented a 17.78 percent reduction to the Puerto Rico capital rate as a result of Public Law 105–33. In FY 2003, a small part of that reduction was restored.

For FY 2011, the special capital rate for hospitals located in Puerto Rico was $197.66 (75 FR 50441). Consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of –2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in

case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in this proposed rule, we are not proposing to make any additional adjustments for the effect of documentation and coding that did not reflect real changes in case-mix to the capital Puerto Rico-specific rate for FY 2012. Therefore, with the changes we are proposing to make to the other factors used to determine the capital rate, the proposed FY 2012 special capital rate for hospitals in Puerto Rico is $205.01.

*B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2012*

Because the 10-year capital PPS transition period ended in FY 2001, all hospitals (except "new" hospitals under § 412.324(b) and under § 412.304(c)(2)) are paid based on 100 percent of the capital Federal rate in FY 2012.

For purposes of calculating payments for each discharge during FY 2012, the capital standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2012 are in section II.A. of this Addendum. For FY 2012, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $23,375.

Currently, as provided in § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

*C. Capital Input Price Index*

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021), we rebased and revised the CIPI to a FY 2006 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV. of the preamble of that final rule.

2. Forecast of the CIPI for FY 2012

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2011), we are forecasting the FY 2006-based CIPI to increase 1.5 percent in FY 2012. This reflects a projected 1.9 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.1 percent increase in other capital expense prices in FY 2012, partially offset by a projected 0.9 percent decline in vintage-weighted interest expenses in FY 2012. The weighted average of these three factors produces the 1.5 percent increase for the FY 2006-based CIPI as a whole in FY 2012.

## IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers (rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals).

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2012 rate-of-increase percentage for updating the target amounts for cancer and children's hospitals and RNHCIs be the estimated percentage increase in the FY 2012 IPPS operating market basket, estimated to be 2.8 percent, in accordance with applicable regulations at § 413.40. We also are proposing to use the most recent data available to determine the estimated percentage increase for the FY 2012 IPPS operating market basket. Based on IHS Global Insight, Inc.'s first quarter 2011 forecast, with historical data through the 2010 fourth quarter, the IPPS operating market basket is 2.8 percent for FY 2012. Therefore, for cancer and children's hospitals and RNHCIs, the proposed FY 2012 rate-of-increase percentage that would be applied to the FY 2011 target amounts in order to determine the FY 2012 target amount is 2.8 percent. (We are proposing to use more recent data when determining the estimated percentage increase for the FY 2012 IPPS operating market basket for the final rule, to the extent that these data are available.)

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment is based on cost-based reimbursement rules under 42 CFR part 413 (certain providers do not receive a transitioning period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

## V. Proposed Changes to the Payment Rate for the LTCH PPS for FY 2012

*A. Proposed LTCH PPS Standard Federal Rate for FY 2012*

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed changes to the payment rates, factors, and specific policies under the LTCH PPS for FY 2012.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Thus, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also considered the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at § 412.523(c)(3)(iv) through (c)(3)(vii).

Several provisions of the Affordable Care Act revised the annual update to the standard Federal rate, beginning in RY 2010. Specifically, section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment" as discussed in section VII.E.2.d. of the preamble of this proposed rule) described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.d. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ "fiscal year" rather than "rate year" for 2011 and subsequent years.)

For FY 2011, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase, including the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i) and (m)(4)(B) of the Act, of 2.0 percent and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii) of the regulations, we established an annual update of −0.49 percent to the standard Federal rate for FY 2011 (75 FR 50443 through 50444).

In this proposed rule, for FY 2012, as discussed in greater detail in section VII.E.2. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.5 percent based on the full estimated increase in the proposed LTCH PPS market basket of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points required under 1886(m)(3)(A)(ii) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. As discussed in greater detail below, for FY 2012, we are not proposing to make an adjustment to account for the increase in case-mix in a prior period (FY 2010) resulting from the effect of documentation and coding.

2. Development of the Proposed FY 2012 LTCH PPS Standard Federal Rate

We continue to believe that the annual update to the LTCH PPS standard Federal rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. We also continue to believe it is appropriate that the standard Federal rate be offset by an adjustment to account for any effect of documentation and coding practices that does not reflect increased severity of illness. Such an adjustment protects the integrity of the Medicare Trust Funds by ensuring that the LTCH PPS payment rates better reflect the true costs of treating LTCH patients. Consistent with past LTCH payment policy, we have continued to monitor the most recent available LTCH data. Based on an analysis of FY 2010 LTCH claims from the December 2010 update of the MedPAR files, it does not appear that an adjustment for the effect of documentation and coding in FY 2010 is warranted. Therefore, in this proposed rule, we are not proposing to make an adjustment for the effect of documentation and coding during FY 2010 in our proposed annual update to the LTCH PPS standard Federal rate for FY 2012. Furthermore, we are proposing that, consistent with our historical practice of using the best available data, if more recent data subsequently become available, we would examine such data for the final rule to determine if an adjustment for the effect of documentation and coding during FY 2010 is warranted.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444), we established an annual update to the LTCH PPS standard Federal rate for FY 2011 based on the full estimated LTCH PPS market basket increase, including the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i), (m)(3)(A)(ii), and (m)(4)(B) of the Act, of 2.0 percent and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii), we established an annual update to the standard Federal rate for FY 2011 of −0.49 percent. That is, we applied an update factor of 0.9951 (calculated as 1.020 × 1 divided by 1.025 = 0.9951 or −0.49 percent) to the RY 2010 Federal rate of $39,794.95 (as established in the June 2, 2010 FY 2010 IPPS/RY 2010 LTCH PPS notice (75 FR 31128 through 31129)) to determine the FY 2011 standard Federal rate. Consequently, we established a standard Federal rate for FY 2011 of $39,599.95, which is applicable to LTCH PPS discharges occurring on or after October 1, 2010, through September 30, 2011.

In this proposed rule, for FY 2012, as noted above and as discussed in greater detail in section VII.E.2. of the preamble of this proposed rule, consistent with our historical practice, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.5 percent, based on the full estimated increase in the proposed LTCH PPS market basket of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points required under 1886(m)(3)(A)(ii) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and(m)(4)(C) of the Act. Accordingly, the proposed update factor to the standard Federal rate for FY 2012 is 1.5 percent. That is, under proposed § 412.523(c)(viii), we are proposing to apply a factor of 1.015 to the FY 2011 standard Federal rate of $39,599.95 (as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444)) to determine the FY 2012 standard Federal rate. Furthermore, as discussed in greater detail in section VII.E.3. of the preamble of this proposed rule, for FY 2012, we are proposing to apply an area wage level budget neutrality factor of 0.99723 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we are proposing to establish a standard Federal rate for FY 2012 of $40,082.61 (calculated as $39,599.95 × 1.015 × 0.99723), which would be applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

*B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2012*

1. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), when we implemented the LTCH PPS, we established a 5-year transition to the full area wage index level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH wage index values are the full LTCH PPS wage index values calculated

based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56017 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment at existing § 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an "urban area" is defined as a Metropolitan Statistical Area (which would include a metropolitan division, where applicable) as defined by the Executive OMB and a "rural area" is defined as any area outside of an urban area.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), in regulations at § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's CBSA designations, which are based on 2000 Census data. We made this revision because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that these are the same CBSA-based designations implemented for acute care hospitals under the IPPS at § 412.64(b), effective October 1, 2004 (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have updated the LTCH PPS CBSA-based labor market area definitions annually since they were adopted for RY 2006 (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. We adopted those changes under the LTCH PPS in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), effective beginning October 1, 2010, and they are also reflected in this FY 2012 proposed rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB—go* to "Agency Information" and click on "Bulletins".

3. Proposed LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-related share of a LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (wages and salaries, employee benefits, professional fees, and all other labor-intensive services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Currently, as established in the RY 2007 LTCH PPS final rule (71 FR 27829 through 27830), the LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the rehabilitation, psychiatric, and long-term care hospital (RPL) market basket based on FY 2002 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For the past 4 years (RY 2008, RY 2009, RY 2010, and FY 2011), we updated the LTCH PPS labor-related share annually based on the latest available data for the FY 2002-based RPL market basket. For FY 2011, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20445), we established a labor-related share of 75.271 percent based on the best available data at that time for the FY 2002-based RPL market basket for FY 2011. (Additional background information on the historical development of the labor-related share under the LTCH PPS and the development of the RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830).)

In section VII.D. of the preamble of this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS beginning in FY 2012. Specifically, we are proposing to adopt the newly created FY 2008-based RPL market basket. We are not proposing to change our definition of the labor-related share. However, we are proposing to rename our aggregate cost categories from "labor-intensive" and "nonlabor-intensive" services to "labor-related" and "nonlabor-related" services (as discussed. in section VII.D.3.b. of the preamble of this proposed rule). As discussed in section VII.D.3.f. of the preamble of this proposed rule, we are proposing a labor-related share under the LTCH PPS for FY 2012 based on IHS Global Insight, Inc.'s first quarter 2011 forecast of the proposed FY 2008-based RPL market basket for FY 2012, as these are the most recent available data at this time that reflect the cost structure of LTCHs. We are also proposing that the labor-related share for FY 2012 is the sum of the proposed FY 2012 relative importance of each labor-related cost category of the proposed FY 2008-based RPL market basket, and reflects the different rates of price change for these cost categories between the proposed base year (FY 2008) and FY 2012.

As discussed in greater detail in section VII.D.3.f. of the preamble of this proposed rule, the sum of the proposed relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-related Services) is 66.689 percent and the proposed labor-related share of capital costs is 3.645 percent. Thus, under the authority set forth in section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish a labor-related share of 70.334 percent (66.689 percent + 3.645 percent) under the LTCH PPS for the FY 2012, which would be effective for discharges occurring on or after October 1, 2011, and through September 30, 2012. Consistent with our historical practice of using the best data available, we also are proposing that if more recent data are available to determine the labor-related share used under the LTCH PPS for FY 2012, we would use these data for determining the FY 2012 LTCH PPS labor-related share in the final rule.

4. Proposed LTCH PPS Wage Index for FY 2012

Historically, under the LTCH PPS, we have established LTCH PPS wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2011 LTCH PPS final rule (75 FR 50445 through 50446), we calculated the FY 2011 LTCH PPS wage index values using the same data used for the FY 2011 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2007), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2011 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). We also continued to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2012, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2008, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2008 data because these data are the most recent

complete data available. These are the same data used to compute the proposed FY 2012 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

The proposed FY 2012 LTCH PPS wage index values we are presenting in this proposed rule are computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this proposed rule and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located (as discussed in section III.F. of the preamble of this proposed rule). Furthermore, we are proposing that, in determining the FY 2012 LTCH PPS wage index values in this proposed rule, we continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50446), we established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and we are proposing to continue to use this methodology for FY 2012. (We refer readers to 73 FR 26817 through 26818 for an explanation of and rationale for our policy.) Under this methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State. As was the case in FY 2011, there are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2012. However, we calculate proposed LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas.

Based on the FY 2008 IPPS wage data that we are proposing to use to determine the proposed FY 2012 LTCH PPS wage index values in this proposed rule, there are no IPPS wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we are proposing to calculate the FY 2012 wage index value for CBSA 25980 as the average of the proposed wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

For FY 2012, using our established methodology, we are proposing to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State (for an explanation of this policy, we refer readers to 73 FR 26818). For this purpose, we define "contiguous" as sharing a border. Based on the FY 2008 IPPS wage data that we are proposing to use to determine the proposed FY 2012 LTCH PPS wage index values in this proposed rule, there are no IPPS wage data for the rural area of Massachusetts (CBSA code 22). Consistent with the methodology described above, the proposed FY 2012 wage index value for rural Massachusetts is computed using the unweighted average of the wage indices from all of the CBSAs contiguous to the rural counties in that State. Specifically, the entire Massachusetts rural area consists of Dukes and Nantucket counties. The borders of Dukes and Nantucket counties are "contiguous" with Barnstable County, MA, and Bristol County, MA. Therefore, the proposed FY 2012 LTCH PPS wage index value for rural Massachusetts is computed as the unweighted average of the proposed FY 2012 wage indexes for Barnstable County and Bristol County, which are shown in Table 12A in the Addendum to this proposed rule). As noted above, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

The proposed FY 2012 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012, are presented in Table 12A (for urban areas) and Table 12B (for rural areas) in the Addendum of this proposed rule.

5. Proposed Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. However, there are currently no statutory or regulatory requirements that the annual update to the LTCH PPS area wage level adjustment at existing § 412.525(c) (that is, the wage index and the labor-related share) be budget neutral such that estimated aggregate LTCH PPS payments would be unaffected (that is, would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes). In section VII.E.3. of the preamble of this proposed rule, under § 412.525(c), we are proposing that, beginning in FY 2012, any changes to the wage index values or labor-related share be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this proposal, we are also proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment would be budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Therefore, under proposed § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor of 0.99723 (determined under the proposed methodology described in section VII.E.3. of the preamble of this proposed rule) to determine the proposed FY 2012 LTCH PPS standard Federal rate. (The development of the proposed LTCH PPS standard Federal rate for FY 2012 is discussed in section V.A.2. of this Addendum.)

*C. Proposed LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii*

In the August 30, 2002 final rule (67 FR 56022), we established, under § 412.525(b), a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

For FY 2011 and in prior years, we used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the payments for LTCHs in Alaska and Hawaii. Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality.

We do not believe it is appropriate to propose to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska or Hawaii.

Therefore, for FY 2012, we are proposing to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii. We believe using these COLA factors would appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii consistent with § 412.525(b). (We note that this proposal is consistent with the proposed adjustment for cost-of-living in Alaska and Hawaii for IPPS hospitals discussed in section II.B.2. of this Addendum.) We invite public comment on this proposal.

In this proposed rule, for FY 2012, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, consistent with our current policy, we are proposing to apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart below because they are the most recent available data at this time. As discussed above, these factors were obtained from the OPM and are also proposed to be used under the IPPS for FY 2012.

**Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Hospitals for the LTCH PPS for FY 2012**

| | |
|---|---|
| Alaska: | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.23 |
| All other areas of Alaska | 1.25 |
| Hawaii: | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.18 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: http://www.opm.gov/oca/cola/rates.asp.)

*D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases*

1. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under § 412.525(a) in the regulations (in conjunction with § 412.503), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the MS–LTC–DRG plus a fixed-loss amount. Specifically, in accordance with § 412.525(a)(3) (in conjunction with § 412.503), we make an additional payment to an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (adjusted MS–LTC–DRG payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the LTCH PPS HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single "overall" or "total" LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its

operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2010 update of the PSF, we are proposing to establish a total CCR ceiling of 1.210 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish a total CCR ceiling for FY 2012 in the final rule.

c. Proposed LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on "total" IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) and the SSO policy at § 412.529(f)(4)(iii), the fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the fiscal intermediary or MAC may consider in determining a LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data and using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS total CCR data from the December 2010 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012, in Table 8C of the Addendum to this proposed rule. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish LTCH PPS statewide average total CCRs for FY 2012 in the final rule.

All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C listed in section VI. of the Addendum to this proposed rule and available via the Internet. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although North Dakota and Puerto have areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of March 2011. Therefore, there is no rural statewide average total CCR listed for rural North Dakota in Table 8C listed in section VI. of the Addendum to this proposed rule and available via the Internet.

In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this proposed rule, we are using, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We use this proxy because we believe that the CCR data on the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note that under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases, respectively, are subject to reconciliation. Specifically, any reconciliation of outlier payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. For additional information, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for FY 2012

When we implemented the LTCH PPS, as discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56026), under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under § 412.525(a)(3) (in conjunction with § 412.503), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount).

In this proposed rule, we are proposing to continue to use our existing methodology to calculate the proposed fixed-loss amount for FY 2012 (based on updated data and the proposed rates and policies presented in this proposed rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. (For an explanation of our rationale for establishing an HCO payment "target" of 8 percent of total estimated LTCH payments, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Consistent with our historical practice of using the best data available, in determining the proposed fixed-loss amount for FY 2012, we are using the most recent available LTCH claims data and CCR data at this time. Specifically, we are using LTCH claims data from the December 2010 update of the FY 2010 MedPAR files and CCRs from the December 2010 update of the PSF to determine a fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2012 because these data are the most recent complete LTCH data currently available. Consistent with the historical practice of using the best available data, we also are proposing that if more recent LTCH claims data become available, we would use them for determining the fixed-loss amount for FY 2012 in the final rule. Furthermore, we are proposing to determine the proposed FY 2012 fixed-loss amount based on the proposed MS–LTC–DRG classifications and relative weights from the version of the GROUPER that would be in effect as of the beginning of FY 2012, that is, proposed Version 29.0 of the GROUPER.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing to establish a fixed-loss amount of $19,270 for FY 2012. Thus, we would make an additional payment to an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the MS–LTC–DRG and the proposed fixed-loss amount of $19.270). We also note that the proposed fixed-loss amount of $19,270 for FY 2012 is slightly higher than the FY 2011 fixed-loss amount of $18,785. Based on

our payment simulations using the most recent available data at this time, the proposed increase in the fixed-loss amount for FY 2012 would be necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (For further information on the existing 8 percent HCO "target" requirement, as noted above, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024.) Maintaining the fixed-loss amount at the current level would result in HCO payments that are greater than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases as well as a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believed that proposing a slight increase in the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as a SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as a HCO case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as a HCO. Thus, for a SSO case in FY 2012, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $19,270 and the amount paid under the SSO policy as specified in § 412.529).

*E. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2012*

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under § 412.525(c), the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the appropriate LTCH PPS wage index (as shown in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule and available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the appropriate cost-of-living factor (shown in the chart in section V.C.5. of the Addendum of this proposed rule) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish a proposed standard Federal rate for FY 2012 of $40,082.61, as discussed above in section V.A.2. of the Addendum of this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS Federal rate for FY 2012 in the following example:

*Example:*

During FY 2012, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974). The FY 2012 LTCH PPS wage index value for CBSA 16974 is 1.0632 (Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet). The Medicare patient is classified into proposed MS–LTC–DRG 28 (Spinal Procedures with MCC), which has a proposed relative weight for FY 2012 of 1.7360 (Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet).

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient, we compute the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed standard Federal rate ($40,082.61) by the proposed labor-related share (70.334 percent) and the proposed wage index value (1.0632). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted proposed standard Federal rate (29.666 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (1.7360) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2012 ($72,676.47). The table below illustrates the components of the calculations in this example.

| | |
|---|---|
| Proposed Unadjusted Standard Federal Prospective Payment Rate | $40,082.61 |
| Proposed Labor-Related Share | x 0.70334 |
| Proposed Labor-Related Portion of the Federal Rate | = $28,191.70 |
| Proposed Wage Index (CBSA 16974) | x 1.0632 |
| Proposed Wage-Adjusted Labor Share of Federal Rate | = $29,973.42 |
| Proposed Nonlabor-Related Portion of the Federal Rate ($40,082.61 x 0.29666) | + $11,890.91 |
| Proposed Adjusted Federal Rate Amount | = $41,864.33 |
| Proposed MS-LTC-DRG 28 Relative Weight | x 1.7360 |
| Total Proposed Adjusted Federal Prospective Payment | = $72,676.47 |

**VI. Tables Referenced in this Proposed Rule and Available Only Through the Internet on the CMS Web Site**

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, IPPS tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 7A, 7B, 8A, 8B, 9A, 9C, and 10, and LTCH PPS tables 8C, 11, 12A, and 12B will no longer be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings. Instead, these tables, along with new LTCH PPS tables 13A and 13B, and new IPPS table 14 will be available only through the Internet. IPPS tables 1A, 1B, 1C, and 1D, and LTCH PPS table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual and final rules. We note that previously tables 6G, 6H, 6I, 6I.1, 6I.2, 6J, 6J.1, 6J.2, and 6K were already made available only through the Internet. We will continue to post these tables through the Internet.

Readers who experience any problems accessing any of the tables that are posted on

the CMS Web sites identified below should contact Ing Jye Cheng at (410) 786–4548.

The following IPPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, "FY 2012 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download".

Table 2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2010; Proposed Hospital Wage Indexes for Federal Fiscal Year 2012; Hospital Average Hourly Wages for Federal Fiscal Years 2010 (2006 Wage Data), 2011 (2007 Wage Data), and 2012 (2008 Wage Data); and 3-Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2012

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2012

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2012

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index [1]; Urban Areas with Acute Care Hospitals Receiving the Proposed Statewide Rural Floor Wage Index—FY 2012

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2012

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2012

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2012

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2012

Table 6A.—Proposed New Diagnosis Codes—FY 2012

Table 6B.—Proposed New Procedure Codes—FY 2012

Table 6C.—Proposed Invalid Diagnosis Codes—FY 2012

Table 6D.— Proposed Invalid Procedure Codes—FY 2012

Table 6E.—Proposed Revised Diagnosis Code Titles—FY 2012

Table 6F.—Proposed Revised Procedure Code Titles—FY 2012

Table 6G.—Proposed Additions to the CC Exclusions List—FY 2012

Table 6H.—Proposed Deletions from the CC Exclusions List—FY 2012

Table 6I.—Proposed Complete MCC List—FY 2012

Table 6I.1.—Proposed Additions to the MCC List—FY 2012

Table 6I.2.—Proposed Deletions to the MCC List—FY 2012

Table 6J.—Proposed Complete CC List—FY 2012

Table 6J.1.—Proposed Additions to the CC List—FY 2012

Table 6J.2.—Proposed Deletions to the CC List—FY 2012

Table 6K.—Proposed Complete List of CC Exclusions—FY 2012

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—December 2010 GROUPER V28.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—December 2010 GROUPER V29.0 MS–DRGs

Table 8A.—Proposed FY 2012 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2012 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2012

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act—FY 2012

Table 10.—Proposed Geometric Mean Plus the Lesser of .75 of the National Adjusted Operating Standardized Payment Amount (Increased to Reflect the Difference Between Costs and Charges) or .75 of One Standard Deviation of Mean Charges by Medicare Severity Diagnosis-Related Groups (MS–DRGs)

Table 14.—List of Hospitals with Fewer than 1,600 Medicare Discharges Based on the December 2010 Update of the FY 2010 MedPAR File and Their Proposed FY 2012 Low-Volume Payment Adjustment

The following LTCH PPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–P.

Table 8C.—Proposed FY 2012 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for Discharges Occurring from October 1, 2011 through September 30, 2012 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2011 through September 30, 2012

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2011 through September 20, 2012

Table 13A.—Composition of Proposed Low-Volume Quintiles for MS–LTC–DRGs—FY 2012

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2012

**BILLING CODE 4120–01–P**

**TABLE 1A.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2012**

| Full Update (1.50 Percent) | | Reduced Update (-0.50 Percent) | |
|---|---|---|---|
| Labor-related | Nonlabor-related | Labor-related | Nonlabor-related |
| $3,531.06 | $1,601.30 | $3,461.48 | $1,569.75 |

**TABLE 1B.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)--FY 2012**

| Full Update (1.50 Percent) | | Reduced Update (-0.50 Percent) | |
|---|---|---|---|
| Labor-related | Nonlabor-related | Labor-related | Nonlabor-related |
| $3,182.06 | $1,950.30 | $3,119.36 | $1,911.87 |

**TABLE 1C.—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR--FY 2012**

| | Rates if Wage Index is Greater Than 1 | | Rates if Wage Index is Less Than or Equal to 1 | |
|---|---|---|---|---|
| | Labor | Nonlabor | Labor | Nonlabor |
| National | $3,531.06 | $1,601.30 | $3,182.06 | $1,950.30 |
| Puerto Rico | $1,551.84 | $947.10 | $1,549.34 | $949.60 |

**TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2012**

| | Rate |
|---|---|
| National | $422.54 |
| Puerto Rico | $205.01 |

**TABLE 1E.— PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE--FY 2012**

| | Rate |
|---|---|
| Standard Federal Rate | $40,082.61 |

BILLING CODE 4120–01–C

## Appendix A: Regulatory Impact Analysis

### I. Introduction

*A. Overall Impact*

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2012 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million among different types of inpatient cases. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $498 million decrease in FY 2012 operating payments (or −0.5 percent change) and an estimated $146 million increase in FY 2012 capital payments (or 1.8 percent change). The impact analysis of the capital payments can be found in section VIII. of this Appendix. In addition, as described in section IX. of this Appendix, LTCHs are expected to experience a change in payments by $95 million (or 1.9 percent).

Our operating impact estimate includes the proposed −2.5 percent documentation and coding adjustment applied to the hospital-specific rates and the proposed –3.15 percent adjustment for documentation and coding changes to the IPPS standardized amounts. In addition, our operating impact estimate includes the proposed 1.5 percent hospital update to the standardized amount (which includes the proposed 2.8 percent market basket update with the reduction of 1.2 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction required under the Affordable Care Act). Finally, our operating impact estimate includes the proposed 1.1 percent update to the standardized amount and the 0.9 percent update to the hospital-specific rates in light of DC Circuit's decision in *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section IX. of this Appendix. Medicare fiscal intermediaries and MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our proposed regulatory flexibility analysis. Therefore, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that 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 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we now define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I and section VI. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

The analysis that begins in section II of this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. The proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

*B. Need*

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

### II. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate

costs. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

**III. Limitations of Our Analysis**

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2012, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

**IV. Hospitals Included in and Excluded From the IPPS**

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, only the 46 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2011, there are 3,419 IPPS acute care hospitals to be included in our analysis. This represents about 64 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,342 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. (We refer readers to section VII.M. of this Appendix for a further description of the impact of CAH-related proposed policy changes.) There are also 1,290 IPPS-excluded hospitals and 2,119 IPPS-excluded hospital units. These IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and cancer hospitals, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2012 are discussed in section IX. of this Appendix.

**V. Effects on Hospitals and Hospital Units Excluded From the IPPS**

As of March 2011, there were 3,409 hospitals and hospital units excluded from the IPPS. Of these, 78 children's hospitals, 11 cancer hospitals, and 17 RNHCIs are being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers, 235 rehabilitation hospitals and 940 rehabilitation units, and 437 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 512 psychiatric hospitals and 1,179 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by proposed rate updates discussed in this proposed rule. The impacts of the changes to LTCHs are discussed in section IX. of this Appendix.

In the past, certain hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Cancer and children's hospitals continue to be paid on a reasonable cost basis subject to TEFRA limits for FY 2012. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the update is the FY 2012 percentage increase in the IPPS operating market basket. In compliance with section 404 of the MMA, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43930), we replaced the FY 2002-based IPPS operating and capital market baskets with the revised and rebased FY 2006-based IPPS operating and capital market baskets. Therefore, consistent with current law, based on IHS Global Insight, Inc.'s 2011 first quarter forecast, with historical data through the 2010 fourth quarter, we are estimating that the FY 2012 update based on the IPPS operating market basket will be 2.8 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be −1.2 percentage points) and a 0.1 percentage point reduction to the market basket update resulting in a proposed 1.5 percent applicable percentage increase for IPPS hospitals. RNCHIs, children's hospitals and cancer hospitals are not subject to the reduction in the applicable percentage increase required under the Affordable Care Act. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40. Therefore, for RNHCIs, the proposed update is the same as for children's and cancer hospitals, which is the percentage increase in the FY 2012 IPPS operating market basket, estimated to be 2.8 percent, without the reductions required under the Affordable Care Act.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with per-case cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be reimbursed.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus 50 percent of the difference between its reasonable costs and 110 percent of the limit, not to exceed 110 percent of its limit. In addition, under the various provisions set forth in § 413.40, cancer and children's hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

**VI. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs**

*A. Basis and Methodology of Estimates*

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for operating costs of acute care hospitals. Updates to the capital payments to acute care hospitals are discussed in section VIII. of this Appendix. Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2012 operating payments would change by −0.5 percent compared to FY 2011, largely due to the documentation and coding adjustments and the applicable percentage increase applied to the IPPS rates. This amount reflects the proposed FY 2012 adjustments for documentation and coding and recoupment described in section II.D. of the preamble of this proposed rule: −3.15 percent for the IPPS national standardized amounts and −2.5 percent for the IPPS hospital-specific rates. The impacts do not illustrate changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented below are taken from the FY 2010 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use

various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2010 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2012 are discussed in section VIII. of this Appendix.

We discuss the following proposed changes below:

- Effects of the application of the proposed documentation and coding adjustment and applicable percentage increase (including the proposed market basket update, the multifactor productivity adjustment and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- Effects of the proposed increase to the standardized amount and hospital-specific rates in light of D.C. Circuit's decision in *Cape Cod* v. *Sebelius,* 630 F.3d 203 (D.C. Cir. 2011).
- The effects of the proposed annual reclassification of diagnoses and procedures, full implementation of the MS–DRG system and 100 percent cost-based MS–DRG relative weights.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2008, compared to the FY 2007 wage data.
- The effects of the recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the wage and recalibration budget neutrality factors.
- The effects of the proposed geographic reclassifications by the MGCRB that will be effective in FY 2012.
- The effects of the rural floor with the application of the national budget neutrality factor applied to the wage index, as required by the Affordable Care Act.
- The effects of the expiration of applying an imputed floor to States that have no rural areas and to States that have rural areas but no IPPS hospitals are located in those areas.
- The effects of the frontier wage index provision that requires that hospitals located in States that qualify as frontier States cannot have a wage index less than 1.0. This provision is not budget neutral.
- The effects of section 505 of Pub. L. 108–173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
- The total estimated change in payments based on the proposed FY 2012 policies relative to payments based on FY 2011 policies that include the applicable percentage increase of 1.5 percent (or 2.8 percent market basket update with a reduction of 1.2 percentage points for the multifactor productivity adjustment, and a 0.1 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2012 changes, our analysis begins with a FY 2011 baseline simulation model using: the proposed FY 2012 applicable percentage increase of 1.5 percent and the proposed documentation and coding adjustment of −3.15 percent; the FY 2011 MS–DRG GROUPER (Version 28.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2011 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 through FY 2014, the update factor will include a reduction of 2.0 percentage points for any hospital that does not submit quality data in a form and manner and at a time specified by the Secretary. (Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act.) At the time that this impact was prepared, 56 hospitals did not receive the full market basket rate-of-increase for FY 2011 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2012 using a reduced update for these 56 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2012.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2012 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2011 to FY 2012. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2012 using an applicable percentage increase of 1.5 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.8 percent with a proposed reduction of 1.2 percentage points for the multifactor productivity adjustment and a 0.1 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements will receive a proposed update of −0.5 percent (this update includes the 2.0 percentage point reduction for failure to submit these data).) Under section 1886(b)(3)(B)(iv) of the Act, the proposed updates to the hospital-specific amounts for SCHs and for MDHs are also equal to the applicable percentage increase, or 1.5 percent. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 1.5 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2011 to FY 2012 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2011 that are no longer reclassified in FY 2012. Conversely, payments may increase for hospitals not reclassified in FY 2011 that are reclassified in FY 2012.

A third significant factor is that we currently estimate that actual outlier payments during FY 2011 will be 4.9 percent of total MS–DRG payments. Our updated FY 2011 outlier estimate accounts for changes to the FY 2011 IPPS payments required under the Affordable Care Act. When the FY 2011 final rule was published, we projected FY 2011 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2011 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2011 payments per case to estimated FY 2012 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

*B. Analysis of Table I*

Table I displays the results of our analysis of the proposed changes for FY 2012. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,419 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: all urban, which is further divided into large urban and other urban; and rural. There are 2,492 hospitals located in urban areas included in our analysis. Among these, there are 1,369 hospitals located in large urban areas (populations over 1 million), and 1,123 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 927 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2012 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have

implications for capital payments) are 2,514; 1,382; 1,132; and 905, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive DSH payments, or some combination of these two adjustments. There are 2,389 nonteaching hospitals in our analysis, 790 teaching hospitals with fewer than 100 residents, and 240 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next five rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 175 RRCs, 320 SCHs, 195 MDHs, and 120 hospitals that are both SCHs and RRCs, and 18 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2008 or FY 2007 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2012. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 19 cardiac hospitals.

BILLING CODE 4120–01–P

## TABLE I.--IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2012

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **All Hospitals** | 3,419 | -1.6 | 1.1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | -0.2 | -0.5 |
| **By Geographic Location:** | | | | | | | | | | | | | |
| Urban hospitals | 2,492 | -1.6 | 1.1 | 0 | 0 | 0 | -0.2 | 0 | 0 | 0 | 0 | -0.2 | -0.4 |
| Large urban areas | 1,369 | -1.6 | 1.1 | 0 | 0 | 0 | -0.3 | 0 | 0 | 0 | 0 | -0.2 | -0.4 |
| Other urban areas | 1,123 | -1.6 | 1.1 | 0 | 0 | 0 | -0.1 | 0.2 | 0 | 0.1 | 0 | -0.2 | -0.5 |
| Rural hospitals | 927 | -1.3 | 1 | 0 | -0.1 | 0 | 1.7 | -0.2 | 0 | 0 | 0.1 | 0 | -0.8 |
| **Bed Size (Urban):** | | | | | | | | | | | | | |
| 0-99 beds | 634 | -1.6 | 1.1 | 0.1 | -0.1 | -0.1 | -0.5 | 0.2 | 0.1 | 0.1 | 0 | -0.1 | -0.3 |
| 100-199 beds | 777 | -1.6 | 1.1 | 0.1 | 0 | 0.1 | 0 | 0.3 | 0 | 0 | 0 | -0.2 | -0.4 |
| 200-299 beds | 457 | -1.6 | 1.1 | 0.1 | 0.2 | 0.2 | -0.2 | 0 | -0.1 | 0.1 | 0 | -0.1 | -0.4 |
| 300-499 beds | 428 | -1.6 | 1.1 | 0 | -0.1 | -0.1 | -0.2 | -0.1 | 0 | 0.1 | 0 | -0.2 | -0.7 |
| 500 or more beds | 196 | -1.6 | 1.1 | -0.1 | 0.1 | 0 | -0.3 | 0.1 | 0 | 0 | 0 | -0.2 | -0.2 |
| **Bed Size (Rural):** | | | | | | | | | | | | | |
| 0-49 beds | 317 | -1.3 | 1 | 0.1 | 0.1 | 0.1 | 0.6 | -0.2 | 0 | 0.1 | 0.2 | 0 | -1.2 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 50-99 beds | 351 | -1.3 | 1 | 0 | -0.1 | 0 | 0.7 | -0.2 | 0 | 0 | 0.1 | 0 | -1 |
| 100-149 beds | 153 | -1.4 | 1 | 0 | -0.1 | -0.1 | 2.3 | -0.2 | 0.1 | 0 | 0 | 0 | -0.7 |
| 150-199 beds | 60 | -1.4 | 1 | 0 | -0.1 | -0.1 | 2.5 | -0.2 | 0.1 | 0.1 | 0 | 0 | -0.6 |
| 200 or more beds | 46 | -1.4 | 1 | 0 | -0.1 | -0.1 | 2.6 | -0.2 | 0 | 0 | 0 | 0 | -0.5 |
| **Urban by Region:** | | | | | | | | | | | | | |
| New England | 120 | -1.6 | 1.1 | 0.1 | 0.1 | 0.2 | 0.9 | 5 | 0.1 | 0 | 0 | -0.2 | 3.6 |
| Middle Atlantic | 320 | -1.6 | 1.1 | 0 | 0.3 | 0.3 | 0.3 | -0.4 | -0.4 | 0 | 0 | -0.4 | -0.9 |
| South Atlantic | 379 | -1.6 | 1.1 | 0 | -0.3 | -0.3 | -0.4 | -0.3 | 0.1 | 0 | 0 | 0 | -0.8 |
| East North Central | 401 | -1.6 | 1.1 | 0 | -0.4 | -0.3 | -0.3 | -0.3 | 0.1 | 0 | 0 | -0.4 | -1.2 |
| East South Central | 153 | -1.6 | 1.1 | 0 | -0.3 | -0.3 | -0.4 | -0.2 | 0.1 | 0 | 0 | 0 | -1 |
| West North Central | 168 | -1.6 | 1.1 | 0 | 0.3 | 0.2 | -0.6 | -0.3 | 0.1 | 0.5 | 0 | 0 | -0.1 |
| West South Central | 365 | -1.6 | 1.1 | 0 | 0.4 | 0.4 | -0.6 | -0.3 | 0.1 | 0 | 0 | 0 | -0.1 |
| Mountain | 159 | -1.5 | 1.1 | -0.1 | 0 | -0.1 | -0.4 | -0.1 | 0.1 | 0.2 | 0 | 0 | -0.5 |
| Pacific | 377 | -1.6 | 1.1 | 0 | 0.2 | 0.2 | -0.2 | -0.2 | 0.1 | 0 | 0 | -0.1 | -0.3 |
| Puerto Rico | 50 | -1.1 | 0.9 | 0.1 | 0.3 | 0.2 | -0.8 | 0.1 | 0.1 | 0 | 0 | 0 | 0.2 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Rural by Region:** | | | | | | | | | | | | | |
| New England | 23 | -1.3 | 1 | -0.1 | 0.8 | 0.7 | 1.2 | -0.2 | 0 | 0 | 0 | 0 | -0.9 |
| Middle Atlantic | 69 | -1.3 | 1 | 0 | -0.1 | -0.1 | 1.4 | -0.2 | 0 | 0 | 0 | -0.1 | -0.3 |
| South Atlantic | 165 | -1.4 | 1 | 0 | -0.2 | -0.2 | 2.2 | -0.2 | 0.1 | 0 | 0 | 0 | -0.6 |
| East North Central | 120 | -1.3 | 1 | 0 | -0.1 | -0.1 | 1.1 | -0.2 | 0 | 0 | 0.1 | 0 | -0.5 |
| East South Central | 171 | -1.5 | 1.1 | 0.1 | -0.5 | -0.3 | 2.6 | -0.3 | 0.1 | 0 | 0.2 | -0.1 | -1.6 |
| West North Central | 99 | -1.1 | 0.9 | -0.1 | 0.1 | 0 | 0.7 | -0.1 | 0 | 0.1 | 0 | -0.1 | -0.2 |
| West South Central | 184 | -1.5 | 1.1 | 0.1 | 0.4 | 0.4 | 2.4 | -0.3 | 0.1 | 0 | 0.1 | 0 | -1.2 |
| Mountain | 66 | -1.2 | 1 | 0.1 | 0.1 | 0.2 | 0.5 | -0.1 | 0 | 0.6 | 0 | 0 | -0.5 |
| Pacific | 29 | -1.2 | 1 | 0 | -0.4 | -0.4 | 1.7 | -0.1 | 0 | 0 | 0 | 0 | -0.4 |
| Puerto Rico | 1 | -1 | 0.9 | -0.2 | 0.7 | 0.3 | -0.8 | -0.3 | 0 | 0 | 0 | 0 | 0.3 |
| **By Payment Classification:** | | | | | | | | | | | | | |
| Urban hospitals | 2,514 | -1.6 | 1.1 | 0 | 0 | 0 | -0.2 | 0 | 0 | 0 | 0 | -0.2 | -0.4 |
| Large urban areas | 1,382 | -1.6 | 1.1 | 0 | 0 | 0 | -0.3 | 0 | 0 | 0 | 0 | -0.2 | -0.4 |
| Other urban areas | 1,132 | -1.6 | 1.1 | 0 | 0 | 0 | 0 | 0.1 | 0 | 0.1 | 0 | -0.2 | -0.5 |
| Rural areas | 905 | -1.3 | 1 | 0 | -0.1 | -0.1 | 1.5 | -0.2 | 0 | 0 | 0.1 | 0 | -0.8 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Teaching Status:** | | | | | | | | | | | | | |
| Nonteaching | 2,389 | -1.5 | 1.1 | 0.1 | 0 | 0 | 0.2 | 0 | 0 | 0 | 0 | -0.1 | -0.5 |
| Fewer than 100 residents | 790 | -1.6 | 1.1 | 0 | 0 | 0 | -0.2 | -0.1 | -0.1 | 0.1 | 0 | -0.1 | -0.6 |
| 100 or more residents | 240 | -1.6 | 1.1 | -0.1 | 0.1 | 0 | -0.2 | 0.1 | 0 | 0 | 0 | -0.3 | -0.4 |
| **Urban DSH:** | | | | | | | | | | | | | |
| Non-DSH | 738 | -1.6 | 1.1 | 0 | -0.1 | -0.1 | 0 | 0 | -0.2 | 0 | 0 | -0.3 | -0.9 |
| 100 or more beds | 1,543 | -1.6 | 1.1 | 0 | 0 | 0 | -0.2 | 0 | 0 | 0 | 0 | -0.1 | -0.4 |
| Less than 100 beds | 339 | -1.6 | 1.1 | 0.2 | -0.3 | -0.1 | -0.2 | 0.2 | 0.1 | 0.1 | 0 | -0.1 | -0.4 |
| **Rural DSH:** | | | | | | | | | | | | | |
| SCH | 416 | -1.2 | 1 | 0 | 0 | 0 | 0.2 | -0.1 | 0 | 0 | 0.1 | 0 | -1.5 |
| RRC | 222 | -1.4 | 1 | 0 | -0.1 | -0.1 | 2.5 | -0.2 | 0.1 | 0 | 0 | 0 | -0.5 |
| 100 or more beds | 28 | -1.6 | 1.1 | 0.1 | -0.3 | -0.1 | 0.5 | -0.3 | 0.1 | 0 | 0.3 | -0.3 | -1.2 |
| Less than 100 beds | 133 | -1.6 | 1.1 | 0.2 | -0.1 | 0.2 | 1.4 | -0.4 | 0.1 | 0 | 0.4 | -0.1 | -0.6 |
| **Urban teaching and DSH:** | | | | | | | | | | | | | |
| Both teaching and DSH | 825 | -1.6 | 1.1 | 0 | 0 | 0 | -0.3 | 0 | 0 | 0.1 | 0 | -0.2 | -0.4 |
| Teaching and no DSH | 144 | -1.6 | 1.1 | -0.1 | -0.1 | -0.2 | 0.2 | 0.1 | -0.3 | 0 | 0 | -0.4 | -1 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| No teaching and DSH | 1,057 | -1.6 | 1.1 | 0.1 | 0 | 0.1 | 0 | 0.1 | 0.1 | 0 | 0 | 0 | -0.2 |
| No teaching and no DSH | 488 | -1.6 | 1.1 | 0 | -0.1 | -0.1 | -0.3 | -0.2 | -0.1 | 0 | 0 | -0.2 | -0.8 |
| **Special Hospital Types:** | | | | | | | | | | | | | |
| RRC | 175 | -1.6 | 1.1 | 0 | -0.2 | -0.1 | 3.1 | -0.3 | 0.1 | 0.1 | 0 | -0.2 | -0.8 |
| SCH | 320 | -1.1 | 0.9 | -0.1 | 0 | -0.1 | 0.2 | -0.1 | 0 | 0 | 0 | 0 | -1.4 |
| MDH | 195 | -1.4 | 1 | 0 | 0 | 0.1 | 0.2 | -0.1 | 0 | 0 | 0.1 | 0 | -0.4 |
| SCH and RRC | 120 | -1.1 | 0.9 | -0.1 | 0 | -0.1 | 0.8 | -0.1 | 0 | 0 | 0 | 0 | -0.3 |
| MDH and RRC | 18 | -1.1 | 1 | -0.1 | 0.1 | 0 | 0.5 | -0.1 | 0 | 0 | 0 | 0 | -0.3 |
| **Type of Ownership:** | | | | | | | | | | | | | |
| Voluntary | 1,991 | -1.6 | 1.1 | 0 | 0 | 0 | 0 | 0.1 | 0 | 0.1 | 0 | -0.2 | -0.4 |
| Proprietary | 850 | -1.6 | 1.1 | 0.1 | 0.1 | 0.1 | -0.1 | -0.2 | 0.1 | 0 | 0 | -0.1 | -0.5 |
| Government | 574 | -1.5 | 1.1 | 0 | -0.1 | -0.1 | -0.1 | -0.2 | 0.1 | 0 | 0 | -0.1 | -0.7 |
| **Medicare Utilization as a Percent of Inpatient Days:** | | | | | | | | | | | | | |
| 0-25 | 359 | -1.5 | 1.1 | -0.1 | 0 | -0.1 | -0.3 | -0.3 | 0.1 | 0 | 0 | 0 | -0.4 |
| 25-50 | 1,703 | -1.6 | 1.1 | 0 | 0 | 0 | -0.2 | 0 | 0 | 0.1 | 0 | -0.2 | -0.4 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 50-65 | 1,089 | -1.5 | 1.1 | 0 | -0.1 | 0 | 0.7 | 0.1 | 0 | 0 | 0 | -0.2 | -0.7 |
| Over 65 | 195 | -1.5 | 1.1 | 0.1 | -0.1 | 0.1 | 0.5 | 0 | -0.3 | 0 | 0 | -0.3 | -0.6 |
| **FY 2012 Reclassifications by the Medicare Geographic Classification Review Board:** | | | | | | | | | | | | | |
| All Reclassified Hospitals | 805 | -1.5 | 1.1 | 0 | -0.1 | 0 | 1.9 | 0.3 | 0 | 0 | 0 | -0.4 | -0.3 |
| Non-Reclassified Hospitals | 2,614 | -1.6 | 1.1 | 0 | 0 | 0 | -0.7 | -0.1 | 0 | 0.1 | 0 | -0.1 | -0.5 |
| Urban Hospitals Reclassified | 469 | -1.6 | 1.1 | 0 | -0.1 | 0 | 1.6 | 0.5 | 0 | 0 | 0 | -0.6 | -0.2 |
| Urban Nonreclassified Hospitals, FY 2012: | 1,990 | -1.6 | 1.1 | 0 | 0 | 0 | -0.7 | -0.1 | 0 | 0.1 | 0 | -0.1 | -0.5 |
| All Rural Hospitals Reclassified FY 2012: | 336 | -1.4 | 1 | 0 | -0.1 | -0.1 | 2.7 | -0.2 | 0.1 | 0 | 0 | 0 | -0.6 |
| Rural Nonreclassified Hospitals FY 2012: | 529 | -1.3 | 1 | 0 | 0 | 0 | -0.3 | -0.2 | 0 | 0.1 | 0.2 | -0.1 | -1.2 |

| | Number of Hospitals[1] (1) | Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2) | Proposed Cape Cod Adjustment[3] (3) | Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4) | Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5) | Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6) | FY 2012 MGCRB Reclassifications[7] (7) | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8) | Expiration of the Imputed Floor[9] (9) | Proposed Application of the Frontier Wage Index[10] (10) | Proposed FY 2012 Out-Migration Adjustment[11] (11) | Expiration of Section 508[12] (12) | All Proposed FY 2012 Changes[13] (13) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| All Section 401 Reclassified Hospitals: | 40 | -1.1 | 0.9 | -0.1 | 0 | -0.1 | -0.8 | 0.2 | 0 | 0 | 0 | 0 | -0.7 |
| Other Reclassified Hospitals (Section 1886(d)(8)(B)) | 63 | -1.4 | 1 | 0 | 0 | 0 | 2.8 | -0.2 | 0.1 | 0 | 0 | 0 | -0.9 |
| **Specialty Hospitals** | | | | | | | | | | | | | |
| Cardiac specialty Hospitals | 19 | -1.6 | 1.1 | -0.1 | 0 | -0.1 | -0.8 | -0.4 | 0.1 | 0.2 | 0 | 0 | -0.6 |

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2010, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

[2] This column displays the payment impact of the proposed hospital rate update and documentation and coding adjustment including the 1.5 percent adjustment to the national standardized amount (the 2.8 percent market basket update reduced by the proposed 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the -3.15 percent documentation and coding adjustment to the national standardized amount and the proposed -2.5 documentation and coding adjustment to the hospital-specific rate.

[3] This column displays the payment impact of the proposed 1.1 percent adjustment to the national standardized amount and the 0.9 percent adjustment to the hospital-specific rate in light of the decision in Cape Cod v. Sebelius.

[4] This column displays the payment impact of the proposed changes to the Version 29.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2010 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.998418, in accordance with section 1886(d)(4)(C)(iii) of the Act.

[5.] This column displays the payment impact of the proposed update to wage index data using FY 2008 cost report data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and will be calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000113.

[6] This column displays the combined payment impact of the proposed changes in Columns 4 through 5 and the cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.998532 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

7. Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2012 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2012. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991528.

8 This column displays the effects of the rural floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. The rural floor budget neutrality factor is 0.993834.

9. This column displays the effects of the expiration of the imputed floor, finalized in the FY 2009 IPPS rule (73 FR 48570 through 48574 and 48584).

10/ This column shows the impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

11. This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

12. This column displays the impact of the expiration of section 508 of the MMA as extended by the MMEA, a non-budget neutral reclassification provision.

13 This column shows the proposed changes in payments from FY 2011 to FY 2012. It reflects the impact of the proposed FY 2012 hospital update, the proposed reductions due to the documentation and coding effect and the proposed adjustment in light of the decision in Cape Cod v. Sebelius. The proposed FY 2012 documentation and coding adjustment is -3.15 percent to the IPPS standardized amounts and -2.5 percent to the hospital-specific rates. It also reflects changes in hospitals' reclassification status in FY 2012 compared to FY 2011. It incorporates all of the proposed changes displayed in Columns 2, 3, 6, 7, 8, 10, 11 and 12 (the changes displayed in Columns 4 and 5 are included in Column 6). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

**BILLING CODE 4120–01–C**

1. Effects of the Proposed Hospital Update and Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed hospital update including the 2.8 percent market basket update, the reduction of 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2012 documentation and coding adjustment of −3.15 percent on the national standardized amount and the proposed −2.5 percent documentation and coding adjustment on the hospital-specific rates. As a result, we are proposing to apply a −1.65 percent adjustment to the national standardized amount and −1.0 percent adjustment to the hospital specific rate. Overall, hospitals will experience a −1.6 percent decrease in payments due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Hospital categories that experience less than a 1.6 percent decrease in payments have hospitals that are paid under the hospital-specific rate, which is reduced by 1.0 percent. In addition, Puerto Rico hospitals will experience a −1.0 percent decrease in payments, a smaller decrease than average, because we are not proposing any documentation and coding adjustment to the Puerto Rico-specific rate, which is 25 percent of Puerto Rico's payment rate.

2. Effects of the Proposed Adjustment to the Standardized Amount for Cape Cod Hospital v. Sebelius (Column 3)

Column 3 shows the impact of the proposed 1.1 percent adjustment to the national standardized amount and the proposed 0.9 percent adjustment to the hospital-specific rate in light of the decision in *Cape Cod Hospital* v. *Sebelius,* as discussed in section II. of the Addendum to this proposed rule.

Overall, hospitals will experience a 1.1 percent increase in payments due to the effects of the adjustment on the national standardized amount. Hospital categories that experience less than a 1.1 percent increase in payments include hospitals that are paid under the hospital-specific rate, which we are proposing to increase by 0.9 percent. Rural hospitals will experience a 1.0 percent increase in payments because many rural hospitals are paid under the hospital-specific rate, which we are proposing to increase by 0.9 percent.

3. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights with Recalibration Budget Neutrality (Column 4)

Column 4 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2012 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2012, the proposed MS–DRGs are calculated using the FY 2010 MedPAR data grouped to the Version 29.0 (FY 2012) MS–DRGs. The methods of calculating the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this proposed rule.

The "All Hospitals" line in Column 4 indicates that proposed changes due to MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.998413 on to the standardized amount. The changes in payments due to the proposed MS–DRGs, relative weights and GROUPER are modest with no hospital category seeing an increase or decrease of more than 0.2 percent.

4. Effects of Proposed Wage Index Changes (Column 5)

Column 5 shows the impact of updated wage data with the application of the wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2012 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2007 and before October 1, 2008. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 5 by holding the other payment parameters constant in this simulation. That is, Column 5 shows the percentage change in payments when going from a model using the FY 2011 wage index, based on FY 2007 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2012 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2008 wage data (while holding other payment parameters such as use of the Version 29.0 MS–DRG GROUPER constant). The occupational mix adjustment is based on the 2007–2008 occupational mix survey.

In addition, the column shows the impact of the application of wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2012, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed wage budget neutrality factor is 1.000113, and the overall payment change is 0 percent.

Column 5 shows the impacts of updating the wage data using FY 2008 cost reports. Overall, the new wage data will lead to a 0.0 percent change for all hospitals before being combined with the wage budget neutrality adjustment shown in Column 5. Among the regions, the largest increase is in the rural New England region, which experiences a 0.8 percent increase due to increases in the wage index among rural Connecticut and rural Massachusetts hospitals. The largest decline from updating the wage data is seen in the rural East South Central region (−0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.4 percent compared to FY 2011. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.4 percent increase in average hourly wage. Of the 3,424 hospitals with wage data for both FYs 2011 and 2012, 1,681, or 49.1 percent, experienced an average hourly wage increase of 3.4 percent or more.

The following chart compares the shifts in proposed wage index values for hospitals for FY 2012 relative to FY 2011. Among urban hospitals, 37 will experience an increase of more than 5 percent and less than 10 percent and 5 will experience an increase of more than 10 percent. Among rural hospitals, 1 will experience an increase of more than 5 percent and less than 10 percent, and none will experience an increase of more than 10 percent. However, 915 rural hospitals will experience increases or decreases of less than 5 percent, while 2,397 urban hospitals will experience increases or decreases of less than 5 percent. Fifty-six urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. Sixteen urban hospitals will experience decreases in their wage index values of greater than 10 percent. One rural hospital will experience a decrease of more than 10 percent. Ten rural hospitals will experience decreases in their wage index values of greater than 5 percent but less than 10 percent. These figures reflect changes in the wage index which is an adjustment to either 68.8 percent or 62 percent of the labor share of a hospital's standardized amount, depending upon whether its wage index is greater than 1.0 or less than or equal to 1.0. Therefore, these figures illustrate a somewhat larger change in the wage index than will occur to the hospital's total payment.

The following chart shows the projected impact for urban and rural hospitals.

| Percentage Change in Area Wage Index Values | Number of Hospitals | |
|---|---|---|
| | Urban | Rural |
| Increase more than 10 percent | 5 | 0 |
| Increase more than 5 percent and less than 10 percent | 37 | 1 |
| Increase or decrease less than 5 percent | 2,397 | 915 |
| Decrease more than 5 percent and less than 10 percent | 56 | 10 |
| Decrease more than 10 percent | 16 | 1 |

5. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 6)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a proposed wage budget neutrality factor of 1.000113, and a proposed recalibration budget neutrality factor of 0.998419 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two proposed budget neutrality factors is the proposed cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.998532, or approximately −0.15 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this proposed rule, we are estimating that the changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 change in payments.

We estimate that the combined impact of the proposed changes to the relative weights and MS–DRGs and the proposed updated wage data with budget neutrality applied will result in no change in payments for urban or rural hospitals. Urban West South Central hospitals would experience a 0.4 percent increase in payments due to increases in their wages compared to the national average, while the urban East South Central and East North Central area would experience a −0.3 decrease in payments because of below average increases in wages. Among the rural hospital categories, rural New England hospitals would experience the greatest increase in payment (0.7 percent) primarily due to above average increases in the wage data, while the rural Pacific area would experience a 0.4 percent decrease in payments due to decreases in the wage data.

6. Effects of MGCRB Reclassifications (Column 7)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on other bases than where they are geographically located). The changes in Column 7 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2012 which affect hospitals' wage index area assignments.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for the purposes of this impact analysis, we are applying an adjustment of 0.991528 to ensure that the effects of the section 1886(d)(10) reclassifications are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that geographic reclassification will increase payments to rural hospitals by an average of 1.7 percent. By region, all the rural hospital categories, with the exception of the one rural Puerto Rico hospital, will experience increases in payments due to MGCRB reclassification. Rural hospitals in the East South Central region will experience a 2.6 percent increase in payments and rural hospitals in the Mountain region will experience a 0.5 percent increase in payments. Urban hospitals in New England and the Middle Atlantic will experience an increase in payments of 0.9 percent and 0.3 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet reflects the approved reclassifications for FY 2012.

7. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 8)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FY 2011 IPPS/LTCH PPS final rule and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. Beginning with FY 2008, we apply a uniform budget neutrality adjustment is applied to the wage index. For FY 2012 (and in FY 2011), the Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index, nationally. The proposed FY 2012 rural floor budget neutrality factor applied to the wage index is 0.993834, which would reduce wage indexes by −0.62 percent.

Column 8 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the post-reclassification FY 2012 wage index of providers before the rural floor adjustment and the post-reclassification FY 2012 wage index of providers with the rural floor adjustment. Only urban hospitals can benefit from the rural floor provision. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) experience a decrease in payments due to the budget neutrality adjustment applied nationally to their wage index.

We project that, in aggregate, rural hospitals will experience a −0.2 percent decrease in payments as a result of the application of rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.2 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 5.0 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the applicable national rural floor budget neutrality as required by the Affordable Care Act. All 60 urban providers in Massachusetts are expected to receive the rural floor wage index of 1.3614. During most past years, there have been no IPPS hospitals located in rural areas in Massachusetts. There was one urban IPPS hospital that was reclassified to rural Massachusetts (under section 1886(d)(8)(E) of the Act) which established the Massachusetts rural floor, but the wage index resulting from that hospital's data was not high enough for any urban hospital to benefit from the rural floor policy. However, beginning with the FY 2012 wage index, the rural floor for the State

is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. Massachusetts hospitals can expect approximately an 8-percent increase in IPPS payments due to the application of rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of a Puerto Rico rural floor. Similar to Massachusetts, this is the first year in which urban Puerto Rico hospitals will receive a rural floor as a result of a new IPPS hospital located in rural Puerto Rico setting a rural floor. We are proposing to apply a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.989226 or 1.1 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

8. Effects of the Expiration of the Imputed Floor (Column 9)

As discussed in section III.F.2. of the preamble of this proposed rule, the imputed floor, which is budget neutral, is set to expire with the FY 2011 wage index, and we are not proposing to extend it.

Column 9 shows the effects of the expiration of the imputed floor. This column compares payments that would have been made if the imputed floor were still in place to payments that are estimated to be made with only the rural floor. There are 39 hospitals in New Jersey that are affected by the expiration of the imputed floor. Therefore, only urban providers in the Middle Atlantic Region (New Jersey) will experience a decrease by 0.4 percent, from the imputed floor no longer being applied in that State. Hospitals in other regional categories will experience an increase in payments as they will no longer have payments reduced because of the imputed floor to ensure budget neutrality.

9. Effects of the Proposed Application of the Frontier Wage Index (Column 10)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in "frontier States." The term "frontier States" is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, five States (Montana, North Dakota, Nevada, South Dakota, and Wyoming) are considered frontier States and 47 hospitals located in those States will receive a frontier wage index of 1.0. This provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $48 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will experience an increase in payments by 0.5 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region will experience an increase in payments by 0.6 percent and 0.1 percent, respectively.

10. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 11)

Section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. Overall, rural hospitals will experience a 0.1 percent increase in payments as a result of the outmigration adjustment. Rural providers with less than 50 beds will experience a 0.2 percent increase in payments in FY 2012. We included these additional payments to providers in the impact table shown above, and we estimate the impact of these providers receiving the out-migration increase to be approximately $14 million.

11. Effects of the Expiration of Section 508 (Column 12)

Column 12 shows our estimate of the changes in payments due to the expiration of section 508, a non-budget neutral reclassification provision, applied under the MMEA. Because this provision is not budget neutral, the expiration of this reclassification provision results in a −0.2 percent decrease in payments, overall. Section 508 hospitals are generally urban hospitals, resulting in a −0.2 percent decrease in payments among the urban hospital category and a 0.0 percent change in payments among rural hospitals. Urban New England and Urban Middle Atlantic regions will experience a decrease in payments of −0.2 percent and −0.4 percent respectively because many section 508 hospitals are located in those regions. Urban teaching hospitals that do not receive DSH will experience a −0.3 percent decrease in payments due to the expiration of section 508.

12. Effects of All Proposed FY 2012 Changes (Column 13)

Column 13 shows our estimate of the changes in payments per discharge from FY 2011 and FY 2012, resulting from all proposed changes reflected in this proposed rule for FY 2012. It includes combined effects of the previous columns in the table.

The average decrease in payments under the IPPS for all hospitals is approximately −0.5 percent. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2012 documentation and coding adjustment of −3.15 percent on the national standardized amount and −2.5 percent on the hospital-specific rates. In addition, this column includes the proposed annual hospital update of 1.5 percent to the national standardized amount. This annual hospital update includes the 2.8 percent market basket update, the reduction of −1.2 percentage points for the multifactor productivity adjustment, and the −0.1 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the proposed annual hospital update, combined with the proposed documentation and coding adjustment, results in a −1.6 percent decrease in payments in FY 2012 relative to FY 2011. As described in Column 3, the proposed 1.1 percent adjustment to the national standardized amount and the proposed 0.9 percent adjustment to the hospital specific rate in light of a recent court decision related to rural floor budget neutrality results in a 1.1 percent increase in payments in FY 2012 relative to FY 2011. In addition, column 12 describes a −0.2 percent decrease in payments due to the expiration of section 508 reclassifications that had been extended for FY 2011 under the MMEA. Section 508 was not a budget-neutral provision. There might also be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 13 may not equal the sum of the percentage changes described above.

The overall change in payments per discharge for hospitals paid under the IPPS in FY 2012 is estimated to decrease by −0.5 percent. The payment decreases among the hospital categories are largely attributed to the proposed documentation and coding adjustments. Hospitals in urban areas would experience an estimated −0.4 percent decrease in payments per discharge in FY 2012 compared to FY 2011. Hospital payments per discharge in rural areas are estimated to decrease by −0.8 percent in FY 2012 as compared to FY 2011.

Among urban census divisions, the largest estimated payment decreases will be 1.2 percent in the East North Central region because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2011 that have expired for FY 2012. Urban Middle Atlantic providers will experience a −0.9 percent decrease in payments due to the expiration of the imputed floor that had previously benefited urban hospitals in this region. Urban hospitals in the New England will see the largest payment increases (3.6 percent) because the Massachusetts hospitals are benefitting from the rural floor in their State. Furthermore, urban Puerto Rico hospitals will experience a 0.2 percent increase in payments due to the application of the rural floor.

Among the rural regions, the providers in the East South Central region will experience the largest decrease in payments of −1.6 percent due to decreases in wage data. Rural hospitals in the West North Central region will experience a decrease in payments by −0.2 percent, which is better than average, because the rural providers in this region benefit from MGCRB reclassification and the frontier State wage index provision, implemented under the Affordable Care Act.

Among special categories of hospitals, MDHs will receive an estimated payment decrease of −0.4 percent. MDHs are paid the higher of the IPPS rate based on the national standardized amount, that is, the Federal rate, or, if the hospital-specific rate exceeds

the Federal rate, the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate. MDHs will experience a decrease in payments because of the proposed documentation and coding adjustments applied to both the Federal rate and the hospital-specific rate. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs will experience an estimated decrease in payments by −1.4 percent due to the proposed documentation and coding adjustments to the national standardized amount and the hospital-specific rates.

Rural hospitals reclassified for FY 2012 are anticipated to receive a −0.6 percent payment decrease, and rural hospitals that are not reclassifying are estimated to receive a payment decrease of −1.2 percent. Urban reclassified hospitals will experience payment decreases better than average at −0.2 percent due to the benefits under MGCRB reclassification and the rural floor. Urban non-reclassified hospitals will experience a payment decrease of −0.5 percent.

Cardiac hospitals are expected to experience a payment decrease of 0.6 percent in FY 2012 relative to FY 2011.

*C. Impact Analysis of Table II*

Table II presents the projected impact of the proposed changes for FY 2012 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2011 with the proposed payments per discharge for FY 2012, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 13 of Table I.

BILLING CODE 4120–01–P

# TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2012 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

| | Number of Hospitals | Average FY 2011 Payment Per Discharge (2) | Average Proposed FY 2012 Payment Per Discharge (3) | All Proposed FY 2012 Changes (4) |
|---|---|---|---|---|
| All hospitals | 3,419 | $10,257 | $10,209 | -0.5 |
| **By Geographic Location:** | | | | |
| Urban hospitals | 2,492 | $10,667 | $10,620 | -0.4 |
| Large urban areas (populations over 1 million) | 1,369 | $11,249 | $11,203 | -0.4 |
| Other urban areas (populations of 1 million or fewer) | 1,123 | $9,950 | $9,904 | -0.5 |
| Rural hospitals | 927 | $7,656 | $7,595 | -0.8 |
| **Bed Size (Urban):** | | | | |
| 0-99 beds | 634 | $8,173 | $8,149 | -0.3 |
| 100-199 beds | 777 | $9,004 | $8,970 | -0.4 |
| 200-299 beds | 457 | $9,814 | $9,777 | -0.4 |
| 300-499 beds | 428 | $10,971 | $10,894 | -0.7 |
| 500 or more beds | 196 | $13,208 | $13,176 | -0.2 |
| **Bed Size (Rural):** | | | | |
| 0-49 beds | 317 | $6,173 | $6,101 | -1.2 |
| 50-99 beds | 351 | $7,134 | $7,061 | -1 |
| 100-149 beds | 153 | $7,545 | $7,491 | -0.7 |
| 150-199 beds | 60 | $8,235 | $8,188 | -0.6 |
| 200 or more beds | 46 | $9,485 | $9,434 | -0.5 |
| **Urban by Region:** | | | | |
| New England | 120 | $11,138 | $11,544 | 3.6 |
| Middle Atlantic | 320 | $11,788 | $11,679 | -0.9 |
| South Atlantic | 379 | $9,814 | $9,736 | -0.8 |
| East North Central | 401 | $10,051 | $9,930 | -1.2 |
| East South Central | 153 | $9,502 | $9,403 | -1 |
| West North Central | 168 | $10,260 | $10,245 | -0.1 |
| West South Central | 365 | $10,006 | $9,999 | -0.1 |
| Mountain | 159 | $10,815 | $10,763 | -0.5 |
| Pacific | 377 | $13,104 | $13,059 | -0.3 |
| Puerto Rico | 50 | $5,284 | $5,297 | 0.2 |
| **Rural by Region:** | | | | |
| New England | 23 | $10,176 | $10,080 | -0.9 |
| Middle Atlantic | 69 | $8,040 | $8,015 | -0.3 |
| South Atlantic | 165 | $7,363 | $7,316 | -0.6 |
| East North Central | 120 | $7,963 | $7,920 | -0.5 |
| East South Central | 171 | $7,023 | $6,907 | -1.6 |
| West North Central | 99 | $8,136 | $8,123 | -0.2 |
| West South Central | 184 | $6,729 | $6,645 | -1.2 |
| Mountain | 66 | $8,500 | $8,460 | -0.5 |

| | Number of Hospitals | Average FY 2011 Payment Per Discharge (2) | Average Proposed FY 2012 Payment Per Discharge (3) | All Proposed FY 2012 Changes (4) |
|---|---|---|---|---|
| Pacific | 29 | $10,326 | $10,281 | -0.4 |
| Puerto Rico | 1 | $2,280 | $2,287 | 0.3 |
| **By Payment Classification**: | | | | |
| Urban hospitals | 2,514 | $10,652 | $10,605 | -0.4 |
| Large urban areas (populations over 1 million) | 1,382 | $11,234 | $11,187 | -0.4 |
| Other urban areas (populations of 1 million or fewer) | 1,132 | $9,930 | $9,885 | -0.5 |
| Rural areas | 905 | $7,732 | $7,672 | -0.8 |
| **Teaching Status:** | | | | |
| Non-teaching | 2,389 | $8,591 | $8,551 | -0.5 |
| Fewer than 100 Residents | 790 | $10,161 | $10,103 | -0.6 |
| 100 or more Residents | 240 | $15,094 | $15,041 | -0.4 |
| **Urban DSH:** | | | | |
| Non-DSH | 738 | $8,955 | $8,879 | -0.9 |
| 100 or more beds | 1,543 | $11,154 | $11,114 | -0.4 |
| Less than 100 beds | 339 | $7,615 | $7,586 | -0.4 |
| **Rural DSH:** | | | | |
| SCH | 416 | $7,120 | $7,015 | -1.5 |
| RRC | 222 | $8,466 | $8,427 | -0.5 |
| 100 or more beds | 28 | $6,290 | $6,213 | -1.2 |
| Less than 100 beds | 133 | $5,962 | $5,923 | -0.6 |
| **Urban teaching and DSH:** | | | | |
| Both teaching and DSH | 825 | $12,198 | $12,148 | -0.4 |
| Teaching and no DSH | 144 | $9,863 | $9,766 | -1 |
| No teaching and DSH | 1,057 | $9,116 | $9,095 | -0.2 |
| No teaching and no DSH | 488 | $8,533 | $8,463 | -0.8 |
| **Rural Hospital Types:** | | | | |
| RRC | 175 | $8,557 | $8,486 | -0.8 |
| SCH | 320 | $8,157 | $8,039 | -1.4 |
| MDH | 195 | $6,472 | $6,447 | -0.4 |
| SCH and RRC | 120 | $9,414 | $9,390 | -0.3 |
| MDH and RRC | 18 | $8,466 | $8,442 | -0.3 |
| **Type of Ownership**: | | | | |
| Voluntary | 1,991 | $10,381 | $10,336 | -0.4 |
| Proprietary | 850 | $9,131 | $9,085 | -0.5 |
| Government | 574 | $10,958 | $10,885 | -0.7 |
| **Medicare Utilization as a Percent of Inpatient Days:** | | | | |
| 0-25 | 359 | $14,311 | $14,257 | -0.4 |
| 25-50 | 1,703 | $10,902 | $10,857 | -0.4 |
| 50-65 | 1,089 | $8,503 | $8,446 | -0.7 |
| Over 65 | 195 | $7,426 | $7,381 | -0.6 |

| | Number of Hospitals | Average FY 2011 Payment Per Discharge (2) | Average Proposed FY 2012 Payment Per Discharge (3) | All Proposed FY 2012 Changes (4) |
|---|---|---|---|---|
| **Hospitals Reclassified by the Medicare Geographic Classification Review Board: FY 2012 Reclassifications:** | | | | |
| All Reclassified Hospitals FY 2012 | 805 | $10,011 | $9,979 | -0.3 |
| All Non-Reclassified Hospitals FY 2012 | 2,614 | $10,346 | $10,292 | -0.5 |
| Urban Reclassified Hospitals FY 2012: | 469 | $10,735 | $10,709 | -0.2 |
| Urban Non-reclassified Hospitals FY 2012 | 1,990 | $10,665 | $10,613 | -0.5 |
| Rural Reclassified Hospitals FY 2012 | 336 | $8,246 | $8,199 | -0.6 |
| Rural Nonreclassified Hospitals FY 2012: | 529 | $6,819 | $6,738 | -1.2 |
| All Section 401 Reclassified Hospitals: | 40 | $8,594 | $8,537 | -0.7 |
| Other Reclassified Hospitals (Section 1886(d)(8)(B)) | 63 | $7,260 | $7,193 | -0.9 |
| **Specialty Hospitals** | | | | |
| Cardiac Hospitals | 19 | $11,159 | $11,093 | -0.6 |

BILLING CODE 4120–01–C

## VII. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

### *A. Effects of Proposed Policy on HACs, Including Infections*

In section II.F. of the preamble of this proposed rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3.e. of the preamble of this proposed rule, it is possible to have two severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

In section II.F. of the preamble of this proposed rule, we discuss our proposal to add an additional HAC for FY 2012: Contrast-Induced Acute Kidney Injury. In that discussion, we stated that, in FY 2009, there were 38,324 inpatient discharges coded as acute renal failure using ICD–9–CM diagnosis code 584.9 and reported as not present on admission (POA status = N) when reported with one of the above procedure codes submitted through Medicare claims. These cases had an average charge of $29,122 for the entire hospital stay. Further analysis of the FY 2009 claims showed that the average charge was approximately $9,122 more than the average charge for inpatient discharges coded as acute renal failure using ICD–9–CM diagnosis code 584.9 and reported as present on admission (POA status = Y).

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

| Year | Savings (in millions) |
|---|---|
| FY 2012 | $23 |
| FY 2013 | $24 |
| FY 2014 | $26 |
| FY 2015 | $28 |
| FY 2016 | $30 |

### *B. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments*

In section II.I. of the preamble to this proposed rule, we discuss the three applications for add-on payments for new medical services and technologies for FY 2012, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2011. As explained in that section, add-on payments for new technology under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this proposed rule, we have yet to determine whether any of the three applications we received for consideration for new technology add-on payments for FY 2012 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of any potential new technology add-on payments for FY 2012. We note that if any of the three applications are found to be eligible for new technology add-on payments for FY 2012 in

the FY 2012 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2012 in that final rule.

However, because we are proposing to continue to make new technology add-on payments in FY 2012 for the AutoLITT™ (because the technology is still within the 3-year anniversary of the product's entry onto the market), we are providing an estimate of total payments for this technology for FY 2012. We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimate below is based on the increase in add-on payments for FY 2012 as if every claim that would qualify for a new technology add-on payments would receive the maximum add-on payment. Therefore, we currently estimate that payments for the AutoLITT™ will increase overall FY 2012 payments by $900,000. For FY 2011, the applicant estimates that approximately 170 Medicare beneficiaries would be eligible for the AutoLITT™. Therefore, based on the applicant's estimate from FY 2011, we currently estimate that payments for the AutoLITT™ will increase overall FY 2012 payments by $900,000.

*C. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program*

In section VII.C. of Appendix A of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50662 through 50663), we discussed the impact of the FY 2011 through FY 2014 Hospital Inpatient Quality Reporting (IQR) Program requirements we adopted in that final rule. We estimated that 95 hospitals would not receive the full payment update in any fiscal year from FY 2012 through FY 2014. At the time that analysis was prepared, 104 hospitals did not receive the full payment update in FY 2010.

In section IV.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full update to the standardized amount for FY 2012 through FY 2015. We now estimate that approximately 104 hospitals may not receive the full update in any fiscal year. (In this proposed rule, we are proposing to retire eight of the FY 2011 measures for the FY 2014 payment determination. We believe that this proposal would not have a significant effect on our estimate.) We believe that most of these hospitals would be either small rural or small urban hospitals. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2012 through FY 2015.

In section IV.A.7. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229), we established Hospital IQR validation requirements for the FY 2012 and FY 2013 payment determinations. Beginning with the FY 2012 payment update, hospitals must pass our validation requirement of a minimum of 75 percent reliability, based upon our chart-audit validation process, for four quarters of data from the last quarter of CY 2011 through the third quarter of CY 2012.

In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. In section IV.A.6.a. of the preamble of this proposed rule and in proposed § 412.140(d)(1), beginning with the FY 2012 we are proposing to reduce the deadline from 45 days to 30 days for hospitals to return requested medical record documentation to support our validation requirement. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with our QIO regulations at § 476.78 and the total burden would be 18 charts for each for the four quarters that must be copied and mailed in a 30-day period for FY 2012 and subsequent years.

In addition, we are proposing to add a new § 478.78(b)(2)(2) that will require the submission of medical information within 21 days in those situations in which a "serious reportable event" or other circumstance has been identified during the course of a QIO review. We do not believe this will cause a significantly higher administrative burden on the hospitals, since CMS reimburses providers returning medical records to QIOs at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Given that we reimburse for the data collection effort, we believe that this proposed requirement represents a minimal burden to providers. We have continued our efforts to ensure that QIOs provide assistance to all hospitals that wish to participate in the Hospital IQR Program.

In section IV.A.6.b. of the preamble of this proposed rule, for FY 2014 payment determinations and subsequent years, we are proposing to add two strata to the current Hospital IQR validation sample of SCIP, AMI, HF, and PN cases. For the first stratum, we are proposing to select three cases per selected hospital per quarter to validate the CLABSI measure using a two step selection process that would target potential patients with positive infection from blood culture results and a Central Venous Catheter. The requirement of an additional 3 charts per hospital submitted for validation for the CLABSI measure would result in approximately 2,400 total additional charts per quarter being submitted to CMS by all selected hospitals. We reimburse hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. Thus, we would expend approximately $88,800 per quarter to collect the additional charts we need to validate the CLASBI measure. Additionally, we will collect the CLABSI-specific data elements from all charts currently requested for Hospital IQR validation. We would validate a total of 15 records per quarter per validated hospital in 5 strata (SCIP, AMI, HF, PN, CLABSI and the proposed ED/Global Immunization measure).

In section IV.A.6.b. of the preamble of this proposed rule, for FY 2014 and subsequent years, we are proposing to add a second stratum to our validation sample, which would enable us to validate the EDT and the Immunization for Influenza and Immunization for Pneumonia global measures. Thus, we would be validating a total of 18 records per quarter per selected hospital in 6 strata ((1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures). Under the assumptions outlined above, we would expend approximately $88,800 per quarter to collect the additional charts for the EDT/immunization measures. The proposed total requirement of 18 charts per hospital (should we adopt both the proposed CLABSI validation requirement and the proposed EDT/immunization validation requirement) would result in approximately 14,400 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2014 Hospital IQR Program, we estimate that CMS would have expenditures of approximately $532,800 per quarter related to the validation requirement. Additionally, we will collect the CLABSI-specific data and the EDT/Immunization data elements from all charts currently requested for Hospital IQR validation. We would validate a total of 18 records per quarter per validated hospital in 6 strata (SCIP, AMI, HF, PN, CLABSI and the proposed ED/Global Immunization measure). We do not believe this will be an additional burden on the hospitals since this data will be abstracted from records already submitted.

Given that we reimburse for the data collection effort, we believe that a requirement for 18 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

Finally, with respect to our proposed validation requirements, we also are proposing for FY 2015 to select additional hospitals for validation if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation selections. This proposal could affect data collection costs and burdens, but we are unable to estimate any impact at this time.

We are proposing to adjust the Hospital IQR Program data submission deadline from 4½ months to 104 days. While the proposed shortened time frame may create a new administrative burden for hospitals, we believe that this burden is reduced because many hospitals currently report AMI, HF, SCIP, and PN data to the Joint Commission within 4 months following a discharge quarter. We believe that our proposed 104 day deadline is relatively consistent with other industry submission deadlines.

*D. Effects of Additional Proposed Hospital Value-Based Purchasing (VBP) Program Requirements*

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through

a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

In section IV.B. of the preamble of this proposed rule, we are proposing additional requirements for the FY 2014 Hospital VBP Program. Specifically, we are proposing the addition of a Medicare Spending per Beneficiary Measure, how the proposed measure would be scored, and the measure's proposed performance period and proposed baseline period. Because this additional measure is claims-based and is required for the Hospital IQR Program, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

*E. Effects of Proposed Requirements for Hospital Readmissions Reduction Program*

In section IV.C. of the preamble of this proposed rule, we are proposing the selection of three high cost, high volume conditions for the Hospital Readmission Reduction Program FY 2013 payment reduction, and the definition of readmission for these conditions. We also are proposing the use of the following three measures for these conditions for the FY 2013 payment determination:

- Heart failure [HF] 30-day Risk Standardized Readmission Measure
- Acute Myocardial Infarction [AMI] 30-day Risk Standardized Readmission Measure
- Pneumonia [PN] 30-day Risk Standardized Readmission Measure

These three risk-adjusted NQF endorsed measures will be calculated by CMS for hospitals subject to this provision using Medicare FFS Part A and B claims data, and require no submission of additional data by the hospital. Therefore, there is no data collection burden associated with this provision for FY 2013. These measures also are used under the Hospital IQR Program, and have been publicly reported on the *Hospital Compare* Web site since 2009. Therefore, there is a high degree of familiarity and acceptance among the stakeholder community with regard to these measures.

We also are proposing a methodology for calculating the Excess Readmission Ratio using these three measures for the FY 2013 payment determination. This would be defined as a ratio of the number of risk-adjusted readmissions (based on actual readmissions) for the given condition at a specified hospital compared with the number of readmissions that would be expected for an average hospital caring for the same patients. Below is a description of this calculation:

Numerator—Adjusted number of readmissions at specific hospital (calculated for each patient and add up results for all patients):

*Hospital-specific readmission effect* + average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

Denominator—Number of readmissions if an average hospital treated the same patients (calculated for each patient and summed for all patients):

Average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

We are proposing a minimum case threshold of 25 cases for a given condition in order to have an Excess Readmission Ratio calculated. Using the proposed 25 case threshold, we have analyzed the distribution of Excess Readmission Ratio calculations on various types of IPPS hospitals. The results of these analyses are shown in the three tables below.

**BILLING CODE 4120–01–P**

**Distribution of Excess Readmission Ratio for Acute Myocardial Infarction (AMI): AMI Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 AMI cases between July 2006-June 2009)**

| Hospital Characteristic | Hospitals with (≥ 25 cases over 3-year period) | Hospitals with Excess Readmission Ratio ≤ 1* | Percentage of Hospitals with Excess Readmission Ratio ≤ 1* | Percentile | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Mean | 5th | 10th | 25th | 50th | 75th | 90th | 95th | Hospitals with < 25 cases (not included in distribution) |
| **OVERALL** | 2,477 | 1,248 | 50.4 | 1.0019 | 0.8953 | 0.9238 | 0.9627 | 0.9997 | 1.0412 | 1.0795 | 1.1065 | 1,999 |
| **Region**** | | | | | | | | | | | | |
| New England | 148 | 72 | 48.6 | 1.0060 | 0.9172 | 0.9331 | 0.9623 | 1.0049 | 1.0400 | 1.0949 | 1.1104 | 30 |
| Mid Atlantic | 338 | 106 | 31.4 | 1.0325 | 0.9266 | 0.9544 | 0.9894 | 1.0292 | 1.0690 | 1.1137 | 1.1546 | 61 |
| South Atlantic | 448 | 235 | 52.5 | 0.9977 | 0.8918 | 0.9207 | 0.9608 | 0.9951 | 1.0370 | 1.0717 | 1.0938 | 203 |
| East North Central | 408 | 210 | 51.5 | 1.0046 | 0.9022 | 0.9260 | 0.9649 | 0.9991 | 1.0435 | 1.0884 | 1.1154 | 268 |
| East South Central | 171 | 69 | 40.4 | 1.0143 | 0.9338 | 0.9467 | 0.9747 | 1.0084 | 1.0518 | 1.0803 | 1.0967 | 209 |
| West North Central | 166 | 92 | 55.4 | 0.9930 | 0.8839 | 0.9190 | 0.9502 | 0.9928 | 1.0311 | 1.0710 | 1.0922 | 428 |
| West South Central | 288 | 149 | 51.7 | 0.9964 | 0.8928 | 0.9225 | 0.9612 | 0.9952 | 1.0352 | 1.0632 | 1.0799 | 300 |
| Mountain | 131 | 94 | 71.8 | 0.9726 | 0.8758 | 0.8913 | 0.9328 | 0.9744 | 1.0067 | 1.0511 | 1.0717 | 188 |
| Pacific | 275 | 172 | 62.5 | 0.9797 | 0.8707 | 0.8979 | 0.9355 | 0.9839 | 1.0229 | 1.0591 | 1.0750 | 191 |
| Associated Areas | 25 | 9 | 36.0 | 1.0306 | 0.9610 | 0.9649 | 0.9846 | 1.0276 | 1.0632 | 1.1039 | 1.1364 | 21 |
| **Bed Size**** | | | | | | | | | | | | |
| 1 to 99 beds | 395 | 220 | 55.7 | 0.9987 | 0.9279 | 0.9451 | 0.9710 | 0.9953 | 1.0275 | 1.0516 | 1.0717 | 1,556 |
| 100 to 199 beds | 731 | 358 | 49.0 | 1.0015 | 0.9096 | 0.9345 | 0.9646 | 1.0019 | 1.0375 | 1.0713 | 1.0926 | 274 |
| 200 to 299 beds | 517 | 272 | 52.6 | 0.9979 | 0.8868 | 0.9137 | 0.9541 | 0.9961 | 1.0423 | 1.0771 | 1.1059 | 41 |
| 300 to 399 beds | 320 | 164 | 51.3 | 0.9994 | 0.8686 | 0.9036 | 0.9507 | 0.9989 | 1.0511 | 1.0923 | 1.1145 | 19 |
| 400 to 499 beds | 170 | 78 | 45.9 | 1.0116 | 0.8816 | 0.9021 | 0.9610 | 1.0067 | 1.0636 | 1.1090 | 1.1391 | 7 |
| 500+ beds | 265 | 116 | 43.8 | 1.0125 | 0.8839 | 0.9007 | 0.9643 | 1.0115 | 1.0632 | 1.1139 | 1.1516 | 2 |
| **Teaching Status**** | | | | | | | | | | | | |
| Teaching | 896 | 439 | 49.0 | 1.0061 | 0.8840 | 0.9121 | 0.9580 | 1.0028 | 1.0530 | 1.0992 | 1.1293 | 175 |
| Non-Teaching | 1,502 | 769 | 51.2 | 0.9994 | 0.9058 | 0.9284 | 0.9649 | 0.9987 | 1.0353 | 1.0672 | 1.0914 | 1,724 |
| **Urban/Rural Status**** | | | | | | | | | | | | |
| Urban | 2,279 | 1,146 | 50.3 | 1.0017 | 0.8928 | 0.9211 | 0.9615 | 0.9998 | 1.0418 | 1.0797 | 1.1072 | 972 |
| Rural | 119 | 62 | 52.1 | 1.0061 | 0.9409 | 0.9517 | 0.9713 | 0.9966 | 1.0328 | 1.0761 | 1.0887 | 927 |

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 2,398.

**Distribution of Excess Readmission Ratio for Heart Failure (HF): Heart Failure Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 HF cases between July 2006-June 2009)**

| Hospital Characteristic | Hospitals with (≥ 25 cases over 3-year period) | Hospitals with Excess Readmission Ratio ≤ 1* | Percentage of Hospitals with Excess Readmission Ratio ≤ 1* | Percentile | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Mean | 5th | 10th | 25th | 50th | 75th | 90th | 95th | Hospitals with < 25 cases (not included in distribution) |
| **OVERALL** | 4,209 | 2,171 | 51.6 | 1.0021 | 0.8799 | 0.9108 | 0.9527 | 0.9971 | 1.0484 | 1.0991 | 1.1362 | 550 |
| **Region**** | | | | | | | | | | | | |
| New England | 174 | 99 | 56.9 | 0.9933 | 0.8830 | 0.9058 | 0.9418 | 0.9879 | 1.0382 | 1.0940 | 1.1121 | 5 |
| Mid Atlantic | 397 | 135 | 34.0 | 1.0376 | 0.9020 | 0.9314 | 0.9788 | 1.0354 | 1.0936 | 1.1485 | 1.1788 | 6 |
| South Atlantic | 639 | 323 | 50.5 | 1.0021 | 0.8860 | 0.9097 | 0.9517 | 0.9993 | 1.0507 | 1.0962 | 1.1304 | 26 |
| East North Central | 672 | 378 | 56.3 | 0.9933 | 0.8740 | 0.8983 | 0.9413 | 0.9890 | 1.0423 | 1.0937 | 1.1302 | 20 |
| East South Central | 381 | 156 | 40.9 | 1.0225 | 0.9059 | 0.9291 | 0.9646 | 1.0142 | 1.0708 | 1.1313 | 1.1708 | 14 |
| West North Central | 519 | 304 | 58.6 | 0.9918 | 0.8876 | 0.9174 | 0.9482 | 0.9867 | 1.0267 | 1.0730 | 1.1143 | 136 |
| West South Central | 560 | 256 | 45.7 | 1.0112 | 0.8920 | 0.9212 | 0.9650 | 1.0082 | 1.0549 | 1.1052 | 1.1373 | 81 |
| Mountain | 271 | 188 | 69.4 | 0.9664 | 0.8511 | 0.8789 | 0.9315 | 0.9706 | 1.0118 | 1.0435 | 1.0628 | 93 |
| Pacific | 418 | 247 | 59.1 | 0.9892 | 0.8671 | 0.9035 | 0.9458 | 0.9841 | 1.0392 | 1.0823 | 1.1111 | 83 |
| Associated Areas | 34 | 12 | 35.3 | 1.0304 | 0.9365 | 0.9515 | 0.9877 | 1.0253 | 1.0665 | 1.1122 | 1.1461 | 14 |
| **Bed Size**** | | | | | | | | | | | | |
| 1 to 99 beds | 1,755 | 947 | 54.0 | 0.9999 | 0.8980 | 0.9206 | 0.9556 | 0.9939 | 1.0394 | 1.0865 | 1.1190 | 414 |
| 100 to 199 beds | 983 | 467 | 47.5 | 1.0080 | 0.8833 | 0.9145 | 0.9584 | 1.0042 | 1.0517 | 1.1119 | 1.1427 | 38 |
| 200 to 299 beds | 547 | 284 | 51.9 | 1.0019 | 0.8647 | 0.8959 | 0.9476 | 0.9966 | 1.0565 | 1.1125 | 1.1485 | 15 |
| 300 to 399 beds | 337 | 176 | 52.2 | 1.0003 | 0.8626 | 0.8939 | 0.9449 | 0.9964 | 1.0586 | 1.1052 | 1.1314 | 4 |
| 400 to 499 beds | 176 | 93 | 52.8 | 0.9979 | 0.8501 | 0.8857 | 0.9290 | 0.9920 | 1.0596 | 1.1275 | 1.1578 | 3 |
| 500+ beds | 267 | 131 | 49.1 | 1.0004 | 0.8506 | 0.8908 | 0.9397 | 1.0017 | 1.0549 | 1.1051 | 1.1577 | 4 |
| **Teaching Status**** | | | | | | | | | | | | |
| Teaching | 1,036 | 547 | 52.8 | 1.0005 | 0.8681 | 0.9001 | 0.9454 | 0.9937 | 1.0534 | 1.1085 | 1.1476 | 49 |
| Non-Teaching | 3,029 | 1,551 | 51.2 | 1.0027 | 0.8838 | 0.9149 | 0.9554 | 0.9980 | 1.0469 | 1.0978 | 1.1328 | 429 |
| **Urban/Rural Status**** | | | | | | | | | | | | |
| Urban | 3,160 | 1,666 | 52.7 | 0.9996 | 0.8742 | 0.9048 | 0.9487 | 0.9941 | 1.0476 | 1.1005 | 1.1366 | 205 |
| Rural | 905 | 432 | 47.7 | 1.0110 | 0.9126 | 0.9312 | 0.9631 | 1.0043 | 1.0517 | 1.0984 | 1.1378 | 273 |

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 4,065.

**Distribution of Excess Readmission Ratio for Pneumonia (PN):**
**Pneumonia Readmission Distribution of Excess Readmission Ratio**
**(for hospitals with greater than 25 Pneumonia cases between July 2006-June 2009)**

| Hospital Characteristic | Hospitals with (≥ 25 cases over 3-year period) | Hospitals with Excess Readmission Ratio ≤ 1* | Percentage of Hospitals with Excess Readmission Ratio ≤ 1* | Percentile | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Mean | 5th | 10th | 25th | 50th | 75th | 90th | 95th | Hospitals with < 25 cases (not included in distribution) |
| **OVERALL** | 4,450 | 2,351 | 52.8 | 1.0021 | 0.8763 | 0.9019 | 0.9435 | 0.9944 | 1.0531 | 1.1134 | 1.1538 | 363 |
| **Region**** | | | | | | | | | | | | |
| New England | 178 | 88 | 49.4 | 1.0086 | 0.8750 | 0.9045 | 0.9488 | 1.0011 | 1.0603 | 1.1262 | 1.1605 | 3 |
| Mid Atlantic | 399 | 143 | 35.8 | 1.0458 | 0.9021 | 0.9360 | 0.9735 | 1.0326 | 1.1033 | 1.1773 | 1.2288 | 5 |
| South Atlantic | 653 | 301 | 46.1 | 1.0135 | 0.8858 | 0.9187 | 0.9586 | 1.0073 | 1.0639 | 1.1207 | 1.1494 | 16 |
| East North Central | 679 | 368 | 54.2 | 1.0003 | 0.8614 | 0.8907 | 0.9340 | 0.9889 | 1.0557 | 1.1231 | 1.1645 | 12 |
| East South Central | 381 | 132 | 34.6 | 1.0381 | 0.9032 | 0.9248 | 0.9719 | 1.0329 | 1.0938 | 1.1544 | 1.2052 | 17 |
| West North Central | 618 | 379 | 61.3 | 0.9831 | 0.8766 | 0.9027 | 0.9365 | 0.9785 | 1.0207 | 1.0741 | 1.1052 | 42 |
| West South Central | 590 | 343 | 58.1 | 0.9917 | 0.8682 | 0.8928 | 0.9344 | 0.9871 | 1.0399 | 1.0922 | 1.1427 | 59 |
| Mountain | 323 | 236 | 73.1 | 0.9605 | 0.8487 | 0.8812 | 0.9187 | 0.9615 | 1.0027 | 1.0525 | 1.0748 | 47 |
| Pacific | 443 | 273 | 61.6 | 0.9822 | 0.8590 | 0.8865 | 0.9369 | 0.9827 | 1.0258 | 1.0774 | 1.1090 | 65 |
| Associated Areas | 36 | 11 | 30.6 | 1.0395 | 0.9343 | 0.9575 | 0.9820 | 1.0382 | 1.0819 | 1.1441 | 1.1605 | 13 |
| **Bed Size**** | | | | | | | | | | | | |
| 1 to 99 beds | 1,982 | 1,187 | 59.9 | 0.9910 | 0.8784 | 0.9019 | 0.9386 | 0.9812 | 1.0348 | 1.0914 | 1.1327 | 214 |
| 100 to 199 beds | 989 | 501 | 50.7 | 1.0067 | 0.8771 | 0.9044 | 0.9466 | 0.9989 | 1.0616 | 1.1199 | 1.1555 | 36 |
| 200 to 299 beds | 547 | 261 | 47.7 | 1.0081 | 0.8684 | 0.8920 | 0.9450 | 1.0028 | 1.0609 | 1.1270 | 1.1670 | 18 |
| 300 to 399 beds | 37 | 142 | 42.1 | 1.0139 | 0.8567 | 0.8933 | 0.9551 | 1.0154 | 1.0710 | 1.1370 | 1.1708 | 4 |
| 400 to 499 beds | 177 | 80 | 45.2 | 1.0167 | 0.8763 | 0.9194 | 0.9488 | 1.0105 | 1.0646 | 1.1383 | 1.2018 | 3 |
| 500+ beds | 268 | 103 | 38.4 | 1.0296 | 0.8579 | 0.9105 | 0.9583 | 1.0215 | 1.0819 | 1.1573 | 1.2268 | 4 |
| **Teaching Status**** | | | | | | | | | | | | |
| Teaching | 1,049 | 470 | 44.8 | 1.0144 | 0.8614 | 0.8997 | 0.9492 | 1.0108 | 1.0682 | 1.1383 | 1.1971 | 46 |
| Non-Teaching | 3,251 | 1,804 | 55.5 | 0.9981 | 0.8786 | 0.9015 | 0.9418 | 0.9892 | 1.0476 | 1.1072 | 1.1428 | 233 |
| **Urban/Rural Status**** | | | | | | | | | | | | |
| Urban | 3,215 | 1,651 | 51.4 | 1.0032 | 0.8671 | 0.8953 | 0.9421 | 0.9976 | 1.0565 | 1.1182 | 1.1595 | 179 |
| Rural | 1,085 | 623 | 57.4 | 0/9985 | 0.8924 | 0.9120 | 0.9460 | 0.9871 | 1.0405 | 1.1027 | 1.1416 | 100 |

* With ≥ 25 cases over 3-year period.
** Total number of hospitals with available hospital characteristics and with ≥ 25 cases over 3-year period equals 4,300.

BILLING CODE 4120–01–C

The three tables above show the distribution of Excess Readmission Ratios for AMI hospitalizations, HF hospitalizations, and PN hospitalizations respectively. The data for these tables come from the publicly-reported risk-standardized rates of readmission reported in 2010 on *Hospital Compare* (representing hospitalizations between July 2006 and June 2009). The distributions of the ratios are shown only for hospitals with at least 25 cases included in the measures over the 3-year period.

The first column of the tables lists hospital characteristics (census region, bed size, teaching status, and urban/rural location) and the second column shows the number of hospitals included in the distribution for the particular category. For example, for the first table, AMI readmission, a total of 2,477 hospitals had at least 25 included hospitalizations between July 2006 and June 2009. Of these hospitals, 148 were in the New England region.

The third and fourth columns show the number and percentage of hospitals (of those with 25 or more cases) in the particular category with an Excess Readmission Ratio less than or equal to 1; such hospitals would not have their payments adjusted due to the Readmission Reduction Program because they would not be found to have "excess" readmissions. For example in the first table, for AMI readmissions, 72 of the 148 hospitals in the New England region (that had 25 or more AMI hospitalizations) had an Excess Readmission Ratio of less than or equal to 1, which means that 48.6 percent of the hospitals in the New England region (with at least 25 cases of AMI in 3 years) would not have their payments affected by the Hospital Readmission Reduction Program, whereas the remaining hospitals would be at risk of a payment reduction based on excess readmissions.

The following eight columns show the distribution of the excess readmissions. For example, for AMI, in the New England region the mean Excess Readmission Ratio is 1.0060, the lowest 5th percentile hospitals had ratios of 0.9172 or less and the highest 95th percentile of hospitals had Excess Readmission Ratios of 1.1104 or greater.

The final column of each table shows the number of hospitals, within the given category, that are not included in the distribution based on sample size. For example, for AMI, in the New England region 30 hospitals are not included in the distribution because they had fewer than 25 AMI hospitalizations over the 3-year period. Currently, 25 hospitalizations is the minimum number of hospitalizations for public reporting. Hospitals with fewer than 25 cases for a given condition do not have risk-standardized rates of readmission reported on *Hospital Compare.* We are proposing to use this threshold for inclusion in the Readmission Reduction Program.

Overall these analyses show, for all three conditions, that in all hospital categories approximately half of the hospitals are at risk of payment reductions based on excess readmissions. This percentage does not vary greatly by region; however for all three measures the Mid-Atlantic region has the lowest percentage of hospitals with Excess Readmission Ratios of less than or equal to 1 and, therefore, the Mid-Atlantic region is the region with the highest percentage of hospitals at risk of payment reduction. By contrast, the Mountain region has the largest percentage of hospitals with ratios of less than or equal to 1. The distributions do not differ greatly by bed size, though the largest hospitals have slightly lower percentages of hospitals with ratios less than or equal to 1 for AMI and PN. The distributions do not vary greatly by teaching status or rural/urban location for any of the measures.

We also are proposing to publicly report the readmission rates for these three measures on the *Hospital Compare* Web site using the current processes employed for public reporting of these measures, which includes a preview period. We believe that this also poses no additional burden to hospitals, as they currently employ this system for Hospital IQR public reporting.

*F. Effects of Proposed Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)*

In section IV.G. of the preamble of this proposed rule, we proposed to exclude from the hospital's disproportionate patient percentage (DPP) of the Medicare DSH calculation and from the available bed day count used to calculate the DSH payment adjustment and the IME payment adjustments, patient days for hospice patients receiving inpatient hospice services in a hospital setting. For the purpose of the DSH payment calculation, the patient days for hospice patients receiving inpatient hospice services in the hospital would be excluded from both the numerator and the denominator of the Medicare and Medicaid fractions. As such, the impact on hospitals' DSH payment adjustment would vary based on the demographic composition of an individual hospital's patient population. In other words, under this proposal, some hospitals may receive increased DSH payment adjustments and other hospitals may expect to receive lower DSH payment adjustments, depending on the extent to which a hospital provides inpatient hospice services to hospice patients.

The proposed change in policy to exclude from the available bed count, patient days for hospice patients receiving hospice services in an inpatient hospital setting only impacts DSH payments for limited situations. Specifically, urban hospitals with fewer than 100 beds or rural hospitals with fewer than 500 beds, with the exception of rural referral centers or MDHs, are subject to a cap of their DSH payment adjustment of 12 percent. Thus, a decrease in the number of available beds due to the exclusion of beds used to provide inpatient hospice services only impacts a provider's DSH payments if it results in the hospital's bed count falling below the bed count threshold. Should a hospital fall below the bed count threshold, it would become subject to the Medicare DSH payment adjustment cap and its DSH payment could decrease.

For IME payment purposes, a decrease in a hospital's number of available beds results in an increase in the resident-to-bed ratio. The exclusion of bed days associated with hospice patients from the available bed count for IME would reduce the available beds, increase the resident-to-bed ratio, and, consequently, may increase IME payments to teaching hospitals depending on the extent to which these hospitals were providing inpatient hospice services to hospice patients.

*G. Effects of the FY 2012 Low-Volume Hospital Payment Adjustment*

As discussed in section IV.E. of the preamble to this proposed rule, we discuss the provisions of sections 3125 and 10314 of the Affordable Care Act that expand eligibility for the low-volume hospital payment adjustment at section 1886(d)(12) of the Act for FYs 2011 and 2012 to hospitals with less than 1,600 Medicare discharges (instead of the prior requirement of less than 800 total, Medicare and non-Medicare, discharges) and hospitals that are located more than 15 miles from other IPPS hospitals (rather than the prior requirement of more than 25 miles). The payment adjustment is also changed from an empirically determined additional 25 percent payment adjustment to qualifying hospitals with less than 200 total discharges (69 FR 49099 through 49102 and 70 FR 47432 through 47434) to a continuous, linear sliding scale adjustment ranging from an additional 25 percent payment adjustment to qualifying hospitals with 200 or fewer Medicare discharges to no additional payment to hospitals with 1,600 or more Medicare discharges (75 FR 50241).

Based on FY 2010 claims data (December 2010 update of the MedPAR file), we estimate that 492 out of the 502 hospitals in our database that qualified as a low-volume hospital for FY 2011 would continue to meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012. For purposes of this impact analysis, we are assuming that all of these 492 hospitals would continue to meet the distance criterion in FY 2012. If all 492 hospitals qualified for the low-volume payment adjustment in FY 2012, we estimate that these hospitals would receive an additional estimated $280 million based on the proposed FY 2012 low-volume payment adjustment (described in section IV.E. of the preamble of this proposed rule) as compared to FY 2012 payments without the proposed low-volume adjustment. (As discussed in section IV.E. of the preamble of this proposed rule, for FY 2012, we are proposing to determine a hospital's number of Medicare discharges based on the most recent update of the FY 2010 MedPAR files (that is, the December 2010 update for this proposed rule.)

In addition, we identified an additional 89 hospitals in our database that would meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012 based on our proposal set forth in section IV.E. of the preamble of this proposed rule. (We note that these 89 hospitals did not meet the discharge criterion to qualify as a low-volume hospital for FY 2011.) However, we are not able to estimate the number of these 89 hospitals that would also meet the distance criterion. The actual number of hospitals that would also meet the distance criterion to qualify as

a low-volume hospital would very likely be significantly less than the estimated 89 maximum number of potential additional low-volume hospitals for FY 2012 (as compared to FY 2011). (We note that approximately 40 percent of the hospitals that met the discharge criterion for FY 2011 also met the mileage criterion and, therefore, are eligible to receive the low-volume payment adjustment in FY 2011.) If all these 89 hospitals were to qualify as low-volume hospitals in FY 2012, we estimate that an additional $26 million in payments would be made for the FY 2012 low-volume payment adjustment at section 1886(d)(12) of the Act.

*H. Effects of Proposed Changes Relating to MDHs*

As discussed in section IV.H. of the preamble to this proposed rule, section 3124 of Public Law 111–148 extended the MDH program for 1 additional year, from the end of FY 2011 (that is, for discharges before October 1, 2011) to the end of FY 2012 (that is, for discharges before October 1, 2012). The extension had no impact on FY 2011. For FY 2012, the extension allows the continuation of MDH status and the payment methodology, for an MDH to be paid its hospital-specific rate, based on its FY 1982, 1987, or 2002 updated costs per discharge, rather than the Federal rate, if this results in a greater aggregate payment. Therefore, the impact of the extension is one additional year of hospital-specific rate payments, when greater than Federal rate payments, for these hospitals as MDHs, rather than Federal rate payments for these hospitals without special treatment as MDHs.

*I. Effects of Proposed Policy Relating to CRNA Services Furnished in Rural Hospitals and CAHs*

In section IV.I. of this preamble of this proposed rule, we discuss the interim final rule with comment that appeared in the November 24, 2010 **Federal Register** (75 FR 72256) regarding pass-through payment for CRNA services. In that interim final rule with comment period, we stated that we were changing the effective date of our policy to allow hospitals and CAHs that have reclassified as rural under 42 CFR 412.103 to be eligible for CRNA pass-through from "cost reporting periods beginning on or after October 1, 2010" to "December 2, 2010." In section IV.I. of the preamble of this proposed rule, we state that we intend to respond to comments received on the interim final rule with comment period in the FY 2012 IPPS/LTCH PPS final rule. Also in the interim final rule with comment (75 FR 72258), we stated that a change to the effective date would only affect at most a small subset of hospitals and CAHs affected by the change to the regulations adopted in the FY 2010 IPPS/LTCH PPS final rule and, for this reason, we expected the change to the effective date in the interim final rule with comment period to have a minor impact on Federal expenditures.

*J. Effects of Proposed Changes Relating to ESRD Add-On Payment*

In section IV.L. of the preamble of this proposed rule, we discuss our proposal to clarify that the term "Medicare discharges" as used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A; that is, discharges associated with individuals entitled to Part A, including discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs).

We are not able to provide a detailed analysis of the impact of the clarification of this definition. We are not proposing any changes to the existing regulations at § 412.104 under which we will continue to provide an additional Medicare payment to a hospital for inpatient services provided to Medicare beneficiaries with ESRD who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant, where the beneficiary received dialysis services during the inpatient stay, are 10 percent or more of its total Medicare discharges. We note that this clarification could change both the denominator (total Medicare discharges) and the numerator (ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant) associated with this calculation. As a result of our proposed clarification, these discharges would be included in the denominator of the calculation for the determination of eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, we also would include all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain MS–DRG codes described above. Depending on whether or not the additional discharges are for ESRD beneficiaries, the calculation may increase or decrease.

*K. Effects of Proposed Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding and Wage Reporting Purposes*

In sections III.D.3. and IV.M. of the preamble of this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. We are setting forth two distinct proposals: One proposal for determining and reporting defined benefit pension costs on the cost report for Medicare cost finding purposes and the other for determining and reporting defined benefit pension costs for Medicare wage index purposes. The allowable pension cost under the current rules and the proposed policies are based on the amount funded. The current rules impose an actuarially based limit on the allowable amount and the proposed rules limit the costs based on historical funding data. Because the current rules and the proposed policies are both tied to the amount funded, we expect that there would be minimal impact. We note that it is not possible to determine a precise impact for Medicare cost-finding purposes because we do not currently have data in the form and manner required to calculate the pension costs for all providers under our proposal. Moreover, because we lack these data, we are unable to determine a hospital-level impact for the Medicare wage index. We note that our proposal may result in redistribution within the Medicare wage index, but section 1886(d)(3)(E) of the Act requires any adjustments or updates made to the Medicare wage index to be budget neutral.

*L. Effects of Implementation of Rural Community Hospital Demonstration Program*

In section IV.N. of the preamble of this proposed rule, we discuss our implementation of section 410A of Public Law 108–173, as amended, which, prior to the amendments made by the Affordable Care Act, required the Secretary to establish a demonstration that would modify reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." As discussed in section IV.N. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 7 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented" but does not identify the range across which aggregate payments must be held equal.

An extension of this demonstration was mandated by the Affordable Care Act. The demonstration is extended for an additional 5 years and expanded to include up to a total of 30 hospitals. We are proposing to make an adjustment in the FY 2012 IPPS final rule of $52,642,213 to the national IPPS rates. This amount accounts for an estimate of the demonstration cost for FY 2012 for the 8 hospitals that are currently participating in the demonstration and, in addition, an estimate of the cost of participation in the demonstration for the 19 additional hospitals selected to participate as a result of the expansion of the demonstration under the Affordable Care Act. In addition, for this FY 2012 proposed rule, we are proposing that the budget neutrality adjustment also account for any differences between the cost of the

demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008, represented by their cost reports beginning in FYs 2007 and 2008, and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008. The estimated $52,642,213 that we are proposing to offset does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008 and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 because the specific numeric value associated with this component of the proposed adjustment to the national IPPS rates cannot be known at this time. This is because settled cost reports beginning in FYs 2007 and 2008 of the hospitals participating during FYs 2007 and 2008 in the demonstration are not available yet. We anticipate that those settled cost reports may be available prior to the publication of the FY 2012 IPPS/LTCH PPS final rule. To this extent that they become available prior to publication of the FY 2012 IPPS/LTCH PPS final rule, under our proposal these costs would be included in the amount to be offset by the FY 2012 budget neutrality adjustment.

*M. Effects of Proposed Changes to the List of MS–DRGs Subject To Postacute Care Transfer and DRG Special Pay Policy*

In section IV.P. of the preamble to this proposed rule, we discuss proposed changes to the list of MS–DRGs subject to the postacute care transfer and DRG special payment policies. As reflected in Table 5 listed in section VI of the Addendum to this proposed rule and available via the Internet, using criteria set forth in regulation at § 412.4, we evaluated MS–DRG charges, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special pay policies. We note that we are making no proposal to change these payment policies in this FY 2012 proposed rule. We are proposing to change the status of certain MS–DRGs as a result of proposals to revise the MS–DRGs for FY 2012. We are proposing to change the status of eight MS–DRGs to qualify for the postacute care transfer policy in FY 2012, after not qualifying in FY 2011. An additional five MS–DRGs that qualified under the policy in FY 2011 do not qualify in FY 2012, and we are proposing to change their statuses accordingly. Finally, three MS–DRGs now qualify for the MS–DRG special pay policy in FY 2012 after not qualifying in FY 2011, and we are proposing to add them to the list of qualifying MS–DRGs. Column 4 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods determining the proposed changes due to the MS–DRGs and relative weights accounts for and includes changes in MS–DRG postacute care transfer and special pay policy statuses. We refer readers to section VI.D. of this Appendix for a more detailed discussion of payment impacts due to MS–DRG reclassification policies.

*N. Effects of Proposed Changes Relating to Hospital Services Furnished Under Arrangements*

In section VI.B. of the preamble of this proposed rule, we are proposing to clarify that only diagnostic and therapeutic services (that is, ancillary services) may be provided outside the hospital under arrangement. Routine services must be provided in the hospital in which the patient is a registered inpatient. We are aware of only a few cases where routine services are being provided outside the hospital other than where the patient is a registered inpatient. Therefore, we have determined that the impact of this clarification is negligible.

*O. Effects of Proposed Change Relating to CAH Payment for Ambulance Services*

In section VI.C. of the preamble of this proposed rule, we discuss our proposal to revise the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. In addition, we are proposing to revise the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity located more than a 35-mile drive from the CAH, the CAH owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. We believe this proposal would continue to allow for sufficient ambulance services to CAHs. We do not have sufficient information or data to determine how many CAH-owned and operated entities would qualify under the proposal. As a result, we are unable to quantify the financial impact of this proposed for payment based on 101 percent of reasonable cost. However, even those entities that do not qualify for payment based on 101 percent of reasonable cost would be paid for ambulance services under the Medicare ambulance fee schedule.

## VIII. Effects of Proposed Changes in the Capital IPPS

*A. General Considerations*

For the impact analysis presented below, we used data from the December 2010 update of the FY 2010 MedPAR file and the December 2010 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2010 update of the most recently available hospital cost report data (FYs 2008 and 2009) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described below. In addition, as discussed in section V.E. of the preamble to this proposed rule, we are proposing to make a −1.0 percent documentation and coding adjustment to the national capital rate for FY 2012 in addition to the −0.6 percent adjustment established for FY 2008, the −0.9 percent adjustment for FY 2009, and the −2.9 percent adjustment for FY 2011. This results in a proposed cumulative adjustment factor of 0.9479 that we applied in determining the proposed FY 2012 national capital rate to account for improvements in documentation and coding that do not reflect real changes in case mix under the MS–DRGs. We note that we applied a −2.6 percent documentation and coding adjustment to the Puerto Rico-specific capital rate in FY 2011, which reflects the entire amount of our current estimate of the effects of documentation for FYs 2008 and 2009 that do not reflect real changes in case-mix under the MS–DRGs. Therefore, we are not proposing to adjust the proposed Puerto Rico-specific capital rate in FY 2012 to account for changes in documentation and coding.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2010 update of the FY 2010 MedPAR file, we simulated payments under the capital IPPS for FY 2011 and FY 2012 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating proposed capital IPPS payments in FY 2012 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other proposed adjustments, hospitals may also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

• We estimate that the Medicare case-mix index would increase by 1.0 percent in both FYs 2011 and 2012.

• We estimate that the Medicare discharges would be approximately 11.8 million in FY 2011 and 12.2 million in FY 2012.

• The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the preamble of this proposed rule, the proposed update is 1.5 percent for FY 2012.

• In addition to the proposed FY 2012 update factor, the proposed FY 2012 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality factor of 1.0005, and a proposed outlier adjustment factor of 0.9406. As discussed in section III.A.4. of the Addendum to this proposed rule, an exceptions adjustment factor is not necessary in FY 2012 because there are no longer any hospitals eligible to receive special exceptions payments in FY 2012. However, the special exceptions adjustment factor was not built permanently into the capital rate; that is, was not applied cumulatively. Therefore, because there will be no special exceptions payments in FY 2012, we are only applying an adjustment to restore the special exceptions adjustment that was applied to the FY 2011 capital rate, that is, 1.0004 (calculated as 1/0.9996).

• For FY 2012, as discussed above and in section V.E. of the preamble to this proposed rule, we are proposing to apply a cumulative 0.9479 adjustment in determining the proposed FY 2012 national capital rate for changes in documentation and coding that are expected to increase case-mix under the MS–DRGs but do not reflect real case-mix change. This cumulative adjustment of 0.9479 reflects the proposed additional −1.0 percent adjustment in FY 2012 for the effects of documentation and coding in FYs 2008 and 2009.

*B. Results*

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2012 on total capital payments per case, using a universe of 3,419 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2010 update of the FY 2010 MedPAR file, the December 2010 update to the PSF, and the most recent cost report data from the December 2010 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2011 and estimated total payments per case proposed for FY 2012 based on the proposed FY 2012 payment policies. Column 2 shows estimates of payments per case under our model for FY 2011. Column 3 shows estimates of payments per case under our model for FY 2012. Column 4 shows the total percentage change in payments from FY 2011 to FY 2012. The proposed change represented in Column 4 includes the proposed 1.5 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2012 are expected to increase as compared to capital payments per case in FY 2011. The proposed capital rate for FY 2012 would increase approximately 0.60 percent as compared to the FY 2011 capital rate. The proposed changes to the GAFs are expected to result, on average, in a slight decrease in capital payments for most regions with the following exceptions. We estimate that the GAFs will result in a slight increase in capital payments for the West North Central and West South Central urban and rural regions, as well as a slight increase for Puerto Rico and the Pacific rural region. The West North Central urban and rural regions include the frontier States that have a wage index of no less than 1.0 under the provisions of section 10324 of the Affordable Care Act, which creates the slight increase in capital IPPS payments for FY 2012. For the West South Central urban and rural regions, increases in their wage data are creating the estimated increase in their FY 2012 capital IPPS payments. The GAFs for hospitals located in Puerto Rico results in a positive effect in estimated capital IPPS payments in FY 2012 because of the application of a Puerto Rico rural floor—FY 2012 is the first year an IPPS hospital is located in rural Puerto Rico and, therefore, setting a rural floor. The most significant increase resulting from the proposed changes to the GAFs is for the New England urban region. We estimate the proposed changes to the GAFs would result in a 3.9 percent increase in capital payments per case in FY 2012 compared to FY 2011 due to the application of the rural floor in Massachusetts. Previously, there had been no IPPS hospitals in Massachusett's rural areas, but the conversion of a CAH in rural Massachusetts to an IPPS hospital has set a rural floor for that State for FY 2012.

We also are estimating a slight decrease in outlier payments from FY 2011 to FY 2012 due primarily to an estimated increase in capital IPPS payments per discharge. Because capital payments per discharge are projected to be higher in FY 2012 compared to FY 2011, fewer cases would qualify for outlier payments.

The net impact of these proposed changes, as discussed above, is an estimated 1.7 percent change in capital payments per discharge from FY 2011 to FY 2012 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals, urban and rural, are expected to experience an increase in capital IPPS payments per case in FY 2012 as compared to FY 2011. Capital IPPS payments per case for urban hospitals are estimated to increase 1.7 percent, while rural hospitals are expected to experience a 1.4 percent increase.

The change comparisons by region shows that most urban regions would experience, on average, increases in capital IPPS payments of between 1.0 percent for the East North Central urban region, and 5.4 percent for the New England urban region. As discussed above, the New England urban region is estimated to have a larger than average increase in capital payments per case in FY 2012 as compared to FY 2011 due to the application of a rural floor. The rural regions show estimates of a 0.8 percent change in capital payments from FY 2011 to FY 2012 in the East North Central rural region to a 3.0 percent increase for the Puerto Rico rural region. This estimated increase in capital IPPS payments for the Puerto Rico rural region is due to the application of a rural floor, as discussed above.

By type of ownership, government hospitals are estimated to experience a 1.6 percent increase in capital payments per case; voluntary hospitals, an estimated 1.7 percent increase in capital payments; and proprietary hospitals, an estimated 1.8 percent increase in capital payments from FY 2011 to FY 2012.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2012. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index.

To present the effects of the hospitals being reclassified for FY 2012, we show the average capital payments per case for reclassified hospitals for FY 2011. All reclassified and non-reclassified hospitals are expected to experience an increase in capital payments in FY 2012 as compared to FY 2011. Urban reclassified hospitals are estimated to experience the largest increase of 1.9 percent, while urban nonreclassified and rural reclassified are both estimated to have a 1.6 percent increase. For rural nonreclassified hospitals, the estimated increase in capital payments per case is 1.2 percent. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience an increase of 0.7 percent in capital payments from FY 2011 to FY 2012.

BILLING CODE 4120–01–P

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2011 PAYMENTS COMPARED TO PROPOSED FY 2012 PAYMENTS]

| | Number of hospitals | Average FY 2011 payments/ case | Proposed Average FY 2012 payments/ case | Change |
|---|---|---|---|---|
| By Geographic Location: | | | | |
| All hospitals | 3,419 | 787 | 800 | 1.7 |
| Large urban areas (populations over 1 million) | 1,369 | 866 | 881 | 1.7 |
| Other urban areas (populations of 1 million of fewer) | 1,123 | 775 | 787 | 1.6 |
| Rural areas | 927 | 542 | 550 | 1.4 |
| Urban hospitals | 2,492 | 825 | 839 | 1.7 |
| 0-99 beds | 634 | 666 | 678 | 1.7 |
| 100-199 beds | 777 | 711 | 723 | 1.7 |
| 200-299 beds | 457 | 769 | 781 | 1.7 |
| 300-499 beds | 428 | 842 | 854 | 1.4 |
| 500 or more beds | 196 | 1,001 | 1,021 | 2.0 |
| Rural hospitals | 927 | 542 | 550 | 1.4 |
| 0-49 beds | 317 | 431 | 439 | 1.8 |
| 50-99 beds | 351 | 499 | 506 | 1.4 |
| 100-149 beds | 153 | 546 | 554 | 1.5 |
| 150-199 beds | 60 | 598 | 606 | 1.4 |
| 200 or more beds | 46 | 658 | 667 | 1.3 |
| By Region: | | | | |
| Urban by Region | 2,492 | 825 | 839 | 1.7 |
| New England | 120 | 863 | 910 | 5.4 |
| Middle Atlantic | 320 | 879 | 889 | 1.1 |
| South Atlantic | 379 | 770 | 781 | 1.3 |
| East North Central | 401 | 801 | 809 | 1.0 |
| East South Central | 153 | 730 | 738 | 1.1 |
| West North Central | 168 | 816 | 832 | 1.9 |
| West South Central | 365 | 780 | 797 | 2.2 |
| Mountain | 159 | 848 | 863 | 1.7 |
| Pacific | 377 | 983 | 1,000 | 1.8 |
| Puerto Rico | 50 | 378 | 389 | 2.9 |
| Rural by Region | 927 | 542 | 550 | 1.4 |
| New England | 23 | 721 | 728 | 0.9 |
| Middle Atlantic | 69 | 554 | 563 | 1.5 |
| South Atlantic | 165 | 529 | 537 | 1.6 |
| East North Central | 120 | 574 | 579 | 0.8 |
| East South Central | 171 | 498 | 503 | 1.1 |
| West North Central | 99 | 570 | 582 | 2.0 |
| West South Central | 184 | 483 | 493 | 2.0 |
| Mountain | 66 | 575 | 582 | 1.3 |
| Pacific | 29 | 685 | 700 | 2.2 |
| Puerto Rico | 1 | 163 | 168 | 3.0 |
| By Payment Classification: | | | | |
| All hospitals | 3,419 | 787 | 800 | 1.7 |
| Large urban areas (populations over 1 million) | 1,382 | 865 | 880 | 1.7 |
| Other urban areas (populations of 1 million of fewer) | 1,132 | 775 | 788 | 1.6 |
| Rural areas | 905 | 544 | 551 | 1.4 |
| Teaching Status: | | | | |
| Non-teaching | 2,389 | 671 | 682 | 1.7 |
| Fewer than 100 Residents | 790 | 786 | 797 | 1.5 |
| 100 or more Residents | 240 | 1,113 | 1,135 | 1.9 |
| Urban DSH: | | | | |
| 100 or more beds | 1,543 | 849 | 864 | 1.8 |
| Less than 100 beds | 339 | 591 | 601 | 1.6 |
| Rural DSH: | | | | |
| Sole Community (SCH/EACH) | 416 | 475 | 483 | 1.7 |

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2011 PAYMENTS COMPARED TO PROPOSED FY 2012 PAYMENTS]

| | Number of hospitals | Average FY 2011 payments/ case | Proposed Average FY 2012 payments/ case | Change |
|---|---|---|---|---|
| Referral Center (RRC/EACH) | 222 | 596 | 605 | 1.5 |
| Other Rural: | | | | |
| 100 or more beds | 28 | 480 | 483 | 0.7 |
| Less than 100 beds | 133 | 452 | 458 | 1.3 |
| Urban teaching and DSH: | | | | |
| Both teaching and DSH | 825 | 919 | 935 | 1.7 |
| Teaching and no DSH | 144 | 807 | 816 | 1.1 |
| No teaching and DSH | 1,057 | 711 | 724 | 1.9 |
| No teaching and no DSH | 488 | 734 | 744 | 1.3 |
| Rural Hospital Types: | | | | |
| Non special status hospitals | 2,396 | 829 | 843 | 1.7 |
| RRC/EACH | 56 | 741 | 749 | 1.0 |
| SCH/EACH | 33 | 725 | 740 | 2.0 |
| Medicare-dependent hospitals (MDH) | 12 | 557 | 569 | 2.0 |
| SCH, RRC and EACH | 17 | 769 | 784 | 1.9 |
| Hospitals Reclassified by the Medicare Geographic Classification Review Board: | | | | |
| FY2012 Reclassifications: | | | | |
| All Urban Reclassified | 469 | 836 | 851 | 1.9 |
| All Urban Non-Reclassified | 1,990 | 825 | 838 | 1.6 |
| All Rural Reclassified | 336 | 587 | 596 | 1.6 |
| All Rural Non-Reclassified | 529 | 474 | 479 | 1.2 |
| Other Reclassified Hospitals (Section 1886(d)(8)(B)) | 55 | 547 | 551 | 0.7 |
| Type of Ownership: | | | | |
| Voluntary | 1,991 | 801 | 814 | 1.7 |
| Proprietary | 850 | 709 | 721 | 1.8 |
| Government | 574 | 807 | 819 | 1.6 |
| Medicare Utilization as a Percent of Inpatient Days: | | | | |
| 0-25 | 359 | 1,006 | 1,025 | 1.9 |
| 25-50 | 1,703 | 837 | 851 | 1.7 |
| 50-65 | 1,089 | 667 | 676 | 1.4 |
| Over 65 | 195 | 580 | 588 | 1.4 |

BILLING CODE 4120–01–C

## IX. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

### *A. Introduction and General Considerations*

In section VII. of the preamble and section V. of the Addendum to this proposed rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2012. In the preamble, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rates, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 422 LTCHs includes the data for 82 nonprofit (voluntary ownership control) LTCHs and 322 proprietary LTCHs. Of the remaining 18 LTCHs, 12 LTCHs are government-owned and operated and the ownership type of the other 6 LTCHs is unknown. In the impact analysis, we used the proposed rates, factors, and policies presented in this proposed rule, including the proposed 1.5 percent annual update, which is based on the full increase of the proposed LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, including the proposed application of a budget neutrality adjustment for changes to the area wage adjustment, and the best available claims and CCR data to estimate the change in payments for FY 2012. The proposed standard Federal rate for FY 2012 is $40,082.61. This proposed rate reflects the proposed 1.5 percent annual update to the standard Federal rate and the proposed area wage level budget neutrality factor of 0.99723, which ensures that the proposed changes in the wage indexes and labor-related share do not influence estimated aggregate payments.

Based on the best available data for the 422 LTCHs in our database, we estimate that the proposed update to the standard Federal rate for FY 2012 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2012 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments and an estimated increase in SSO payments, would result in an increase in estimated payments from FY 2011 of approximately $95.0 million (or about 1.9 percent). Based on the 422 LTCHs in our database, we estimate FY 2012 LTCH PPS payments to be approximately $5.233 billion, an increase from FY 2011 LTCH PPS payments which were approximately $5.138 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are approximately $100 million, this proposed rule is considered a major economic rule, as defined in this section. We note the approximately $95 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2011 to FY 2012 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also would affect overall payment changes.

The projected 1.9 percent increase in estimated proposed payments per discharge from FY 2011 to FY 2012 is attributable to several factors, including the proposed 1.5 percent annual update to the standard Federal rate, and projected increases in proposed estimated HCO and SSO payments. As Table IV shows, the change attributable

solely to the proposed update to the standard Federal rate is projected to result in an increase of 1.3 percent in estimated payments per discharge from FY 2011 to FY 2012, on average, for all LTCHs. Because we are proposing to apply an area wage level budget neutrality factor to the standard Federal rate, the proposed update to the wage data and labor-related share does not impact the proposed increase in payments.

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2012 based on the most recent available data. In addition, we are proposing a decrease in the labor-related share from 75.271 percent to 70.334 percent under the LTCH PPS for FY 2012, based on the most recent available data on the relative importance of the proposed labor-related share of operating and capital costs of the proposed FY 2008-based RPL market basket. We also are proposing to apply an area wage level budget neutrality factor to the standard Federal rate to ensure that annual changes to the area wage level adjustment (that is, the wage index and labor-related changes) are budget neutral. We are proposing an area wage level budget neutrality factor of 0.99723, which reduces the proposed standard Federal rate by 0.28 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in aggregate LTCH PPS payments.

Table IV below shows the impact of the proposed payment rate and proposed policy changes on LTCH PPS payments for FY 2012 presented in this proposed rule by comparing estimated FY 2011 payments to estimated FY 2012 payments. The projected increase in payments per discharge from FY 2011 to FY 2012 is 1.9 percent (shown in Column 8). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (1.3 percent in Column 6), as well as the effect of the estimated increase in payments for HCO cases and SSO cases in FY 2012 as compared to FY 2011 (0.2 percent and 0.3 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2011 to FY 2012 in order to ensure that estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2012. An analysis of the most recent available LTCH PPS claims data (that is, FY 2010 claims data from the December 2010 update of the MedPAR file) indicates that the FY 2011 HCO threshold of $18,785 (as established in the FY 2011 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2011 that fall slightly below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 7.8 percent of the estimated total LTCH PPS payments in FY 2011. We estimate that the impact of the increase in HCO payments would result in approximately a 0.2 percent increase in estimated payments from FY 2011 to FY 2012, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2011 to FY 2012 for HCO and SSO cases, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries, which increases estimated payments by 0.3 percent relative to last year. We note that estimated payments for all SSO cases comprise approximately 13 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise approximately 8 percent of the estimated total LTCH PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (over 65 percent) are based on the estimated cost of the SSO case.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts would result in appropriate Medicare payments.

*B. Impact on Rural Hospitals*

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.8 percent increase in estimated payments per discharge for FY 2012 as compared to FY 2011 for rural LTCHs that would result from the proposed changes presented in this proposed rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 26 rural LTCHs in our database (out of 422 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2011 to FY 2012 for rural LTCHs is primarily due to the higher than average impacts from the proposed changes to the area wage level adjustment, specifically, the proposed reduction to the labor-related share from 75.271 to 70.334. Although we are proposing to apply an area wage level budget neutrality factor for proposed changes to the wage indexes and labor-related share to ensure that there is no change in aggregate LTCH PPS payments due to those changes, we estimate rural hospitals would experience a 0.8 percent increase in payments due to the proposed changes to the area wage level adjustment, as shown in Column 7 below. Rural hospitals generally have a wage index of less than 1; therefore, a proposed decrease to the labor-related share results in their proposed wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2012 as compared to FY 2011.

*C. Anticipated Effects of Proposed LTCH PPS Payment Rate Change and Policy Changes*

1. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs "maintain budget neutrality." We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

As discussed above in section IX.A. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2012 of approximately $95 million (or 1.9 percent) based on the 422 LTCHs in our database.

2. Anticipated Effects of Proposed Requirements for LTCH Quality Reporting Program

In section VII.C. of the preamble of this proposed rule, we discuss our proposed requirements for LTCHs to report quality data under the LTCH quality reporting program. As set forth at section 1886(m)(5)(A) of the Act, beginning with FY 2014, the Secretary must reduce by 2.0 percentage points any annual update to the standard Federal rate for discharges for any LTCH which does not comply with the LTCH quality data submission requirements. When the policy is implemented for FY 2014, we estimate that few LTCHs would not receive the full payment update in any fiscal year. We believe that most of these LTCHs would be either small rural or small urban LTCHs. However, at this time, information is not available to determine the precise number of LTCHs that will not meet the requirements for the full hospital market basket increase for FY 2014.

In section VII.C. of the preamble of this proposed rule, we are proposing three quality reporting measure for LTCHs for FY 2014: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. We estimate that the total LTCH costs to report these data, including: NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission to be $1,128,440.

3. Impact of Proposed Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(1)(B) of Public Law 110–173

As discussed in section VII.F. of the preamble of this proposed rule, at proposed § 412.23(e)(8), for the period beginning October 1, 2011, and ending December 28, 2012, we are proposing to apply the moratorium on the increase in the number of beds under section 114(d)(1)(B) of the MMSEA, and specified in paragraph (e)(7) to LTCHs and LTCH satellite facilities that were established or classified as such after the December 29, 2007 under one of the exceptions to the moratorium at section 114(d)(2) of the MMSEA, as set forth in paragraph (e)(6)(ii). The proposed regulation precludes an LTCH or LTCH satellite that was developed under an exception to the establishment of new LTCHs and LTCH satellites from increasing the number of Medicare-certified beds beyond the initial number for which the facility was first paid under the LTCH PPS. Approximately 50 LTCHs and 8 satellite facilities were developed under the exceptions at § 412.23(e)(6)(ii). Because additional

increases in the number of LTCH beds in these facilities could result in added costs to the Medicare program, the impact of precluding additional growth in the number of Medicare certified beds in these facilities is expected to result in no additional spending under the Medicare program from these LTCHs and LTCH satellites.

4. Impact of the Proposed Clarification to the Greater than 25 Day Average Length of Stay Requirement for LTCHs

In section VII.E.5. of the preamble of this proposed rule, we have proposed two clarifications to our existing policy for determining whether a hospital is meeting the greater than 25 day average length of stay requirement for payment under the LTCH PPS. First, we are proposing to clarify and revise the regulations at § 412.23(e)(3)(iv) dealing with the average length of stay determination when there is a change of ownership of either a hospital seeking to qualify as an LTCH or of an existing LTCH. Second, we describe, and are proposing to clarify, our existing policy regarding the inclusion of Medicare Advantage days in the average length of stay calculation. Because typically LTCHs track the lengths of stay of their Medicare patients on an on-going basis for purposes of maintaining their LTCH status and Medicare contractors are already tasked with evaluating each LTCH's average length of stay, we do not believe that there is any actual impact resulting from the clarification of these existing policies nor do they impose any additional burdens on either LTCHs or Medicare contractors.

5. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth in § 412.515 through § 412.536. In addition to the basic MS–LTC–DRG payment (the standard Federal rate multiplied by the MS–LTC–DRG relative weight), we make adjustments for differences in area wage levels, the COLA for Alaska and Hawaii, and SSOs. Furthermore, LTCHs may also receive HCO payments for those cases that qualify based on the threshold established each year.

To understand the impact of the proposed changes to the LTCH PPS payments presented in this proposed rule on different categories of LTCHs for FY 2012, it is necessary to estimate payments per discharge for FY 2011 using the rates, factors (including the FY 2011 GROUPER (Version 28.0)), and relative weights and the policies established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50364 through 50400 and 50442 through 50449). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates, factors, policies, and GROUPER (proposed Version 29.0) for FY 2012 (as discussed in VII. of the preamble and section V. of the Addendum to this proposed rule). These estimates of FY 2011 and FY 2012 LTCH PPS payments are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. We also evaluated the proposed change in estimated FY 2011 payments to estimated FY 2012 payments (on a per discharge basis) for each category of LTCHs.

Hospital groups were based on characteristics provided in the OSCAR data, FY 2008 through FY 2009 cost report data in HCRIS, and PSF data. Hospitals with incomplete characteristics were grouped into the "unknown" category. Hospital groups include the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

To estimate the impacts of the proposed payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2010 MedPAR file to estimate payments for FY 2011 and to estimate payments for FY 2012 for 422 LTCHs. We believe that the discharges based on the FY 2010 MedPAR data for the 422 LTCHs in our database, which includes 322 proprietary LTCHs, provide sufficient representation in the MS–LTC–DRGs containing discharges for patients who received LTCH care for the most commonly treated LTCH patients' diagnoses.

6. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge payments under the LTCH PPS, we simulated payments on a case-by-case basis using LTCH claims from the FY 2010 MedPAR files. For modeling estimated LTCH PPS payments for FY 2011, we applied the FY 2011 standard Federal rate (that is, $39,599.95, under which LTCH discharges occurring on or after October 1, 2010, to September 30, 2011 are paid). For modeling estimated LTCH PPS payments for FY 2012, we applied the proposed FY 2012 standard Federal rate of $40,082.61, which would be effective for LTCH discharges occurring on or after October 1, 2011, and through September 30, 2012. The proposed FY 2012 standard Federal rate of $40,082.61 includes the proposed application of an area wage level budget neutrality factor of 0.99723 (as discussed in section VII.E.4. of the preamble of this proposed rule).

Furthermore, in modeling estimated LTCH PPS payments for both FY 2011 and FY 2012 in this impact analysis, we applied the FY 2011 and the proposed FY 2012 adjustments for area wage levels and the proposed COLA for Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2011 payments using the current LTCH PPS labor-related share of 75.271 percent (75 FR 50445) and the wage index values established in the Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646). We also applied the FY 2011 COLA factors shown in the table in section V.B.5. of the Addendum to that final rule (75 FR 50446) to the FY 2011 nonlabor-related share (24.729 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining estimated FY 2012 payments using the proposed LTCH PPS FY 2012 labor-related share of 70.334 percent and the proposed FY 2012 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2012 COLA factors shown in the table in section V.B.5. of the Addendum to the FY 2011 IPPS/LTCH PPS final rule to the proposed FY 2012 nonlabor-related share (29.666 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated increase in payments for HCO cases (as described in section V.C. of the Addendum to this proposed rule). In modeling proposed payments for SSO and HCO cases in FY 2012, we applied an inflation factor of 1.055 (determined by OACT) to the estimated costs of each case determined from the charges reported on the claims in the FY 2010 MedPAR files and the best available CCRs from the December 2010 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2012 in this impact analysis, we used the proposed FY 2012 fixed-loss amount of $19,270 (as discussed in section V.C. of the Addendum to this proposed rule).

These impacts reflect the estimated "losses" or "gains" among the various classifications of LTCHs from the FY 2011 to FY 2012 based on the proposed payment rates and policy changes presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the LTCH PPS among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases.
- The fourth column shows the estimated payment per discharge for FY 2011 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2012 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 due to the proposed update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and proposed labor-related share) including the proposed application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to the proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2011 (Column 4) to FY 2012 (Column 5) for all proposed changes (and includes the effect of estimated proposed changes to HCO and SSO payments).

BILLING CODE 4120–01–P

# TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2012 (ESTIMATED FY 2011 PAYMENTS COMPARED TO ESTIMATED PROPOSED FY 2012 PAYMENTS*)

| LTCH Classification (1) | Number of LTCHs (2) | Number of LTCH PPS Cases (3) | Average FY 2011 LTCH PPS Payment Per Case[1] (4) | Average FY 2012 LTCH PPS Proposed Payment Per Case[2] (5) | Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for the Proposed Annual Update to the Federal Rate [2] (6) | Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality[3] (7) | Percent Change in Payments Per Discharge from FY 2011 to FY 2012 for All Proposed Changes[4] (8) |
|---|---|---|---|---|---|---|---|
| ALL PROVIDERS | 422 | 134,805 | $38,115 | $38,820 | 1.3 | 0.0 | 1.9 |
| | | | | | | | |
| BY LOCATION: | | | | | | | |
| RURAL | 26 | 5,854 | $33,611 | $34,550 | 1.4 | 0.8 | 2.8 |
| URBAN | 396 | 128,951 | $38,320 | $39,014 | 1.3 | 0.0 | 1.8 |
| LARGE | 204 | 77,381 | $40,098 | $40,745 | 1.3 | -0.2 | 1.6 |
| OTHER | 192 | 51,570 | $35,651 | $36,416 | 1.4 | 0.3 | 2.2 |
| | | | | | | | |
| BY PARTICIPATION DATE: | | | | | | | |
| BEFORE OCT. 1983 | 16 | 5,884 | $33,874 | $34,280 | 1.3 | -0.6 | 1.2 |
| OCT. 1983 - SEPT. 1993 | 44 | 16,648 | $40,063 | $40,762 | 1.3 | -0.3 | 1.7 |
| OCT. 1993 - SEPT. 2002 | 186 | 63,258 | $37,248 | $37,938 | 1.3 | 0.1 | 1.9 |
| AFTER OCTOBER 2002 | 173 | 48,210 | $39,117 | $39,870 | 1.4 | 0.1 | 1.9 |
| UNKNOWN PARTICIPATION DATE | 3 | 805 | $36,962 | $38,300 | 1.4 | 1.7 | 3.6 |
| | | | | | | | |
| BY OWNERSHIP TYPE: | | | | | | | |
| VOLUNTARY | 82 | 19,507 | $39,280 | $40,097 | 1.3 | -0.1 | 2.1 |
| PROPRIETARY | 322 | 113,029 | $37,836 | $38,521 | 1.3 | 0.0 | 1.8 |
| GOVERNMENT | 12 | 1,693 | $43,296 | $44,059 | 1.3 | -0.5 | 1.8 |
| UNKNOWN OWNERSHIP TYPE | 6 | 576 | $38,191 | $38,970 | 1.3 | 0.0 | 2.0 |
| | | | | | | | |
| BY REGION: | | | | | | | |
| NEW ENGLAND | 15 | 7,283 | $33,832 | $34,156 | 1.3 | -0.7 | 1.0 |
| MIDDLE ATLANTIC | 30 | 7,957 | $39,016 | $39,739 | 1.3 | 0.0 | 1.9 |
| SOUTH ATLANTIC | 57 | 15,487 | $41,372 | $42,106 | 1.3 | -0.2 | 1.8 |
| EAST NORTH CENTRAL | 68 | 19,780 | $39,942 | $40,516 | 1.3 | -0.4 | 1.4 |

| LTCH Classification (1) | Number of LTCHs (2) | Number of LTCH PPS Cases (3) | Average FY 2011 LTCH PPS Payment Per Case[1] (4) | Average FY 2012 LTCH PPS Proposed Payment Per Case[2] (5) | Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for the Proposed Annual Update to the Federal Rate [2] (6) | Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality[3] (7) | Percent Change in Payments Per Discharge from FY 2011 to FY 2012 for All Proposed Changes[4] (8) |
|---|---|---|---|---|---|---|---|
| EAST SOUTH CENTRAL | 29 | 8,158 | $37,727 | $38,521 | 1.3 | 0.2 | 2.1 |
| WEST NORTH CENTRAL | 26 | 5,899 | $39,847 | $40,743 | 1.3 | 0.3 | 2.3 |
| WEST SOUTH CENTRAL | 141 | 50,707 | $33,617 | $34,412 | 1.4 | 0.5 | 2.4 |
| MOUNTAIN | 32 | 6,724 | $41,617 | $42,293 | 1.3 | -0.3 | 1.6 |
| PACIFIC | 24 | 12,810 | $48,649 | $49,242 | 1.3 | -0.6 | 1.2 |
| | | | | | | | |
| BY BED SIZE: | | | | | | | |
| BEDS: 0-24 | 29 | 3,728 | $32,665 | $33,483 | 1.4 | 0.5 | 2.5 |
| BEDS: 25-49 | 196 | 43,731 | $37,536 | $38,247 | 1.4 | 0.1 | 1.9 |
| BEDS: 50-74 | 112 | 35,963 | $38,762 | $39,518 | 1.4 | 0.1 | 2.0 |
| BEDS: 75-124 | 49 | 22,005 | $40,891 | $41,555 | 1.3 | -0.3 | 1.6 |
| BEDS: 125-199 | 21 | 14,824 | $36,329 | $36,961 | 1.3 | 0.0 | 1.7 |
| BEDS: 200 + | 15 | 14,554 | $37,275 | $37,942 | 1.3 | 0.1 | 1.8 |

[1] Estimated FY 2012 LTCH PPS payments based on the proposed payment rates and policy changes presented in the preamble and the Addendum to this proposed rule.
[2] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for the proposed annual update to the standard Federal rate, as discussed in section V.A.2. of the Addendum to this proposed rule.
[3] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for proposed changes to the area wage level adjustment at §412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).
[4] Percent change in estimated payments per discharge from FY 2011 LTCH PPS (shown in Column 4) to FY 2012 LTCH PPS (shown in Column 5), including all of the proposed changes presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the standard Federal rate (column 5) and the proposed changes to the area wage level adjustment with budget neutrality (Column 6) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

BILLING CODE 4120–01–C

7. Results

Based on the most recent available data for 422 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and policy changes presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase approximately 1.9 percent, on average, for all LTCHs from FY 2011 to FY 2012 as a result of the proposed payment rate and policy changes presented in this proposed rule, as well as estimated increases in HCO and SSO payments. We note that we applied a proposed 1.5 percent annual update in determining the proposed standard Federal rate for FY 2012, based on the latest estimate of the proposed LTCH PPS market basket increase (2.8 percent), the proposed reduction of 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction required under sections 1886(m)(3) and (m)(4) of the Act. We noted earlier in this section that for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of approximately 1.5 percent for the proposed annual update to the standard Federal rate is projected to result in approximately a 1.3 percent change in estimated payments per discharge for all LTCHs from FY 2011 to FY 2012. Because payments to cost-based SSO cases and a portion of payments to SSO cases that are paid based on the "blend" option of the SSO payment formula at § 412.529(c)(2)(iv) are not affected by the proposed annual update to the standard Federal rate, we estimate that the effect of the proposed 1.5 percent annual update to the standard Federal rate would result in a 1.3 percent increase on estimated aggregate LTCH PPS payments to *all* LTCH PPS cases, including SSO cases. Furthermore, as discussed previously in this regulatory impact analysis, the average increase in estimated payments per discharge from the FY 2011 to FY 2012 for all LTCHs of approximately 1.9 percent (as shown in Table IV) was determined by comparing estimated FY 2012 LTCH PPS payments (using the proposed rates and policies discussed in this proposed rule) to estimated FY 2011 LTCH PPS payments (as described above in section IX.C.5. of this Appendix).

a. Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2011 to FY 2012 for all hospitals is 1.9 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be 2.8 percent, while for urban LTCHs, we estimate the increase to be 1.8 percent. Large urban LTCHs are projected to experience an increase of 1.6 percent in estimated payments per discharge from FY 2011 to FY 2012, while other urban LTCHs are projected to experience an increase of 2.2 percent in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV.

b. Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) after October 2002. Based on the most recent available data, the majority (approximately 47 percent) of the LTCH cases are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and are projected to experience nearly the average increase (1.9 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV.

In the participation category where LTCHs began participating in the Medicare program before October 1983, LTCHs are projected to experience a lower than average percent increase (1.2 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV. Approximately 4 percent of LTCHs began participating in Medicare before October 1983. The LTCHs in this category are projected to experience a lower than average increase in estimated payments because of decreases in payments due to the proposed changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in Medicare between October 1983 and September 1993. These LTCHs are also projected to experience a slightly lower than average increase (1.7 percent) in estimated payments from FY 2011 to FY 2012. LTCHs that began participating in Medicare after October 2002 currently represent approximately 41 percent of all LTCHs, and are projected to experience an average increase (1.9 percent) in estimated payments from FY 2011 to FY 2012.

c. Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). We expect that, for these LTCHs in the voluntary category, estimated FY 2012 LTCH payments per discharge would increase higher than the average (2.1 percent) in comparison to estimated payments in FY 2011 primarily because we project an increase in estimated HCO payments and SSO payments to be higher than the average for these LTCHs. The majority (76 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience a nearly average increase (1.8 percent) in estimated payments per discharge from FY 2011 to FY 2012. Finally, government-owned and operated LTCHs (3 percent) are also expected to experience a nearly average increase in payments of 1.8 percent in estimated payments per discharge from FY 2011 to FY 2012.

d. Census Region

Estimated payments per discharge for FY 2012 are projected to increase for LTCHs located in all regions in comparison to FY 2011. Of the 9 census regions, we project that the increase in estimated payments per discharge would have the largest positive impact on LTCHs in the West South Central region (2.4 percent, as shown in Table IV). The estimated percent increase in payments per discharge from FY 2011 to FY 2012 for the West South Central is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the New England region are projected to experience the smallest increase in estimated payments per discharge from FY 2011 to FY 2012. The average estimated increase in payments of 1.0 percent for LTCHs in the New England region is primarily due to estimated decreases in payments associated with the area wage level adjustment.

e. Bed Size

LTCHs were grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds.

We project that payments for small LTCHs (0–24 beds) would experience a 2.5 percent increase in payments due to increases in the proposed area wage adjustment while large LTCHs (200+ beds) would experience a 1.8 percent increase in payments. LTCHs with between 75 and 124 beds and between 125 and 199 beds are expected to experience a slightly below average increase in payments per discharge from FY 2011 to FY 2012 (1.6 percent and 1.7 percent, respectively) primarily due to an estimated decreases in their payments from FY 2011 to FY 2012 due to the proposed area wage level adjustment.

*D. Effect on the Medicare Program*

As noted previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments in FY 2012 of approximately $95.0 million (or about 1.9 percent) for the 422 LTCHs in our database.

*E. Effect on Medicare Beneficiaries*

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services would enhance the efficiency of the Medicare program.

**X. Alternatives Considered**

*A. General*

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

*B. Alternative Considered for Hospital Inpatient Quality Review (IQR) and Value-Based Purchasing (VBP) Programs: Medicare Spending per Beneficiary Measure*

In section IV.A.3.b.(ii)(B) of the preamble to this proposed rule, we are proposing to adopt a claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital IQR Program. In section IV.B.3.b.(iii) of the preamble of this proposed rule, we are proposing to adopt this claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital VBP Program. For the Medicare spending per beneficiary measure, we considered an alternative approach based on the principle that Medicare spending per beneficiary benchmarks for lower quality hospitals should not exceed the benchmarks for higher quality hospitals. This alternative approach is more complex than our proposal. Due to its increased complexity, we are including the discussion of this alternative approach here rather than earlier in the preamble for ease of presentation: both the efficiency measure and its scoring as part of the Hospital VBP Program can be presented in a continuous narrative.

As noted earlier, the NQF has not endorsed a Medicare spending per beneficiary measure. However, its 2009 report "Measurement Framework: Evaluating Efficiency Across Patient-Focused Episodes of Care" (NQF 2009), discusses four general terms that are helpful in framing the discussion of an alternative Medicare Spending per Beneficiary measure.

- Quality of care is a measure of performance on the Institute of Medicine's (IOM) six aims for healthcare: safety, timeliness, effectiveness, efficiency, equity, and patient centeredness.
- Cost of care is a measure of the total healthcare spending, including total resource use and unit price(s), by payor or consumer, for a healthcare service or group of healthcare services associated with a specified patient population, time period, and unit(s) of clinical accountability.
- Efficiency of care is a measure of cost of care associated with a specified level of quality of care. "Efficiency of care" is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality.
- Value of care is a measure of a specified stakeholder's (such as an individual patient's, consumer organization's, payor's, provider's, government's, or society's) preference-weighted assessment of a particular combination of quality and cost of care performance." (p. 6, Measurement Framework: Evaluating Efficiency Across Patient-Focused Episodes of Care, NQF 2009)

We will examine each of these four terms (Quality of Care, Cost of Care, Efficiency of

Care, and Value of Care) in the context of an alternative to our proposed Medicare Spending per Beneficiary measure.

1. Quality of Care

As discussed in the Hospital VBP Program proposed rule, a hospital's performance on the quality measures (based on the higher of achievement or improvement) is consolidated into a single Total Performance Score for that hospital. For purposes of this discussion, we will refer to the Total Performance Score discussed in the Hospital VBP Program proposed rule as the "total quality score (TQS)."

2. Cost of Care

For purposes of this discussion, we are considering the cost of care to be the Medicare spending per beneficiary amount described in section IV.B.3.b.(3) of the preamble of this proposed rule.

3. Efficiency of Care

The term "efficiency of care" is discussed in the NQF report as a measure of cost of care associated with a specified level of quality of care. "Efficiency of care" is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality. We considered the following approach to measuring the relationship between the cost of care (that is, Medicare spending per beneficiary amount) and quality of care (that is, the TQS). The result of this measurement is an efficiency score for each hospital.

Steps in Measuring the Efficiency of Care Under the Alternative Approach

*Step 1:*—Hospitals are grouped by total quality score (TQS).

Step 1a.—Define the first (highest) Quality Group.

The first Quality Group consists of hospitals with a TQS in the top decile of the TQSs.

$\{Quality_1\} = \{Q_1\}$ = Quality Group 1 = Hospitals in the top decile of quality = Hospitals with a TQS of 100, 99, ...$\alpha_1$

Step 1b.—Define the remaining Quality Groups.

Beginning with the first TQS not included in the first Quality Group (TQS = $\alpha_1$–1), add hospitals with this TQS to the hospitals in the first Quality Group. This group of hospitals forms the second Quality Group:

$\{Quality_2\} = \{Q_2\}$ = Quality Group 2 = Hospitals with a TQS $\geq (\alpha_1 - 1)$

Note that $\{Q_1\} \subset \{Q_2\}$, meaning $\{Q_1\}$ is a subset of $\{Q_2\}$.

The process repeats for the next Quality Group:

$\{Quality_3\} = \{Q_3\}$ = Quality Group 3 = Hospitals with a TQS $\geq (\alpha_1 - 2)$

Note that $\{Q_1\} \subset \{Q_2\} \subset \{Q_3\}$, meaning $\{Q_2\}$ is a subset of $\{Q_3\}$.

It continues with successively lower quality scores until the hospitals with a TQS of 1 are added.

$\{Quality_N\} = \{Q_N\}$ = Last Quality Group N = Hospitals with a TQS $\geq 1$

Note that $\{Q_1\} \subset \{Q_2\} \subset \{Q_3\}$....., $\subset \{Q_N\}$, so all Quality Groups are subsets of $\{Q_N\}$ since $\{Q_N\}$ contains all hospitals with a TQS greater than or equal to 1.

*Step 2:* Determine the cost benchmarks for each hospital.

Step 2a—Determine the cost benchmark for the top Quality Group.

The cost benchmark for the hospitals in the top Quality Group is the mean Medicare spending per beneficiary for the hospitals in the top Quality Group.

Step 2b.—Determine the cost benchmarks for all hospitals that are not in the top Quality Group.

The cost benchmark for each hospital with TQS of j is the lower of: (1) the 10th percentile of Medicare spending per beneficiary for all hospitals in the smallest (in terms of the number of hospitals in the group) Quality Group that contains hospitals with a TQS score of j; and (2) the benchmark for the group of hospitals of next higher quality.

$\{Q\}_{j\epsilon i}$ = Smallest Quality Group $\{Q_i\}$ that contains hospitals with TQS = j

$Cost^{10}_{j\epsilon i}$ = 10th percentile of Medicare spending per beneficiary for all hospitals in $\{Q\}_{j\epsilon i}$

Cost benchmark $_j$ = Cost benchmark for all hospitals with TQS j = min ( $Cost^{10}_{j\epsilon i}$, Cost Benchmark $_{j-1}$ )

*Step 3:* Calculate the efficiency ratio for each hospital.

Calculate the efficiency ratio for hospital k with TQS j.

The efficiency ratio for hospital k with TQS j is the ratio of the Medicare spending per beneficiary for hospital k to the cost benchmark for TQS j.

$Cost_k$ = Medicare spending per beneficiary for hospital k

Efficiency $ratio_k$ = Efficiency ratio for hospital k = $Cost_k$/Cost $Benchmark_j$

*Step 4:* Calculate the efficiency ratio threshold and benchmark.

Step 4a. Calculate the efficiency ratio threshold.

The efficiency ratio threshold is the point at which hospitals can begin to earn efficiency points based on achievement. It is the median efficiency ratio across all hospitals.

Efficiency ratio threshold = Median efficiency ratio across all hospitals

Step 4b. Calculate the efficiency ratio benchmark.

The efficiency ratio benchmark is the point at which hospitals earn the maximum efficiency points (10) based on achievement. It is the 10th percentile of the efficiency ratios across all hospitals.

Efficiency ratio benchmark = 10th percentile efficiency ratio across all hospitals

*Step 5:* Calculate the efficiency points based on achievement.

Calculate the efficiency points based on achievement for hospital k.

Achievement Efficiency Points $_k$ =

$$\left[9 * \frac{(Efficiency\ Ratio_k - Efficiency\ Ratio\ Threshold)}{(Efficiency\ Ratio\ Benchmark - Efficiency\ Ratio\ Threshold)}\right] + .05$$

*Step 6:* Calculate the efficiency points based on improvement.

Calculate the efficiency points based on improvement for hospital k.

The performance period has a corresponding base period, analogous to the base period for other Hospital VBP measures. In order to calculate efficiency points based on improvement, an efficiency ratio would be determined for each hospital k using only the data from the base period and following Step 1 to Step 3 above. Using this base period efficiency ratio for hospital k, the

improvement points for hospital k are calculated as:

Improvement Efficiency Points $_k$ =

$$\left[10 * \frac{(Efficiency\ Ratio_k - Efficiency\ Ratio_{k(base)})}{(Efficiency\ Ratio\ Benchmark - Efficiency\ Ratio_{k(base)})}\right] - .05$$

The efficiency score for hospital k is the higher of the achievement or improvement efficiency points.

4. Value of Care

The term "value of care" is discussed in the NQF report as a measure of a specified stakeholder's (such as an individual patient's, consumer organization's, payor's, provider's, government's, or society's) preference-weighted assessment of a particular combination of quality and cost of care performance. Under our alternative Medicare spending per beneficiary approach, we considered creating an efficiency adjustment to the TQS for a hospital using a function of the general form:

Efficiency adjustment to the total quality score = A*TQS + B*(efficiency score*10) + C, where A is the weight given to the quality score, B is the weight given to the efficiency score, and C is a constant.

We multiply the efficiency score by 10 to put it on the same scale as the TQS (0 to 100).

Depending on the parameters chosen, adopting such a function for valuing efficiency could allow the TQS for a hospital to be adjusted upwards or downwards depending on the hospital's TQS and its efficiency score. For example, suppose two hospitals both have an efficiency score of 5, but one hospital has a much higher TQS than the other. We could choose parameters that would result in a negative efficiency adjustment to the TQS for the lower quality hospital and a positive efficiency adjustment to the TQS for the higher quality hospital. Under this approach, we value the efficiency score of 5 for the higher quality hospital more than the efficiency score of 5 for the lower quality hospital, hence the positive adjustment to the TQS for the higher quality hospital and the negative adjustment to the TQS for the lower quality hospital.

Using the TQS adjusted for efficiency, meaning after we apply the efficiency adjustment the TQS, the linear exchange function approach previously proposed in the Hospital VBP Program proposed rule for the hospital VBP system would be used to determine each hospital's VBP incentive payment such that the overall hospital VBP program remains budget neutral.

## XI. Overall Conclusion

### *A. Acute Care Hospitals*

Table I of section VI. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall proposed decrease of 0.5 percent in operating payments. We estimate that operating payments would decrease by approximately $498 million in FY 2012. For FY 2012, we are proposing to distribute $250 million to hospitals that qualify to receive additional payment under section 1109 of Pub. L. 111–152, which is an additional $100 million than what we had distributed under this provision in FY 2011. In addition, we estimate a savings of $23 million associated with the HACs policies. These estimates, added to our proposed FY 2012 operating estimate of −$498 million, would result in a decrease of $421.2 million for FY 2012. We estimate that capital payments will experience a 1.8 percent increase in payments per case, as shown in Table III of section VIII. of this Appendix. We project that there would be a $146 million increase in capital payments in FY 2012 compared to FY 2011. The proposed cumulative operating and capital payments should result in a net decrease of $275 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

### *B. LTCHs*

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2012. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the proposed change in payments under the LTCH PPS for FY 2012. Accordingly, based on the best available data for the 422 LTCHs in our database, we estimate that proposed FY 2012 LTCH PPS payments would increase approximately $95 million (or about 1.9 percent).

## XII. Accounting Statements and Tables

### *A. Acute Care Hospitals*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the proposed change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

**Table V.—Accounting Statement: Classification of Estimated Expenditures under the IPPS from FY 2011 to FY 2012**

| Category | Transfers |
|---|---|
| Annualized Monetized Transfers | -$275 million |
| From Whom to Whom | Federal Government to IPPS Medicare Providers |
| Total | -$275 million |

### *B. LTCHs*

As discussed in section IX. of this Appendix, the impact analysis for the proposed changes under the LTCH PPS for this proposed rule projects an increase in estimated aggregate payments of approximately $95 million (or about 1.9 percent) for the 422 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to proposed changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the proposed provisions presented in this proposed rule based on the data for the 422 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

**TABLE VI.—Accounting Statement: Classification of Estimated Expenditures from the FY 2011 LTCH PPS to the FY 2012 LTCH PPS**

| Category | Transfers |
|---|---|
| Annualized Monetized Transfers | Positive transfer--Estimated increase in expenditures: $95 million |

**XII. Executive Order 12866**

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

## Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

**I. Background**

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rates for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs, IPFs, and IRFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

**II. Inpatient Hospital Update for FY 2012**

*A. Proposed FY 2012 Inpatient Hospital Update*

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2012 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is based on IHS Global Insight Inc.'s (IGI's) first quarter 2011 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Affordable Care Act, as added by section 3401(a) of the Affordable Care Act, state that the application of the multifactor productivity adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.K.3. of the preamble of this proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent.

Therefore, based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(vii) of the Act and our rules. For hospitals that fail to submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of increase of 2.8 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

*B. Proposed Update for SCHs and MDHs for FY 2012*

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2012 applicable percentage increase in the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs of 1.5 percent for hospitals that submit quality data or −0.5 percent for hospitals that fail to submit quality data.

*C. Proposed FY 2012 Puerto Rico Hospital Update*

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.5 percent.

*D. Proposed Update for Hospitals Excluded From the IPPS*

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Section 1886(j)(3)(C) of the Act addresses the increase factor for the Federal prospective payment rate of IRFs. Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS. In addition, section 124 of Public Law 106–113 provides the statutory authority for updating all aspects of the payment rates for IPFs.

Currently, children's hospitals, cancer hospitals, and RNHCIs are the remaining three types of hospitals still reimbursed under the reasonable cost methodology. We are proposing to provide our current estimate of the FY 2012 IPPS operating market basket percentage increase (2.8 percent) to update the target limits for children's hospitals, cancer hospitals, and RNHCIs.

For FY 2012, as discussed in section VII. of the preamble to this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2012 based on the full proposed LTCH PPS market basket increase estimate (2.8 percent). The proposed annual update also includes the requirement at section 1886(m)(3)(A)(i) of the Act to reduce the annual update by the productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act, which is currently estimated to be 1.2 percent. In addition, the statute at section 1886(m)(3)(A)(ii) of the Act requires that any

annual update for FY 2012 be reduced by the "other adjustment" at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Accordingly, the proposed update factor to the standard Federal rate for FY 2012 is 1.5 percent (that is, we are proposing to apply a factor of 1.015 in determining the proposed LTCH PPS standard Federal rate for FY 2012).

Effective for cost reporting periods beginning on or after January 1, 2005, IPFs are paid under the IPF PPS. IPF PPS payments are based on a Federal per diem rate that is derived from the sum of the average routine operating, ancillary, and capital costs for each patient day of psychiatric care in an IPF, adjusted for budget neutrality. In the RY 2012 IPF PPS proposed rule (76 FR 5000 through 5001), we proposed to extend the IPF PPS RY 2012 by 3 months (a total of 15 months instead of 12 months) through September 30, 2012. Based on IGI's fourth quarter 2010 forecast, with history through the third quarter of 2010, the projected 15-month market basket update based on the proposed FY 2008-based RPL market basket for the proposed 15-month RY 2012 (July 1, 2011 through September 30, 2012) is 3.0 percent. However, if we were not proposing to extend the 2012 IPF PPS rate year by 3 months, we would have proposed a market basket update of 2.6 percent for a 12-month RY 2012. In accordance with section 1886(s)(2)(A)(ii) of the Act, which requires the application of an "other adjustment," described in section 1886(s)(3) of the Act (specifically, section 1886(s)(3)(A) for RYs 2011 and 2012), that reduces the update to the IPF PPS base rate for the rate year beginning in CY 2011, we proposed to adjust the IPF PPS update by 0.25 percentage point for RY 2012. Therefore, we proposed to apply the 15-month FY 2008-based RPL market basket increase of 3.0 percent, which is then adjusted by the "other adjustment" of 0.25 percentage point.

IRFs are paid under the IRF PPS for cost reporting periods beginning on or after January 1, 2002. For cost reporting periods beginning on or after October 1, 2002 (FY 2003), and thereafter, the Federal prospective payments to IRFs are based on 100 percent of the adjusted Federal IRF prospective payment amount, updated annually (69 FR 45721). Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act require the application of a 0.1 percentage point reduction to the market basket increase factor for FYs 2012 and 2013. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment. Increase factors for the IRF PPS will be discussed in future notice and comment rulemaking.

## III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2012. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, we are recommending an applicable percentage increase to the standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an MFP adjustment of 1.2 percentage points for MFP and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and MDHs and the Puerto Rico-specific standardized amount.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for all other types of hospitals. Consistent with our proposal for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 2.8 percent.

For FY 2012, consistent with policy proposal set forth in section VII. of the preamble of this proposed rule, we are recommending an update of 1.5 percent to the LTCH PPS standard Federal rate. In addition, consistent with the proposed update specified in the FY 2012 IRF PPS proposed rule (as described above), we are recommending an update of 1.5 percent (that is, the market basket increase factor of 2.8 percent less 1.2 percentage points for economy-wide productivity and less 0.1 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act) to the IRF PPS Federal rate for FY 2012. Finally, consistent with the proposed update specified in the FY 2012 IPF PPS proposed rule (as described above), we are recommending an update of 3.0 percent reduced by 0.25 percentage point to the IPF PPS Federal rate for RY 2012 for the Federal per diem payment amount.

## IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2011 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates equal to one percent. MedPAC expects Medicare margins to remain low in 2012. At the same time though, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. MedPAC also recommended that Congress should require the Secretary to make adjustments to inpatient payment rates in future years to recover all overpayments due to documentation and coding improvements. MedPAC noted that priority should be given to preventing future overpayments.

*Response:* With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2012, as discussed above, sections 3401(a) and 10319(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act. Section 1886(b)(3)(B), as amended by these sections, sets the requirements for the FY 2012 applicable percentage increase. Therefore, we have proposed an applicable percentage increase for FY 2012 of 1.5 percent, provided the hospital submits quality data, consistent with these statutory requirements.

Similar to our response last year, we agree with MedPAC that hospitals should control costs rather than have Medicare accommodate the current rate of growth. As MedPAC noted, the lack of financial pressure at certain hospitals can lead to higher costs and in turn bring down the overall Medicare margin for the industry.

With regard to MedPAC's recommendation that Congress should require the Secretary to make adjustments to inpatient payment rates in future years to recover all overpayments due to diagnosis and coding improvements, we refer the reader to section III. D. of the preamble to this proposed rule for a complete discussion on the proposed FY 2012 MS–DRG documentation and coding adjustment. In section III. D. of the preamble to this proposed rule, we are proposing a prospective adjustment of 3.15 percent and a recoupment of 2.9 percent to the FY 2012 inpatient payment rates to recover overpayments due to documentation and coding improvements. We note that any recoupments for overpayments due to documentation and coding improvements beyond the authority of section 7(b)(1)(B) of Public Law 110–90 would require additional changes to current law by Congress. Therefore, without a change to current law, our ability to recoup all overpayments due to documentation and coding improvements is limited.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

[FR Doc. 2011–9644 Filed 4–19–11; 4:15 pm]

**BILLING CODE 4120–01–P**

# FEDERAL REGISTER

Vol. 76 Thursday,

No. 87 May 5, 2011


Part III

## Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Rule To Revise the List of Endangered and Threatened Wildlife for the Gray Wolf (*Canis lupus*) in the Eastern United States, Initiation of Status Reviews for the Gray Wolf and for the Eastern Wolf (*Canis lycaon*); Proposed Rule

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**[Docket No. FWS–R3–ES–2011–0029; 92220–1113–000; ABC Code: C6]**

**RIN 1018–AX57**

# Endangered and Threatened Wildlife and Plants; Proposed Rule To Revise the List of Endangered and Threatened Wildlife for the Gray Wolf (*Canis lupus*) in the Eastern United States, Initiation of Status Reviews for the Gray Wolf and for the Eastern Wolf (*Canis lycaon*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule, initiation of status reviews.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service or USFWS) are re-evaluating the listing of the Minnesota population of gray wolves (*Canis lupus*) and propose to revise it to conform to current statutory and policy requirements. We propose to identify the Minnesota population as a Western Great Lakes (WGL) Distinct Population Segment (DPS) of the gray wolf and to remove this DPS from the List of Endangered and Threatened Wildlife. We propose these actions because the best available scientific and commercial information indicates that the WGL DPS does not meet the definitions of threatened or endangered under the Act.

This proposed rule, if made final, would remove the currently designated critical habitat for the gray wolf in Minnesota and Michigan and the current special regulations for gray wolves in Minnesota. We also propose to revise the range of the gray wolf (the species *C. lupus*) by removing all or parts of 29 eastern states that we now recognize were not part of the historical range of the gray wolf. New information indicates that these areas should not have been included in the original listing of the gray wolf.

In this proposed rule, we recognize recent taxonomic information indicating that the gray wolf subspecies *Canis lupus lycaon* should be elevated to the full species *C. lycaon.* Given that a complete status review of this newly recognized species has never been conducted, we are initiating a rangewide review of the conservation status of *C. lycaon* in the United States and Canada. This rule also constitutes the initiation of our five-year review of the status of gray wolves under section 4(c)(2) of the Act, as well as the initiation of status reviews specific to gray wolves in the Pacific Northwest and Mexican wolves in the Southwest United States and Mexico.

**DATES:** *Comment submission:* We will accept comments received or postmarked on or before July 5, 2011.

*Public hearings:* We will hold two public hearings on this proposed rule scheduled on May 18, 2011 and on June 8, 2011. Informational meetings will be held from 6 p.m. to 7:15 p.m., followed by the public hearings from 7:30 p.m. to 9 p.m.

**ADDRESSES:** *Comment submission:* You may submit comments by one of the following methods:

*Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Enter Keyword or ID box, enter FWS–R3–ES–2011–0029, which is the docket number for this rulemaking. Then, in the Search panel at the top of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Submit a Comment."

*By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R3–ES–2011–0029; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; 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).

*Public hearings:* We have scheduled an informational meeting followed by a public hearing in Ashland, Wisconsin, on May 18, 2011, at the Northern Great Lakes Center, 29270 County Highway G. We have scheduled an informational meeting followed by a public hearing in Augusta, Maine, on June 8, 2011, at the Augusta Civic Center, 16 Cony Street. See the Public Hearings section below for more details.

**FOR FURTHER INFORMATION CONTACT:** Laura Ragan, 612–713–5350. Direct all questions or requests for additional information to: GRAY WOLF QUESTIONS, U.S. Fish and Wildlife Service, Federal Building, 1 Federal Drive, Ft. Snelling, Minnesota 55111–4056. Additional information is also available on our Web site at *http://www.fws.gov/midwest/wolf.* Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

**SUPPLEMENTARY INFORMATION:**

## Public Comments

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. In particular, we are seeking targeted information and comments on our national wolf strategy and our proposed revision of the Minnesota listing; see items (1)-(2) below. Also, as part of this proposed rule we are announcing initiation of a 5-year status review for *C. lupus* in the conterminous United States and Mexico; initiation of status reviews specific to, respectively, gray wolves in the Pacific Northwest and in the Southwest United States and Mexico; and initiation of a status review for *C. lycaon* throughout its range in the United States and Canada. For these status reviews to be complete and based on the best available scientific and commercial information, we request information on items (9)–(11) below from governmental agencies, Native American Tribes, the scientific community, industry, and any other interested parties.

(1) Biological, commercial trade, or other relevant information concerning our analysis of the current gray wolf listing and the adequacy of our national wolf strategy, with particular respect to our recommended gray wolf listing units (*i.e.,* taxonomic or population units);

(2) Information that forms the basis for revising the currently listed Minnesota group of gray wolves under section 4(c) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), with particular respect to the factors in section 4(a) of the Act, which are:

(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.

(3) Biological, commercial trade, or other relevant data concerning any current or likely future threat, or lack thereof, to wolves in the WGL DPS;

(4) Additional information concerning the range, distribution, population size, population trends, and threats with respect to wolves in the WGL DPS;

(5) Current or planned activities in the WGL DPS and their possible impacts on the wolves and their habitat;

(6) Information concerning the adequacy of the recovery criteria described in the 1992 Recovery Plan for the Eastern Timber Wolf;

(7) The extent and adequacy of Federal, state, and Tribal protection and management that would be provided to wolves in the WGL DPS as delisted species; and

(8) The proposed geographic boundaries of the WGL DPS, and scientific and legal supporting information for alternative boundaries that might result in a larger or smaller DPS, including information on the discreteness and significance of the proposed DPS.

(9) New information concerning the biology and conservation of the gray wolf in the conterminous United States and Mexico that may be informative to the 5-year status review of *Canis lupus,* with particular attention to the listing units described under (1) above, including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends;

(e) Historical, current, and projected levels of suitable gray wolf habitat;

(f) Past, ongoing, and emerging threats to extant gray wolf populations, their habitat, or both; and

(g) Past and ongoing conservation measures for the gray wolf, its habitat, or both.

(10) Information concerning the status of the gray wolf in the Pacific Northwest United States and the gray wolf subspecies *baileyi* (Mexican wolf) in the Southwest United States and Mexico, including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends;

(e) Historical, current, and projected levels of suitable habitat;

(f) Past, ongoing, and emerging threats to these populations, their habitat, or both; and

(g) Past and ongoing conservation measures for these populations, their habitat, or both.

(11) Information concerning the biology, range, and population trends of *Canis lycaon,* including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends;

(e) Historical, current, and projected levels of suitable habitat;

(f) Past, ongoing, and emerging threats to extant populations, their habitat, or both;

(g) Past and ongoing conservation measures for the species, its habitat, or both; and

(h) The potential role that any portion of the historical range of the *C. lycaon* in the United States may play in the persistence and viability of the species.

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. We will not accept comments sent by e-mail or fax or to an address not listed in **ADDRESSES**. Comments must be submitted to *http://www.regulations.gov* before midnight (Eastern Daylight Time) on the date specified in **DATES.** Finally, we will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in **DATES**.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* If you provide personal identifying information, such as your street address, phone number, or e-mail address, 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.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R3–ES–2011–0029, or by appointment, during normal business hours at the following Ecological Services offices:

- Twin Cities, Minnesota Ecological Services Field Office, 4101 American Blvd. E., Bloomington, MN; 612–725–3548.
- Green Bay, Wisconsin Ecological Services Field Office, 2661 Scott Tower Dr., New Franken, WI; 920–866–1717.
- East Lansing, Michigan Ecological Services Field Office, 2651 Coolidge Road, Suite 101, East Lansing, MI; 517–351–2555.
- New England Ecological Services Field Office, U.S. Fish and Wildlife Service, 70 Commercial St., Suite 300, Concord, NH; 603–223–2541.

## Public Hearings

We have scheduled an informational meeting followed by a public hearing in Ashland, Wisconsin, on May 18, 2011, at the Northern Great Lakes Center, 29270 County Highway G. The informational meeting will be held from 6 p.m. to 7:15 p.m., followed by a public hearing from 7:30 p.m. to 9 p.m.

A second informational meeting followed by a public hearing will be held in Augusta, Maine, on June 8, 2011, at the Augusta Civic Center, 16 Cony Street. The informational meeting will be held from 6 p.m. to 7:15 p.m., followed by a public hearing from 7:30 p.m. to 9 p.m.

## Peer Review

In accordance with our policy, "Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities," which was published on July 1, 1994 (59 FR 34270), we will seek the expert opinion of at least three appropriate independent specialists regarding scientific data and interpretations contained in this proposed rule. The purpose of such review is to ensure that our decisions are based on scientifically sound data, assumptions, and analysis. We will send copies of this proposed rule to the peer reviewers immediately following publication in the **Federal Register**.

## Background

### *National Overview*

Below we provide an overview of our proposed national approach to recovery of wolves in the conterminous United States and Mexico. This overview provides the context for our proposed actions for wolves in the eastern United States. In this overview, we discuss the listing history for the gray wolf, evaluate the current gray wolf listing, present the structured decision-making process we have used to date to formulate our national wolf strategy, and describe the strategy itself.

## Gray Wolf Listing History

Here we present a brief overview of previous Federal actions relating to the listing of gray wolves and the recovery plans that have been developed pursuant to these listing actions. Additional Federal actions for western Great Lakes wolves are discussed in *Previous Federal Actions for WGL Wolves* below.

Gray wolves were originally listed as subspecies or as regional populations of subspecies in the conterminous United States and Mexico. In 1967, we listed the eastern timber wolf (*Canis lupus lycaon*) in the Great Lakes region (32 FR 4001, March 11, 1967), and in 1973 we listed *C. l. irremotus* in the northern

Rocky Mountains (38 FR 14678, June 4, 1973). Both listings were promulgated under the Endangered Species Conservation Act of 1969; subsequently, on January 4, 1974, these subspecies were listed under the Endangered Species Act of 1973 (39 FR 1171). We listed a third gray wolf subspecies, the Mexican wolf (*C. l. baileyi*) as endangered on April 28, 1976 (41 FR 17740), in the southwestern United States and Mexico. On June 14, 1976 (41 FR 24064), we listed the Texas gray wolf subspecies (*C. l. monstrabilis*) as endangered in Texas and Mexico.

In 1978, we published a rule (43 FR 9607, March 9, 1978) reclassifying the gray wolf as an endangered population at the species level (*C. lupus*) throughout the conterminous 48 States and Mexico, except for the Minnesota gray wolf population, which was classified as threatened. At that time, we considered the Minnesota group of gray wolves to be a listable entity under the Act, and we considered the gray wolf group in Mexico and the 48 conterminous States other than Minnesota to be another listable entity (43 FR 9607, 9610, respectively, March 9, 1978). This reclassification was undertaken because of uncertainty about the taxonomic validity of some of the previously listed subspecies and because we recognized that wolf populations were historically connected, and that subspecies boundaries were thus malleable.

However, the 1978 rule also stated that "biological subspecies would continue to be maintained and dealt with as separate entities" (43 FR 9609), and offered "the firmest assurance that [the Service] will continue to recognize valid biological subspecies for purposes of its research and conservation programs" (43 FR 9610, March 9, 1978). Accordingly, recovery plans were developed for the wolf populations in the following regions of the United States: the northern Rocky Mountains in 1980, revised in 1987; the Great Lakes in 1978, revised in 1992; and the Southwest in 1982, the revision of which is now underway.

More detail on previous Federal actions for the Southwest and northern Rocky Mountains wolves is provided, respectively, within the 90-day finding for Mexican wolves (75 FR 46894) and in various notices and rulemakings for the management of northern Rocky Mountains wolves (59 FR 60252, November 22, 1994; 59 FR 60266, November 22, 1994; 68 FR 15804, April 1, 2003; 68 FR 15879, April 1, 2003; 70 FR 1286, January 6, 2005; 71 FR 6634, February 8, 2006; 71 FR 43410, August 1, 2006; 73 FR 4720, January 28, 2008; 73 FR 10514, February 27, 2008; 74 FR 15123, April 2, 2009) . Further detail on previous Federal actions related to the WGL DPS is provided in *Previous Federal Actions for WGL Wolves* below.

**Evaluation of the 1978 Gray Wolf Listing**

The Service now considers the 1978 *Canis lupus* listing rule at 43 FR 9607 to be in need of revision. This need has been identified based on our review of the best available taxonomic information, which indicates that *C. lupus* historically did not occupy large portions of the eastern United States and on our reconsideration of the listing in light of current statutory and policy requirements under the Act. These considerations are discussed in turn below.

*Taxonomy and Historical Ranges of Wolves in the United States*

Our review of the best available taxonomic information indicates that *Canis lupus* did not occupy large portions of the eastern United States: *i.e.,* the northeastern United States was occupied by the eastern wolf (*C. lycaon*), now considered a separate species of *Canis* rather than a subspecies of *lupus,* and the southeastern United States was occupied by the red wolf (*Canis rufus*) rather than the gray wolf. Our review of North American wolf taxonomy also suggests that changes in listing classification are warranted in other portions of the country.

At the time the gray wolf was listed in 1978, and until the molecular genetics studies of the last few years, the range of the gray wolf prior to European settlement was generally believed to include most of North America. The only areas that were believed to have lacked gray wolf populations were the coastal and interior portions of California, the arid deserts and mountaintops of the western United States, and parts of the eastern and southeastern United States (Young and Goldman 1944, Hall 1981, Mech 1974, and Nowak 1995). We note, however, that some authorities have questioned the reported historical absence of gray wolves in parts of California (Carbyn *in litt.* 2000, Mech *in litt.* 2000).

Furthermore, we note long-held differences of opinion regarding the precise boundary of the gray wolf's historical range in the eastern and southeastern United States. Some researchers regarded Georgia's southeastern corner as the southern extent of gray wolf range (Young and Goldman 1944, Mech 1974); others believed gray wolves did not extend into the Southeast at all (Hall 1981) or did so to a limited extent, primarily at somewhat higher elevations (Nowak 1995). The southeastern and mid-Atlantic States were generally recognized as being within the historical range of the red wolf (*Canis rufus*), and it is not known how much range overlap historically occurred between the two *Canis* species. Morphological work by Nowak (2000, 2002, 2003) supported extending the historical range of the red wolf into southern New England or even farther northward, indicating either that the historical range of the gray wolf in the eastern United States was more limited than previously believed, or that the respective ranges of several wolf species expanded and contracted in the eastern and northeastern United States, intermingling in post-glacial times along contact zones.

The results of recent molecular genetic analyses (*e.g.,* Wilson *et al.* 2000, Wilson *et al.* 2003, Wheeldon and White 2009, Wilson *et al.* 2009, Fain *et al.* 2010, Wheeldon *et al.* 2010) and morphometric studies (*e.g.,* Nowak 1995, 2000, 2002, 2003) explain some of the past difficulties in establishing the gray wolf's range in the eastern United States. These studies show that the mid-Atlantic and southeastern United States historically were occupied by the red wolf (*C. rufus*), and that New England and portions of the upper Midwest (eastern and western Great Lakes regions) historically were occupied by *C. lycaon;* they also indicate that the gray wolf (*C. lupus*) did not occur in the eastern United States.

Based on these recent studies, we view the historical range of the gray wolf as the central and western United States, including portions of the western Great Lakes region, the Great Plains, portions of the Rocky Mountains, the Intermountain West, the Pacific Northwest, and portions of the Southwest. All or parts of 29 southern and eastern States (Maine, Massachusetts, Connecticut, New Hampshire, Rhode Island, Vermont, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Ohio (the part outside WGL DPS), West Virginia, Kentucky, Tennessee, Alabama, Mississippi, Louisiana, Texas (east of Interstate Highway 35), Oklahoma (east of Interstate Highway 35 and southeast of Interstate Highway 44 north of Oklahoma City), Arkansas, Missouri (southeast of Interstate Highway 44 and southeast of Interstate Highway 70 east of St. Louis), Indiana (the part outside WGL DPS), and Illinois (the part outside WGL DPS)) were not within the gray wolf's historical range.

In sum, we now recognize three wolf species with ranges in the conterminous United States: *Canis lupus, Canis lycaon,* and *Canis rufus.* The ranges of *C. lupus* and *C. lycaon* overlap in the western Great Lakes region, as discussed in *Taxonomy of Wolves in the Western Great Lakes Region* below; however, in the eastern United States, the historical range of *C. lupus* is considered to fall outside the historical ranges of *C. lycaon* and *C. rufus.*

*Conformance With the Act's Definition of Species*

Given the assurances we provided in the 1978 *C. lupus* listing that we would continue to treat gray wolf subspecies as separate entities for conservation purposes (as noted in Gray Wolf Listing History, above), we identified a need to reconsider the listing in light of current statutory and policy standards regarding the Act's definition of species. The Act provides for listing at various taxonomic and subtaxonomic levels through its definition of "species" in section 3(16): The term species includes any *subspecies* of fish or wildlife or plants, and any *distinct population segment* of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16) (italics added). As a matter of procedure, then, the Service determines whether it is most appropriate to list an entity as a full species, a subspecies, or a DPS of either a species or subspecies. The gray wolf has a Holarctic range; the current listing encompasses the United States-Mexico segment of the population and consists, in turn, of multiple entities.

The specific provision for listing distinct population segments of vertebrates was enacted through the 1978 Amendments to the Act (Pub. L. 95–362, November 10, 1978); these amendments replaced the ability to list "populations" with the ability to list "distinct population segments" and treat them as species under the Act. To interpret and implement the 1978 DPS amendment, the Service and the National Marine Fisheries Service jointly published the Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (DPS policy) (61 FR 4722, February 7, 1996), setting policy standards for designating populations as "distinct."

The March 1978 gray wolf listing predated the November 1978 amendments to the Act. Although the 1978 rule lists two *C. lupus* entities, *i.e.,* the endangered and threatened entities described above, these listings were not predicated upon a formal DPS analysis and do not comport with current policy standards. Nonetheless, subsequent recovery plans and all gray wolf rulemakings since 1996 have focused on units reflective of the evident intent of the 1978 rule to manage and recover gray wolves as "separate entities" (43 FR 9609), *i.e.,* subspecies or populations. This proposed rule and our proposed National Wolf Strategy, below, constitute an effort to bring the 1978 listing in line, insofar as possible, with the Act's requirements and current policy standards.

**Structured Decision-Making for Wolves**

In 2008, the Service embarked on a structured decision-making process as a means of developing a more integrated and comprehensive strategy for gray wolf conservation in the lower 48 States and Mexico. The overall intent of the process was to identify appropriate wolf entities (*i.e.,* listing units) for full status review, anticipating that such review would lead to either confirmation or revision of the existing gray wolf listing. We aimed to identify a coherent set of listing units based on best available scientific and commercial information, conformance with existing regulatory and policy requirements, and fundamental wolf management objectives.

We first conducted several iterations of the process in an internal Service effort to develop a viable framework for considering the scientific and policy questions that drive decision-making for wolves. The resulting framework incorporated decision analysis principles and techniques for crafting alternative listing units and then assessing the relative performance of each alternative in terms of achieving management objectives.

Management of wolves is shared among the Service, States, and Tribes. Thus, following our development of a satisfactory decision-making framework, representatives from several States involved with gray wolf conservation joined us to further explore alternative units that could qualify for future status review (Tribal representatives declined to participate). After acquainting state participants with the decision-making framework, we convened a State-Federal workshop in August 2010 to generate and assess alternative taxonomic and population units at various scales and in various configurations, including the 1978 listing as the *status quo* alternative.

Workshop participants also explored the different values that drive wolf decision-making; these values were expressed as the following fundamental management objectives: (1) Promote and sustain wolf recovery; (2) comply with the requirements of the Act; (3) minimize the regulatory burden on States, Tribes, and the general public; (4) facilitate State and Tribal management of wolves; (5) minimize wolf-human conflicts; and (6) promote public acceptance of wolf listing and recovery actions.

Workshop outcomes provided important input to our continuing effort to formulate a comprehensive vision of wolf conservation. Based on further Service deliberations, this comprehensive vision has evolved into the proposed national wolf strategy discussed below. It is important to note that this strategy is a broad outline, the components of which are in various stages of execution.

**National Wolf Strategy**

The Service's national wolf strategy is intended to: (1) Lay out a cohesive and coherent approach to addressing wolf conservation needs, including protection and management, in accordance with the Act's statutory framework; (2) ensure that actions taken for one wolf population do not cause unintended consequences for other populations; and (3) be explicit about the role of historical range in the conservation of extant wolf populations.

The strategy is based on three precepts. First, in order to qualify for any type of listing or delisting action, wolf entities must conform to the Act's definition of "species," whether as taxonomic species or subspecies or as distinct population segments. Second, the strategy promotes the continued representation in this country of all substantially unique genetic lineages found historically in the lower 48 States. Third, wolf conservation under the Act is concerned with reducing extinction risks to imperiled entities; the strategy thus focuses on conservation of the four extant gray wolf entities identified through the structured decision-making process and being considered for section 4 actions: (1) The western Great Lakes population, (2) the northern Rocky Mountains (NRM) population, (3) gray wolves in the Pacific Northwest, and (4) the Southwestern population of Mexican wolves.

Various reviews and listing actions are underway for these gray wolf populations. The WGL DPS is proposed for delisting in the proposed rule being published in today's **Federal Register**. With regard to the NRM gray wolf population, Congress is considering legislation that would direct us to reissue our 2009 final rule (74 FR 15123, April 2, 2009), that delisted the NRM DPS in the States of Idaho and Montana,

and in portions of Oregon, Washington, and Utah. This rule retained ESA protections of wolves in Wyoming as non-essential experimental. If passed, we would publish a separate notice in the **Federal Register**. Negotiations regarding potential future post-delisting wolf management in Wyoming are ongoing.

The biological and conservation status of wolves in the Pacific Northwest (we are considering this to be the area west of the NRM gray wolf population, including portions of Oregon, Washington, northern California, and western Nevada) is being assessed to determine their appropriate listing classification. When this review is completed, we will evaluate a potential Pacific Northwest DPS in accordance with our DPS policy and will reclassify this population as appropriate through an additional rulemaking process. The status of the Southwestern population (*i.e.,* Mexican wolves within their historical range) is being reviewed pursuant to our 90-day finding on two listing petitions (75 FR 46894, August 4, 2010). We anticipate that the Southwestern population will be proposed for listing as either the subspecies *C. l. baileyi* or as a DPS of *C. lupus;* in the meantime, recovery planning will continue to proceed for these wolves.

As separate actions move forward for the NRM, Pacific Northwest, and Southwest, wolves in these regions will retain their current classification as endangered, except where delisted and where currently listed as non-essential experimental populations (see 50 CFR 17.84(k)). We plan to move forward with a rulemaking to replace the remainder of the 1978 listing with more targeted regional units, as appropriate, concurrently with publication of the final rule for the WGL DPS.

It is likely that revision of the 1978 gray wolf listing into finer-scale taxonomic or population units will result in removal of the Act's protections in areas of the historical *C. lupus* range, such as the Great Plains States and areas of the western States, that do not support extant wolf populations *and* do not play a role in the recovery of any of the four gray wolf entities. Although some of these areas are within the species' historical range, these areas lack sufficient suitable habitat for wolf pack persistence. Thus, we believe recovery in these areas is both unrealistic and unnecessary. We note, however, that such areas would not necessarily be precluded from wolf conservation efforts under other authorities, *e.g.,* Tribes, States, and Federal land management agencies.

Our national wolf strategy also addresses the two other wolf taxa that fall within the range described for *Canis lupus* in the 1978 listing, *C. lycaon* and *C. rufus.* With regard to *Canis lycaon,* we are announcing a rangewide status review of this species, which occurs in Canada and the western Great Lakes region of the United States. The historical range of *C. lycaon* also extends into the northeastern United States, which the 1978 listing inaccurately treated as part of the range of *C. lupus.* The role of the Northeast region in conservation of *C. lycaon* will be considered in the rangewide review, which will look at the status of extant populations in terms of uniqueness, demography, and extinction risks. A determination as to whether to proceed with any *C. lycaon* listing action—and, if listing is warranted, whether or not to include the northeastern United States in the listed range—will depend on the results of the status review. Notification of our intentions with regard to *C. lycaon* will be provided in conjunction with publication of the final rule for the WGL DPS. Meanwhile, we propose to revise the range of the gray wolf (the species *C. lupus*) by removing all or parts of 29 eastern states that we now recognize were not part of the historical range of the gray wolf. New information indicates that these areas should not have been included in the original listing of the gray wolf. These States are specified under *Taxonomy and Historical Ranges of Wolves in the United States,* above.

Finally, with regard to *Canis rufus,* we propose to remove the southeastern states included in the 1978 gray wolf listing from the List due to error, because we now recognize were not part of the historical range of the gray wolf. These states instead constitute the range of *Canis rufus;* see *Taxonomy and Historical Ranges of Wolves in the United States,* above. Red wolves currently are listed as endangered where found (32 FR 4001, March 11, 1967); this listing will be retained and recovery efforts for red wolves will continue as warranted (Red Wolf Recovery and Species Survival Plan; Service 1990).

## Five-Year Review of Gray Wolves

Under section 4(c)(2) of the Act, we have a duty to review listed species' status every 5 years and determine whether a change in listing status is appropriate. We announce initiation of the 5-year review for the gray wolf in this rule and seek new information as requested in Public Comments above.

## Western Great Lakes Wolves

### *Previous Federal Actions for WGL Wolves*

The eastern timber wolf (*Canis lupus lycaon*) was listed as endangered in Minnesota and Michigan in the first list of species that were protected under the 1973 Act, published in May 1974 (USDI 1974). On March 9, 1978, we published a rule (43 FR 9607) reclassifying the gray wolf at the species level (*Canis lupus*) as endangered throughout the conterminous 48 States and Mexico, except for the Minnesota population, which we classified to threatened. The separate subspecies listings, including *C. l. lycaon,* thus were subsumed into the listings for the gray wolf in Minnesota and the gray wolf in the rest of the conterminous United States and Mexico. In that 1978 rule, we also identified Isle Royale National Park, Michigan, and Minnesota wolf management zones 1, 2, and 3, as critical habitat. We also promulgated special regulations under section 4(d) of the Act for operating a wolf management program in Minnesota at that time. The depredation control portion of the special regulation was later modified (50 FR 50793; December 12, 1985); these special regulations are found in 50 CFR 17.40(d)(2).

On April 1, 2003, we published a final rule revising the listing status of the gray wolf across most of the conterminous United States (68 FR 15804). Within that rule, we identified three DPSs for the gray wolf (see Gray Wolf Listing History, above), including an Eastern DPS, which was reclassified from endangered to threatened, except where already classified as threatened. In addition, we established a second section 4(d) rule that applied provisions similar to those previously in effect in Minnesota to most of the Eastern DPS. The special rule was codified in 50 CFR 17.40(o).

U.S. District Court rulings in Oregon and Vermont on January 31, 2005, and August 19, 2005, respectively, invalidated the April 1, 2003, final rule. Consequently, the status of gray wolves outside of Minnesota reverted back to endangered status, as had been the case prior to the 2003 reclassification. The courts also invalidated the three DPSs identified in the April 1, 2003, rule, as well as the associated special regulations.

On March 27, 2006, we published a proposal (71 FR 15266–15305) to identify a WGL DPS of the gray wolf, to remove the WGL DPS from the protections of the Act, to remove designated critical habitat for the gray wolf in Minnesota and Michigan, and to

remove special regulations for the gray wolf in Minnesota. The proposal was followed by a 90-day comment period, during which we held four public hearings on the proposal.

On February 8, 2007, the Service issued a rule that identified and delisted the WGL DPS of the gray wolf (*Canis lupus*) (72 FR 6052). Three parties challenged this rule (*Humane Society of the United States* v. *Kempthorne,* 579 F. Supp. 2d 7 (D.D.C. 2008)), and on September 29, 2008, the court ruled in favor of the plaintiffs and vacated the rule and remanded it to the Service. On remand, the Service was directed to provide an explanation as to how simultaneously identifying and delisting a DPS is consistent with the Act's text, structure, policy objectives, legislative history, and any relevant judicial interpretations.

The court's primary question was whether the Service has the authority to identify a DPS within a larger already-listed entity and, in the same decision, determine the DPS does not warrant the Act's protections even though the other populations of the species retain the old listing status. Our authority to make these determinations and to revise the list accordingly is a reasonable interpretation of the language of the Act, and our ability to do so is an important component of the Service's program for the conservation of threatened and endangered species.

Our authority to revise the existing listing of a species (the gray wolf in Minnesota and the gray wolf in the lower 48 States and Mexico, excluding Minnesota) to identify a Western Great Lakes DPS and determine that it is healthy enough that it no longer needs the Act's protections is found in the precise language of the Act. Moreover, even if that authority were not clear, our interpretation of this authority to make determinations under section 4(a)(1) and to revise the endangered and threatened species list to reflect those determinations under section 4(c)(1) is reasonable and fully consistent with the Act's text, structure, legislative history, relevant judicial interpretations, and policy objectives.

We consulted with the Solicitor of the Department of the Interior to address the issue in the court's opinion. On December 12, 2008, a formal opinion was issued by the Solicitor, "U.S. Fish and Wildlife Service Authority Under Section 4(c)(1) of the Endangered Species Act to Revise Lists of Endangered and Threatened Species to 'Reflect Recent Determinations'" (U.S. DOI 2008). The Service fully agrees with the analysis and conclusions set out in the Solicitor's opinion. This proposed action is consistent with the opinion. The complete text of the Solicitor's opinion can be found at *http://www.fws.gov/midwest/wolf/.*

On December 11, 2008, we published a notice reinstating protections for the gray wolf in the western Great Lakes (and northern Rocky Mountains) pursuant to court orders (73 FR 75356).

On April 2, 2009, we published a final rule identifying the western Great Lakes populations of gray wolves as a DPS and revising the list of Endangered and Threatened Wildlife by removing the DPS from that list (74 FR 15070). We did not seek additional public comment on the 2009 final rule. On June 15, 2009, five parties filed a complaint against the Department and the Service alleging that we violated the Act, the Administrative Procedure Act (APA), and the court's remand order by publishing the 2009 final rule (74 FR 15070). On July 2, 2009, pursuant to a settlement agreement between the parties, the court issued an order remanding and vacating the 2009 final rule.

On March 1, 2000, we received a petition from Mr. Lawrence Krak of Gilman, Wisconsin, and on June 28, 2000, we received a petition from the Minnesota Conservation Federation. Mr. Krak's petition requested the delisting of gray wolves in Minnesota, Wisconsin, and Michigan. The Minnesota Conservation Federation requested the delisting of gray wolves in a Western Great Lakes DPS. Because the data reviews resulting from the processing of these petitions would be a subset of the review begun by our July 13, 2000, proposal (65 FR 43450) to revise the current listing of the wolf across most of the conterminous United States, we did not initiate separate reviews in response to those two petitions. While we addressed these petitions in our February 8, 2007, final rule (72 FR 6052), this rule was vacated by the subsequent District Court ruling. While we view our actions on these petitions as final upon publication of the **Federal Register** determinations, we nevertheless restate our 90-day findings that the action requested by each of the petitions may be warranted, as well as our 12-month finding that the action requested by each petition is warranted.

On March 15, 2010, we received a petition from the Minnesota Department of Natural Resources requesting that the gray wolf in Minnesota be removed from the List of Endangered or Threatened Wildlife under the Act. Likewise, on April 26, 2010, we received a petition from the Wisconsin Department of Natural Resources requesting that the gray wolf in Minnesota and Wisconsin be delisted. On April 26, 2010, we received a petition from the Sportsmen's Alliance, representing five other organizations, requesting that gray wolves in the Great Lakes area be delisted. On June 17, 2010, we received a petition from Safari Club International, Safari Club International Foundation and the National Rifle Association of America requesting that wolves of the western Great Lakes be delisted. In response to those four petitions, on September 14, 2010, we published a 90-day finding determining that the petitions presented substantial information that delisting may be warranted and reinitiated a full status review. Therefore, this delisting proposal constitutes our 12-month finding that the action requested by each petition is warranted.

In response to a separate petition, on June 10, 2010, we made a 90-day finding that there was no evidence of any breeding population of wolves to support the requested listing of a DPS of the gray wolf in New England (75 FR 32869).

*Species Concepts*

As noted in Conformance with the Act's Definition of Species above, the Act defines "species" as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). It has not been uncommon in the years since the Act was passed for significant controversy to arise over the propriety of recognizing various groups of organisms as eligible for protection under the Act. Our implementing regulations (50 CFR 424.11) require us to use standard taxonomic distinctions (such as species and subspecies) when they are available, clearly defined, and generally accepted. In determining that a taxonomic entity qualifies as a species or subspecies we carefully evaluate the best available taxonomic data to determine whether we have sufficient information to conclude that a taxonomic entity qualifies as a species under the Act.

In identifying species, there is not a single set of criteria, and, therefore, no single species concept that is accepted by all taxonomists. In 1942, Ernst Mayr identified five different species concepts (Mayr 1942), and many more have been recognized since then (Wilkins 2006; 2003; Mayden 1997, pp. 381–384). Many of these species concepts can be associated with one of two major classes of concepts or approaches. The first is the biological species concept (BSC). This concept is based on reproductive relationships among populations. The

ability to interbreed and realize gene flow between two populations is the indication that they belong to the same species. The concept is most commonly associated with Mayr (1963), but has antecedents during the development of evolutionary biology in the 20th century. The second major class of concepts is the phylogenetic species concept (PSC). Under this group of concepts, species are identified by their genealogical (lineages) or phylogenetic (evolutionary) relationships and diagnosability. The many variations of these concepts and others are reviewed by Wiley (1981), Avise (2004), and Coyne and Orr (2004).

There is, likewise, no scientific consensus on what constitutes a subspecies, and some authorities (Wilson and Brown 1953) have questioned the utility of the subspecies level of classification. Following is a description of various subspecies criteria that have been proposed and applied in the taxonomic literature. Because some criteria are more stringent than others, a putative, or generally accepted, subspecies may meet the criteria and be recognized following one concept, but found to be invalid under a more stringent concept. Nowak (1995, p. 394) discussed the standards he used when he revised the subspecies of *Canis lupus:* "My investigation largely disregarded such questions [concerning use of very localized characters] and concentrated on general trends in measurable size and proportion that could be evaluated on a continent-wide or worldwide basis. Substantive statistical breaks in such trends, as discussed above, were taken as evidence of taxonomic division." In The Mammals of North America, Hall (1981, p. viii) included the following in his "Criteria for Species versus Subspecies."

> If crossbreeding occurs in nature at a place or places where the geographic ranges of two kinds of mammals meet, the two kinds are to be treated as subspecies of one species. If no crossbreeding occurs, the two kinds are to be regarded as two distinct, full species.

Mayr (1963, glossary) defined subspecies as, "an aggregate of local populations of a species inhabiting a geographic subdivision of the range of the species, and differing taxonomically from other populations of the species." He further explains "differing taxonomically" as differing "by diagnostic morphological characters" (Mayr 1963, p. 348). Mayr (1969, p. 190) also describes a quantitative method for determining whether populations differ taxonomically: "A so-called 75-percent rule is widely adopted. According to this, a population is recognized as a valid subspecies if 75 percent of the individuals differ from "all" (97 percent) of the individuals of a previously recognized subspecies. At the point of intersection between the two curves where this is true, about 90 percent of population A will be different from about 90 percent of the individuals of population B (to supply a symmetrical solution)".

Patten and Unitt (2002, p. 27) provide another definition of subspecies as "diagnosable clusters of populations of biological species occupying distinct geographic ranges." They do not require that diagnosability be absolute, but advocate 90 percent separation as a more stringent criterion than the 75-percent rule.

Avise (2004, p. 362) attempted to incorporate phylogenetic information within a biological species concept in providing the following guidance on recognizing subspecies: "Within such units [=species], "subspecies" warranting formal recognition could then be conceptualized as groups of actually or potentially interbreeding populations (normally mostly allopatric) that are genealogically highly distinctive from, but reproductively compatible with, other such groups. Importantly, the empirical evidence for genealogical distinction must come, in principle, from concordant genetic partitions across multiple, independent, genetically based molecular (or phenotypic; Wilson and Brown 1953) traits."

A common feature of all of the above definitions is that they recognize that subspecies are groups of populations, and most recognize that subspecies can be variable and overlap, to some degree, in distinguishing characters. Taxonomists do not assign an individual to one subspecies or another; instead individuals are assigned a specific taxonomic classification based on the population in which they exist.

The existence of multiple concepts of species and subspecies is not the only complicating factor in the debate surrounding the classification of organisms; it is further complicated by the way organisms occur in the natural world. Taxonomists are determined to categorize natural organisms into specific groups and identify and name those groups, while also striving to understand the evolutionary processes that give rise to these specific groups (Hey 2001, pp. 328–329). When viewed on the ground, a particular organism may appear to clearly fit into one group or another, but when their evolutionary history is viewed, these groups are revealed as changeable and without clear boundaries. In the reverse, individuals may appear different (that is be morphometrically distinct) but in fact be of the same taxon (that is, genetically similar). In many situations, it is difficult to determine where one species ends and another begins. This is especially true in wide-ranging species and in the zones where multiple forms (for example, where either two species or two subspecies) contact each other or meet, which is the situation with wolves in the WGL region. Ultimately, species are evolving, dynamic populations, and at times are difficult to categorize. Nevertheless, Congress directs that the Service classify populations as species, subspecies, and DPSs, despite the difficulty and complexity of various taxonomic concepts.

*Taxonomy of Wolves in the Western Great Lakes Region*

The taxonomic status of the wolves in the western Great Lakes region has long been debated. They have been considered a subspecies of gray wolf, *Canis lupus lycaon* (Goldman 1944), Nowak 1995, 2002, 2003); a *Canis lupus* population that has been influenced by interbreeding with coyotes (Lehman *et al.* 1991); members of a full species, *Canis lycaon* (or eastern wolf) that is separate from *Canis lupus* (Wilson *et al.* 2000, Baker *et al.* 2003); possibly the same species as the red wolf, *C. rufus* (Wilson *et al.* 2000); the result of hybridization between *C. rufus* and *C. lupus* (Nowak 2002, 2003, 2009); and, most recently, as a mixed population of *C. lupus, C. lycaon,* and their intercrosses (for example, Wheeldon and White 2009, Fain *et al.* 2010, Wheeldon *et al.* 2010). These varying interpretations of the taxonomic status of western Great Lakes wolves are summarized, respectively, below.

Wolves in Michigan, Wisconsin, and eastern Minnesota were considered by Goldman (1944, p. 437 and Figure 14) to be within the range of the subspecies *Canis lupus lycaon.* Goldman based his classification on variation in body size and proportions, and in pelage (coat) color. According to Goldman, this was the subspecies of gray wolf historically found across a wide range east of the Mississippi River in the United States and in southeastern Canada. Wolves immediately to the west of the Mississippi River were considered to be part of the subspecies *Canis lupus nubilus.* This taxonomic interpretation was followed by Hall and Kelson (1959, p. 849) and Hall (1981, p. 932).

Nowak's (1995, p. 396; 2003, p. 243) revision of the subspecies taxonomy reduced the range of *C. l. lycaon* to southern Ontario and Quebec and northern portions of New York,

Pennsylvania, and Ohio. Nowak's classification was primarily based on statistical analysis of measurements of skull features. He considered gray wolves that historically occupied Michigan, Wisconsin, and Minnesota to be within the range of *C. l. nubilus.* Based on analysis of additional specimens, Nowak (2002, p. 119; 2003; 2009, p. 238) continued to recognize western Great Lakes wolves as *C. l. nubilus,* but noted that historical specimens from the Upper Peninsula (UP) of Michigan were somewhat transitional between the two subspecies.

Based on a study of DNA variation in North American wolves, Wilson *et al.* (2000, p. 2165) proposed that the taxonomic standing of eastern wolves be restored to full species as *Canis lycaon.* They found that eastern wolves were divergent from *Canis lupus* in both mitochondrial DNA (mtDNA) and autosomal microsatellite DNA composition. They considered the geographic range of *C. lycaon* as extending west across the Great Lakes region to Minnesota and Manitoba.

Leonard and Wayne (2008, pp. 2–3) have reported on maternally inherited mtDNA sequence haplotypes (DNA sequences or groups of alleles of different genes on a single chromosome that are inherited together as a single unit) from historical ("prerecovery") wolves from Ontario, Quebec, Michigan, and Wisconsin compared with the recent population of the area. Their interpretation of these results is that the 6 unique haplotypes) identified in 15 historical individuals indicate that the pre-recovery population was "an endemic American wolf," which they call "the Great Lakes wolf" (p. 1). However, only the two haplotypes most common in the historical sample still occur in the modern wolf population of the western Great Lakes area. Leonard and Wayne (2007) conclude that the modern population does not contain the diversity of Great Lakes wolf haplotypes found in the prerecovery population and that the current population is primarily a mixture of *Canis lupus* and coyote hybrids, with minor influence from the endemic Great Lakes wolf (p. 3).

Koblmüller *et al.* (2009) examined wolves from the western Great Lakes region using three types of genetic markers: mtDNA; Y-chromosome haplotypes based on microsatellite DNA loci on the Y-chromosome, which is a paternally-inherited marker; and autosomal microsatellite DNA, which provides information on recent and ongoing interactions among populations rather than evolutionary lineage information. The historical sample from Minnesota was found to exhibit a third Great Lakes wolf mtDNA haplotype that is common in the modern population. However, the Y-chromosome haplotypes identified in the historical sample were more similar to those of western gray wolves, suggesting that interbreeding between Great Lakes wolves and western gray wolves had taken place before 1910, the year of collection.

Koblmüller *et al.* (2009) conclude that, despite what they consider both ancient and recent incidences of interbreeding with coyotes and western gray wolves, Great Lakes wolves remain morphologically distinct and represent a "distinct taxon" of gray wolf (*Canis lupus*) that is adapted to the region. They do not, however, conclude that this taxon is differentiated enough to be recognized as a species separate from gray wolves, as proposed by Wilson *et al.* (2000).

Several recent studies conclude that the eastern wolf is a unique species and should be recognized as *C. lycaon* (Wheeldon and White 2009; Wilson *et al.* 2009; Fain *et al.* 2010, p. 15; Wheeldon *et al.* 2010). Wheeldon and White (2009, pp. 3–4) state that both the present-day and pre-recovery wolf populations in the western Great Lakes region are genetically similar and that both were derived from hybridization between *C. lupus* and the eastern wolf, *C. lycaon.* Fain *et al.* (2010, p. 10) recognize *C. lycaon* as a unique species of North American wolf, and based on mtDNA and Y-chromosome haplotypes and autosomal microsatellite markers, they establish that the population of wolves in the western Great Lakes region comprise *C. lupus, C. lycaon,* and their hybrids. Contrary to Koblmüller *et al.* (2009), Fain *et al.* (2010, p. 14) found no evidence of interbreeding with coyotes. Furthermore, they conclude that the western Great Lakes States were included in the historical range of *C. lycaon* and that hybridization between the two species "predates significant human intervention" (Fain *et al.* 2010, pp. 13–14).

Wheeldon *et al.* (2010, p. 2) used multiple genetic markers to clarify the taxonomic status of *Canis* species in the western Great Lakes region of Minnesota, Wisconsin, Michigan, and western Ontario. They conclude that the current western Great Lakes wolf population is "composed of gray-eastern wolf hybrids that probably resulted from historic hybridization between the parental species" (Wheeldon *et al.* 2010, p. 10), and that the appropriate taxonomic designation for the western Great Lakes hybrid wolves is *C. lupus* × *lycaon,* replacing Nowak's (2009) wolf subspecies designation of *C. lupus lycaon.* We note, however, that a name in the form of *C. lupus* × *lycaon* has no standing as an available species name under the rules of zoological nomenclature (ICZN 1999).

It is clear from the studies discussed above that the taxonomic classification of wolves in the western Great Lakes region is one that has been, and will continue to be, of great debate in the scientific community. Most researchers, however, appear to agree that there is a unique and genetically identifiable form of wolf that occupies the western Great Lakes region, and that this form has hybridized with *Canis lupus,* whose origins were from elsewhere in North America. Researchers differ in whether this unique form of wolf should be recognized as a species (Wilson *et al.* 2000; Fain *et al.* 2010, p. 15; Wheeldon *et al.* 2010), a subspecies (Nowak 1995), or a distinct taxon or ecotype but without applying a formal scientific name to that form (Koblmüller *et al.* 2009). In choosing among these three alternatives, we find that the large divergence of both mtDNA and Y-chromosome haplotypes between Great Lakes wolves and *C. lupus* is greater than that found between subspecies of *Canis lupus* and favors recognition of the eastern wolf as a species. Currently, the best available scientific information supports recognition of the eastern wolf, *C. lycaon,* as a species (rather than, as previous believed, as a subspecies of gray wolf), and establishes that this species has intercrossed with *C. lupus* in the western Great Lakes region to constitute a population composed of *C. lupus, C. lycaon,* and their hybrids (Wheeldon and White 2009, p. 1; Fain *et al.* 2010, p. 14; Mech *et al.* 2010; Wheeldon *et al.* 2010).

The existence of two wolf species in the western Great Lakes region was not known or suspected in 1978, when the Service replaced the listings of four subspecies of gray wolf, including *C. lupus lycaon,* with the listing of all *Canis lupus* and *Canis lupus* subspecies in the conterminous United States and Mexico as endangered, except for the Minnesota population, which was listed as threatened (USFWS 1978). Since that time, increasingly powerful genetic techniques for the characterization of populations have been developed and applied to wild populations, including wolves. These advances have shown that hybridization between species is much more prevalent than was appreciated in 1978 (Schwenk *et al.* 2011); thus the detection of hybridization in western Great Lakes wolves is not unique among mammalian species.

Nowak's (1995, 2002, 2003) exclusion of the western Great Lakes region from *C. l. lycaon* was likely influenced by his inclusion of both *C. lupus* and *C. lycaon* in his western Great Lakes sample. In any event, the various genetic investigations of western Great Lakes wolves clearly show a distribution of eastern wolf (*C. lycaon*) genetic markers throughout the region.

We do not accept the proposal of Wilson *et al.* (2000) that *C. lycaon* and *C. rufus* (red wolf) are the same species. Their conclusion was based on red wolf and *C. lycaon* occurring on the same branch of a phylogenetic network representing mtDNA differences (Wilson *et al.* 2000, Figure 5A). This relationship has not been found in subsequent studies (Wilson *et al.* 2003; Leonard and Wayne 2008, p. 2; Fain *et al.* 2010, p. 9), which placed the red wolf and *C. lycaon* on different branches separated by intervening coyote lineages. This suggests that the red wolf and *C. lycaon* may have evolved independently from common ancestors with modern coyotes, but does not support uniting them as a single species.

*Genetic Composition of Wolves in the Western Great Lakes Region*

Estimates of the genetic composition of the wolves of the western Great Lakes region with respect to the two species (*C. lupus* and *C. lycaon*) are based on the frequencies of different paternal (Y-chromosome) and maternal (mtDNA) markers specific to the each species in samples of wolves from the region. For mtDNA, 66 percent of sampled wolves had *C. lycaon* haplotypes (Fain *et al.* 2010, p. 13; Wheeldon *et al.* 2010). For Y-chromosome haplotypes, 54 percent (Wheeldon *et al.* 2010) or 50 percent (Fain *et al.* 2010, p. 7) of sampled wolves had haplotypes of *C. lycaon.* Male wolves carry both paternal and maternal markers. Of male wolves sampled by Fain *et al.* (2010, p. 12), 41 percent had both maternal and paternal haplotypes of *C. lycaon,* and 13 percent had both maternal and paternal haplotypes of *C. lupus.* Based on a larger sample that also included some wolves from western Ontario, Wheeldon *et al.* (2010) reported 42 percent of the sampled male wolves had both maternal and paternal haplotypes of *C. lycaon* and 21 percent had both maternal and paternal haplotypes of *C. lupus.* Maternal and paternal haplotypes were mixed with respect to the two species for the remaining wolves in both studies.

Although it is clear that *C. lycaon* and *C. lupus* have hybridized in the western Great Lakes region, same-species combinations of paternal and maternal markers in male wolves are more common than expected by random mating (Wheeldon *et al.* 2010). This suggests that there is some constraint on complete hybridization between the two species and that complete blending of the two components of the population is not inevitable. The limited number of historical specimens from the western Great Lakes region that have been genetically characterized all have mtDNA indicative of *C. lycaon* (Leonard and Wayne 2008, pp. 2–3; Wheeldon and White 2009, p. 1), but four of these from the early 20th century also had *C. lupus* Y-chromosome haplotypes, which indicates that hybridization had occurred by that time. The opportunity for hybridization between *C. lycaon,* which belongs to a North American lineage, and *C. lupus,* which evolved in Eurasia, has existed since *C. lupus* entered North America about 500,000 years ago (Kurtén and Anderson 1980), yet a predominantly *C. lycaon* population of wolves still persists in the western Great Lakes region.

*Wolf-Coyote Relationships*

For a discussion on interpretations of wolf-coyote relationships in the western Great Lakes, see the discussion under Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence in this proposed rule.

*Procedural Aspects of Proposal Applying to the Gray Wolf (C. lupus)*

When the Service revised the endangered species list in 1978 to include the species *Canis lupus* in the lower 48 States and Mexico, regulatory protections were applied to all gray wolves in the lower 48 States, including all subspecies of gray wolves, which were subsumed at that time into *C. lupus.* That rule classified the Minnesota gray wolf population as a threatened "species" and gray wolves elsewhere in the lower 48 States and Mexico as another "species" with endangered status. The best scientific information available supports the existence of distinct taxa and populations within the *C. lupus* listing and changes our understanding of North American wolf taxonomy. With regard to the WGL wolf population, current scientific data indicate that *Canis lycaon,* which was understood in 1978 to be a subspecies of *C. lupus,* should be recognized as a full species, and that *C. lycaon* and *C. lupus* both occur, and to some extent, interbreed in the western Great Lakes area (see *Taxonomy of Wolves in the Western Great Lakes Region*).

The existence of this new information does not by itself change the regulatory status of the gray wolf (*C. lupus*) under the Act—such changes must be made through rulemaking. This proposed rule recognizes the taxonomic changes and the improved status of the WGL gray wolf populations and proposes those appropriate and necessary administrative changes for the gray wolf in the WGL and portions of the eastern United States.

Based on our current understanding of wolf systematics, we recognize that not all individual wolves in the WGL region are in fact, gray wolves, *Canis lupus.* Within this rule we are proposing changes to the listing for *C. lupus* and are initiating a status review for *C. lycaon.* These two actions combined will address all wolves in the WGL region.

The procedural aspects of this proposed rule (*e.g.,* the revision of the 1978 listing of the group of gray wolves in Minnesota as a "species" to a DPS and the delisting of that DPS) refer to the gray wolf (*C. lupus*), because that is the named entity currently on the List of Endangered and Threatened Wildlife. Our proposed action here is to establish the existence of a WGL distinct population segment of *C. lupus* and to determine that the DPS is neither endangered nor threatened, despite its proximity to a closely related species, *C. lycaon*—a species whose status we will evaluate for possible protection under the Act in the near future.

**Biology and Ecology of Wolves in the Western Great Lakes**

Gray wolves are the largest wild members of the Canidae, or dog family, with adults ranging from 18 to 80 kilograms (kg) (40 to 175 pounds (lb)) depending upon sex and subspecies (Mech 1974). The average weight of male wolves in Wisconsin is 35 kg (77 lb) and ranges from 26 to 46 kg (57 to 102 lb), while females average 28 kg (62 lb) and range from 21 to 34 kg (46 to 75 lb) (Wisconsin Department of Natural Resources (WI DNR) 1999). Wolves' fur color is frequently a grizzled gray, but it can vary from pure white to coal black. Wolves may appear similar to coyotes (*Canis latrans*) and some domestic dog breeds (such as the German shepherd or Siberian husky) (*C. lupus familiaris*). Wolves' longer legs, larger feet, wider head and snout, and straight tail distinguish them from both coyotes and dogs.

Wolves primarily are predators of medium and large mammals. Wild prey species in North America include white-tailed deer (*Odocoileus virginianus*) and mule deer (*O. hemionus*), moose (*Alces alces*), elk (*Cervus elaphus*), woodland caribou (*Rangifer caribou*) and barren

ground caribou (*R. arcticus*), bison (*Bison bison*), muskox (*Ovibos moschatus*), bighorn sheep (*Ovis canadensis*) and Dall sheep (*O. dalli*), mountain goat (*Oreamnos americanus*), beaver (*Castor canadensis*), snowshoe hare (*Lepus americanus*), and muskrat (*Ondatra zibethicus*), with small mammals, birds, and large invertebrates sometimes being taken (Chavez and Gese 2005, Mech 1974, Stebler 1944, WI DNR 1999, Huntzinger *et al.* 2005). In the WGL DPS, during the last 25 years, wolves have also killed domestic animals including horses (*Equus caballus*), cattle (*Bos taurus*), sheep (*Ovis aries*), goats (*Capra hircus*), llamas (*Lama glama*), pigs (*Sus scrofa*), geese (*Anser sp.*), ducks (*Anas sp.*), turkeys (*Meleagris gallopavo*), chickens (*Gallus sp.*), guinea fowl (*Numida meleagris*), pheasants (*Phasianus colchicus*), dogs, cats (*Felis catus*), and captive white-tailed deer (Paul 2004, 2005; Wydeven 1998; Wydeven *et al.* 2001; Wydeven and Wiedenhoeft 1999, 2000, 2001, 2005).

Wolves are social animals, normally living in packs of 2 to 12 wolves. Winter pack size in Michigan's Upper Peninsula (UP) averaged from 2.7 to 4.6 wolves during the 1995 through 2005 period and ranged from 2 to 14 wolves per pack (Huntzinger *et al.* 2005). Pack size in Wisconsin is similar, averaging 3.8 to 4.1 wolves per pack, and ranging from 2 to 11 wolves in winter 2004–05 (Wydeven and Wiedenhoeft 2005). In Minnesota the average pack size found in the 1988–89, 1997–98, and 2003–04 winter surveys was higher—5.55, 5.4, and 5.3 wolves per pack, respectively (Erb and Benson 2004).

Packs are primarily family groups consisting of a breeding pair, their pups from the current year, offspring from one or two previous years, and occasionally an unrelated wolf. Packs typically occupy, and defend from other packs and individual wolves, a territory of 20 to 214 square (sq) miles (mi) (50 to 550 sq kilometers (km)). Midwest wolf packs tend to occupy territories on the lower end of this size range. Michigan Upper Peninsula territories averaged 103 sq mi (267 sq km in 2000–01 (Drummer *et al.* 2002), Wisconsin territories 37 sq mi (96 sq km) in 2004–05 (Wydeven and Wiedenhoeft 2005), and Minnesota territory size averaged 39 sq mi (102 sq km) in 2003–04 (Erb and Benson 2004). Normally, only the top-ranking ("alpha") male and female in each pack breed and produce pups. Litters are born from early April into May; they range from 1 to 11 pups, but generally include 4 to 6 pups (Michigan Department of Natural Resources (MI DNR) 1997; USFWS 1992; USFWS *et al.* 2001). Normally a pack has a single litter annually, but the production of 2 or 3 litters in one year has been routinely documented in Yellowstone National Park (USFWS *et al.* 2002; Smith *et al.* 2005).

Yearling wolves frequently disperse from their natal packs, although some remain with their natal pack. Adult wolves and pups older than 5 months also may disperse but at much lower frequencies (Fuller 1989). Dispersers may range over large areas as lone animals after leaving their natal pack or they may locate suitable unoccupied habitat and a member of the opposite sex and begin their own pack. These dispersal movements allow a wolf population to quickly expand and colonize areas of suitable habitat that are nearby or even those that are isolated by a broad area of unsuitable habitat. Additional details on extraterritorial movements are found in *Delineating the Boundaries of the Proposed WGL Gray Wolf DPS,* below.

## Recovery of Western Great Lakes Wolves

### *Recovery Criteria*

Recovery plans are not regulatory documents and are instead intended to provide guidance to the Service, States, and other partners on methods of minimizing threats to listed species and achieving recovery. These documents include, among other elements required under section 4(f) of the Act, criteria for determining when a species can be delisted. There are many paths to accomplishing recovery of a species; in fact, recovery of a species is a dynamic process requiring adaptive management that may, or may not, strictly adhere to the guidance provided in a recovery plan.

We use recovery criteria in concert with evidence that threats have been minimized sufficiently and populations have achieved long-term viability to judge when a species can be reclassified from endangered to threatened or delisted. Recovery plans, including recovery criteria, are subject to change based upon new information and are revised accordingly and when practicable. In a similar sense, implementation of planned actions is subject to changing information and availability of resources. We have taken these considerations into account in the following discussion.

The 1978 Recovery Plan (hereafter Recovery Plan) and the 1992 Revised Recovery Plan for the Eastern Timber Wolf (hereafter Revised Recovery Plan) contain the same two recovery criteria. The first recovery criterion states that the survival of the wolf in Minnesota must be assured. We, and the Eastern Timber Wolf Recovery Team (Peterson in litt. 1997, 1998, 1999a, 1999b), have concluded that this recovery criterion remains valid. It addresses a need for reasonable assurances that future state, Tribal, and Federal wolf management and protection will maintain a viable recovered population of wolves within the borders of Minnesota for the foreseeable future.

The Recovery Plan for the Eastern Timber Wolf was based on the best available information on wolf taxonomy at the time of its original publication and subsequent revision. As discussed above in *Taxonomy of Wolves in the Western Great Lakes Region,* since the publication of those plans, several studies have produced conflicting results regarding the taxonomic identity of the wolf that historically occupied the eastern States. Currently, the Service subscribes to the view that what was formerly recognized as the subspecies *C. lupus lycaon* should be recognized as a unique species, *C. lycaon.* Regardless of its taxonomic identity, however, this recovery program has always focused on recovering the wolf population that survived in, and has expanded outward from, northeastern Minnesota. Thus, the Plans guide our analysis of recovery of the wolves in the western Great Lakes area.

Although the recovery criteria identified in the Recovery Plan predate the scientific field of conservation biology, the conservation principles of representation (conserving the genetic diversity of a taxon), resilience (the ability to withstand demographic and environmental variation), and redundancy (sufficient populations to provide a margin of safety) were incorporated into these criteria. Maintenance of the Minnesota wolf population is vital in terms of representation and resilience, because the remaining genetic diversity of wolves in the eastern United States (other than red wolves) was carried by the several hundred wolves that survived in Minnesota into the early 1970s. The Recovery Team insisted that the remnant Minnesota wolf population be maintained and protected to achieve wolf recovery in the eastern United States. The successful growth of the remnant Minnesota population has maintained and maximized the representation of that genetic diversity among wolves in the WGL. Although the Revised Recovery Plan did not establish a specific numerical criterion for the Minnesota wolf population, it did identify, for planning purposes only, a population goal of 1,251–1,400

animals for that Minnesota population (USFWS 1992, p. 28). A population of this size would increase the likelihood of maintaining its genetic diversity over the long term. This large Minnesota wolf population also provides resiliency to reduce the adverse impacts of unpredictable demographic and environmental events. Furthermore, the Revised Recovery Plan specifies a wolf population that is spread across about 40 percent of Minnesota (Zones 1 through 4) (USFWS 1992, p. 28), adding a geographic component to the resiliency of the Minnesota wolf population.

The second recovery criterion in the Recovery Plan states that at least one viable wolf population should be reestablished within the historical range of the eastern timber wolf outside of Minnesota and Isle Royale, Michigan (USFWS 1992, pp. 24–26). The reestablished population enhances both the resiliency and redundancy of the WGL metapopulation.

The Recovery Plan provides two options for reestablishing this second population. If it is an isolated population, that is, located more than 100 mi (160 km) from the Minnesota wolf population, the second population should consist of at least 200 wolves for at least 5 years, based upon late-winter population estimates, to be considered viable. Late-winter estimates are made at a time when most winter mortality has already occurred and before the birth of pups, thus, the count is made at the annual low point of the population. Alternatively, if the second population is located within 100 mi (160 km) of a self-sustaining wolf population (for example, the Minnesota wolf population), it should be maintained at a minimum of 100 wolves for at least 5 years, based on late-winter population estimates, to be considered viable. A nearby second population would be considered viable at a smaller size because it would be geographically close enough to exchange wolves with the Minnesota population (that is, they would function as a metapopulation), thereby bolstering the smaller second population both genetically and numerically.

The original Recovery Plan did not specify where in the eastern United States the second population should be re-established. Therefore, the second population could have been established anywhere within the triangular Minnesota–Maine–Florida area covered by the Recovery Plan and the Revised Recovery Plan, except on Isle Royale (Michigan) or within Minnesota. The Revised Recovery Plan identified potential gray wolf reestablishment areas in northern Wisconsin, the UP of Michigan, the Adirondack Forest Preserve of New York, a small area in eastern Maine, and a larger area of northwestern Maine and adjacent northern New Hampshire (USFWS 1992, pp. 56–58). Neither the 1978 nor the 1992 recovery criteria suggest that the restoration of the gray wolf throughout all or most of what was thought to be its historical range in the eastern United States, or to all of these potential re-establishment areas, is necessary to achieve recovery under the Act.

In 1998, the Eastern Timber Wolf Recovery Team clarified the application of the recovery criterion for the second population to the wolf population that had developed in northern Wisconsin and the adjacent UP of Michigan. This second population is less than 100 mi (160 km) from the Minnesota wolf population. The Recovery Team recommended that the numerical recovery criterion for the Wisconsin–Michigan population be considered met when consecutive late-winter wolf surveys document that the population equals or exceeds 100 wolves (excluding Isle Royale wolves) for the 5 consecutive years between the first and last surveys (Peterson in litt. 1998).

*Recovery Trends for Wolves in the Western Great Lakes Region*

Minnesota Recovery

During the pre-1965 period of wolf bounties and legal public trapping, wolves persisted in the remote northeastern portion of Minnesota but were eliminated from the rest of the State. Estimated numbers of Minnesota wolves before their listing under the Act in 1974 include 450 to 700 wolves in 1950–53 (Fuller *et al.* 1992, p. 43, based on data in Stenlund 1955, p. 19), 350 to 700 wolves in 1963 (Cahalane 1964, p. 10), 750 wolves in 1970 (Leirfallom 1970, p. 11), 736 to 950 wolves in 1971–72 (Fuller *et al.* 1992, p. 44), and 500 to 1,000 wolves in 1973 (Mech and Rausch 1975, p. 85). Although these estimates were based on different methodologies and are not directly comparable, each puts the pre-listing abundance of wolves in Minnesota at 1,000 or less. This was the only significant wolf population in the United States outside Alaska during those time periods.

After the gray wolf was listed as endangered under the Act in 1974, the Minnesota population estimates increased (see table 1 below). Mech estimated the population to be 1,000 to 1,200 wolves in 1976 (USFWS 1978, pp. 4, 50–52), and Berg and Kuehn (1982, p. 11) estimated that there were 1,235 wolves in 138 packs in the winter of 1978–79. In 1988–89, the Minnesota Department of Natural Resources (MN DNR) repeated the 1978–79 survey and also used a second method to estimate wolf numbers in Minnesota. The resulting independent estimates were 1,500 and 1,750 wolves in at least 233 packs; the lower number was derived by a method comparable to the 1978–79 survey (Fuller *et al.* 1992, pp. 50–51).

During the winter of 1997–98, the MN DNR repeated a statewide wolf population and distribution survey, using methods similar to those of the two previous surveys. Field staff of Federal, State, Tribal, and county land management agencies and wood products companies were queried to identify occupied wolf range in Minnesota. Data from 5 concurrent radio telemetry studies tracking 36 packs, representative of the entire Minnesota wolf range, were used to determine average pack size and territory area. Those figures were then used to calculate a statewide estimate of wolf and pack numbers in the occupied range, with single (non-pack) wolves factored into the estimate (Berg and Benson 1999, pp. 1–2).

TABLE 1—MINIMUM WINTER WOLF POPULATIONS IN MINNESOTA, WISCONSIN, AND MICHIGAN (EXCLUDING ISLE ROYALE) FROM 1976 THROUGH 2010. (NOTE THAT THERE ARE SEVERAL YEARS BETWEEN THE FIRST THREE ESTIMATES. MINNESOTA DOES NOT CONDUCT ANNUAL SURVEYS.)

| Year | Number of wolves | | | |
|---|---|---|---|---|
| | Minnesota | Wisconsin | Michigan | Wisconsin and Michigan total |
| 1976 | 1,000–1,200 | | | |
| 1978–79 | 1,235 | | | |
| 1988–89 | 1,500–1,750 | 31 | 3 | 34 |

TABLE 1—MINIMUM WINTER WOLF POPULATIONS IN MINNESOTA, WISCONSIN, AND MICHIGAN (EXCLUDING ISLE ROYALE) FROM 1976 THROUGH 2010. (NOTE THAT THERE ARE SEVERAL YEARS BETWEEN THE FIRST THREE ESTIMATES. MINNESOTA DOES NOT CONDUCT ANNUAL SURVEYS.)—Continued

| Year | Number of wolves | | | |
|---|---|---|---|---|
| | Minnesota | Wisconsin | Michigan | Wisconsin and Michigan total |
| 1989–90 | | 34 | 10 | 44 |
| 1990–91 | | 40 | 17 | 57 |
| 1991–92 | | 45 | 21 | 66 |
| 1992–93 | | 40 | 30 | 70 |
| 1993–94 | | 57 | 57 | 114 |
| 1994–95 | | 83 | 80 | 163 |
| 1995–96 | | 99 | 116 | 215 |
| 1996–97 | | 148 | 113 | 261 |
| 1997–98 | 2,445 | 180 | 139 | 319 |
| 1998–99 | | 205 | 169 | 374 |
| 1999–2000 | | 248 | 216 | 464 |
| 2000–01 | | 257 | 249 | 506 |
| 2001–02 | | 327 | 278 | 604 |
| 2002–03 | | 335 | 321 | 656 |
| 2003–04 | 3,020 | 373 | 360 | 733 |
| 2004–05 | | 435 | 405 | 840 |
| 2005–06 | | 467 | 434 | 899 |
| 2006–07 | | 546 | 509 | 1,055 |
| 2007–08 | 2,921 | 549 | 520 | 1,069 |
| 2008–09 | | 637 | 577 | 1,214 |
| 2009–10 | | 690 | 557 | 1,247 |

The 1997–98 survey concluded that approximately 2,445 wolves existed in about 385 packs in Minnesota during that winter period (90 percent confidence interval from 1,995 to 2,905 wolves) (Berg and Benson 1999, p. 4). This figure indicated the continued growth of the Minnesota wolf population at an average rate of about 3.7 percent annually from 1970 through 1997–98. Between 1979 and 1989 the annual growth rate was approximately 3 percent, and it increased to between 4 and 5 percent in the next decade (Berg and Benson 1999, p. 5; Fuller *et al.* 1992, p. 51). As of the 1998 survey, the number of Minnesota wolves had reached approximately twice the number specified in the recovery planning goal for Minnesota (USFWS 1992, p. 28).

Minnesota DNR conducted another survey of the State's wolf population and range during the winter of 2003–04, again using methodology similar to the previous surveys. That survey concluded that an estimated 3,020 wolves in 485 packs occurred in Minnesota (90 percent confidence interval for this estimate is 2,301 to 3,708 wolves) (Erb and Benson 2004, pp. 7, 9). The MN DNR conducted its most recent survey of wolf population and range during the winter of 2007–08. That survey concluded that an estimated 2,921 wolves in 503 packs occurred in Minnesota (90 percent confidence interval for this estimate is 2,192 to 3,525 wolves). The results of the past three surveys suggest that the wolf population has been numerically stable over the past 10 or more years (Erb 2008, p. 6).

As wolves increased in abundance in Minnesota, they also expanded their distribution. During 1948–53, the primary wolf range was estimated at 11,954 sq mi (31,080 sq km) (Stenlund 1955, p. 19). A 1970 questionnaire survey in Minnesota resulted in an estimated wolf range of 14,769 sq mi (38,400 sq km) (calculated by Fuller *et al.* 1992, p. 43, from Leirfallom 1970). Fuller *et al.* (1992, p. 44), using data from Berg and Kuehn (1982), estimated that Minnesota primary wolf range encompassed 14,038 sq mi (36,500 sq km) during the winter of 1978–79. By 1982–83, pairs or breeding packs of wolves were estimated to occupy an area of 22,000 sq mi (57,050 sq km) in northern Minnesota (Mech *et al.* 1988, p. 86). That study also identified an additional 15,577 sq mi (40,500 sq km) of peripheral range, where habitat appeared suitable but no wolves or only lone wolves existed. The 1988–89 study produced an estimate of 23,165 sq mi (60,200 sq km) as the contiguous wolf range at that time in Minnesota (Fuller *et al.* 1992, pp. 48–49; Berg and Benson 1999, p. 3, 5), an increase of 65 percent over the primary range calculated for 1978–79.

The 1997–98 study concluded that the contiguous wolf range had expanded to 33,971 sq mi (88,325 sq km), a 47 percent increase in 9 years (Berg and Benson 1999, p. 5). By that time the Minnesota wolf population was using most of the available primary and peripheral range identified by Mech *et al.* (1988, p. 86). The wolf population in Minnesota had increased in abundance and distribution to the point that its contiguous range covered approximately 40 percent of the State during 1997–98. In contrast, the 2003–04 survey failed to show a continuing expansion of wolf range in Minnesota, and any actual increase in wolf numbers since 1997–98 was attributed to increased wolf density within a stabilized range (Erb and Benson 2004, p. 7). The results of the 2007–08 survey also indicated that wolf range in Minnesota remained "essentially unchanged" since 2004 (Erb 2008, not paginated).

Although the Minnesota DNR does not conduct a formal wolf population survey annually, it includes the species in its annual carnivore track survey. This survey, standardized and operational since 1994, provides an annual index of abundance for several species of large carnivores by counting their tracks along 20-mile (32-km) long standardized survey routes in northern Minnesota. In 2009, wolves were detected on 71 percent of the 58 routes surveyed, and the resulting indices of abundance and distribution were not appreciably different from recent years (Erb 2009, not paginated).

Summary for Minnesota

The Minnesota wolf population has increased from an estimated 1,000 individuals in 1976 to nearly 3,000 today and the estimated wolf range in the State has expanded by approximately 225 percent (from approximately 15,000 sq mi (24,100 sq km) to approximately 34,000 sq mi (54,700 sq km)) since 1970. Over the past 10–12 years, the population size and range have remained stable, as most of the primary and peripheral habitat has been occupied. Based on the current abundance and distribution of the Minnesota wolf population, we believe its continued survival is ensured, and it achieves the first recovery criterion of the Revised Recovery Plan.

Wisconsin Recovery

Wolves were considered to have been extirpated from Wisconsin by 1960. No formal attempts were made to monitor the State's wolf population from 1960 through 1978. Although individual wolves and an occasional wolf pair were reported from 1960 through 1975, (Thiel 1978, Thiel 1993), there was no documentation of wolf reproduction occurring in Wisconsin, and the wolves that were reported may have been dispersing animals from Minnesota.

Wolves are believed to have reestablished breeding packs in Wisconsin in the winter of 1975–76. The Wisconsin Department of Natural Resources (WI DNR) began wolf population monitoring in 1979–80, estimating a statewide population of 25 wolves at that time (Wydeven and Wiedenhoeft 2000, pp. 151, 159; Wydeven *et al.* 2009c, pp. 93–97). This population remained relatively stable for several years, and then declined to approximately 15 to 19 wolves in the mid-1980s. In the late 1980s, the Wisconsin wolf population began an increase that has continued into 2010, when 690 wolves were counted (Wydeven *et al.* 2010, Figure 3).

Since 1979, WI DNR has intensively surveyed its wolf population on an annual basis using a combination of aerial, ground, and satellite radio telemetry complemented by snow tracking and wolf sign surveys (Wydeven *et al.* 2006a, pp. 4–5; Wydeven *et al.* 2009c, pp. 90–91). Wolves are trapped from May through September and fitted with radio collars, with a goal of having at least one radio collared wolf in approximately half of the wolf packs in Wisconsin. Aerial locations are obtained from each functioning radio collar about once per week, and pack territories are estimated and mapped from the movements of the individuals who exhibit localized patterns. From December through March, the pilots make special efforts to visually locate and count the individual wolves in each radio-tracked pack.

Snow tracking is used to supplement the information gained from aerial sightings and to provide pack size estimates for packs lacking a radio-collared wolf. Tracking is done by assigning survey blocks to trained trackers, who then drive snow-covered roads in their blocks and follow all wolf tracks they encounter. Snowmobiles are used to locate wolf tracks in more remote areas with few roads. The results of the aerial and ground surveys are carefully compared to properly separate packs and to avoid over-counting (Wydeven *et al.* 2006a, pp. 4–5). The estimated number of wolves in each pack is based on the aerial and ground observations made of the individual wolves in each pack over the winter.

Because the monitoring methods focus on wolf packs, lone wolves are likely undercounted in Wisconsin. As a result, the annual population estimates are probably slight underestimates of the actual wolf population within the State during the late-winter period. Fuller (1989, p. 19) noted that lone wolves are estimated to compose from 2 to 29 percent of the total population in the area. Wisconsin DNR surveys have estimated 2–15 percent of the winter population as loners (Wydeven *et al.* 2009c, p. 96). These surveys, however, are focused on heavily forested portions of northern and central Wisconsin; therefore, dispersing wolves traveling other portions of the State are less likely to be detected, and often such wolves are only documented after vehicle collisions or accidental shootings. Broader use of trail cameras by members of the public is improving the WI DNR's ability to detect lone wolves across the State.

As previously stated, population estimates are made at the low point of the annual wolf population cycle. Thus, Wisconsin wolf population estimates are conservative in two respects. They undercount lone wolves, and the count is made at the annual low point of the population. This methodology is consistent with the recovery criteria established in the Revised Recovery Plan, which established numerical criteria to be measured with data obtained by late-winter surveys. Based on these considerations, an estimated 690 to 733 wolves in 181 packs, including 35 wolves on Native American reservations, were in Wisconsin in early 2010, representing an 8 percent increase from 2009 (Wydeven *et al.* 2010, pp. 12–13).

In the winter of 1994–95, wolves were first documented in Jackson County, Wisconsin, well to the south of the area occupied by other Wisconsin wolf packs in the northern part of the State (Thiel *et al.* 2009, pp. 109–110). The number of wolves in this central Wisconsin area has dramatically increased since that time. During the winter of 2009–10, there were 100–106 wolves in 25 packs in the central forest wolf range (Zone 2 in the Wisconsin Wolf Management Plan; Wydeven *et al.* 2010, p. 5) and an additional 46 to 48 wolves in 12 or 13 packs in the marginal habitat in Zone 3, located between Zone 1 (northern forest wolf range) and Zones 2 and 4 (Wydeven *et al.* 2010, p. 5).

During the winter of 2004–05, 11 to 13 wolves were believed to be primarily occupying Native American reservation lands in Wisconsin (Wydeven in litt. 2005); this increased to 16 to 17 in 2005–06, 17 to 19 in 2007–08 (Wydeven and Wiedenhoeft 2008, Summary), approximately 27 in 2008–2009 (Wydeven and Wiedenhoeft 2008, p. 1), and approximately 35 in 2009–10 (Wydeven *et al.* 2010, p. 1). The 2009–10 survey consisted of 3 packs totaling 10–11 wolves on the Bad River Chippewa Reservation and a pack of 2 wolves on the Lac Courtes Oreilles Chippewa Reservation, both in northwestern Wisconsin. There also were two packs of five wolves each on the Lac du Flambeau Reservation in north-central Wisconsin. A pack of four wolves and three pairs occurred on the Menominee Reservation and a three-wolf pack occurred on the Stockbridge Reservation, both in northeastern Wisconsin (Wydeven *et al.* 2010, Table 6). A pack of four to five wolves spent time on portions of the Red Cliff Chippewa Reservation along the Lake Superior shoreline. Wolf packs also used scattered lands of the St. Croix Chippewa in northwest Wisconsin, the Ho Chunk Nation in central Wisconsin, and Potawatomi in northeast Wisconsin. The Tribal land of the Ho-Chunk, St. Croix Chippewa, and Potawatomi are composed mostly of scattered parcels of land, and are not likely to provide significant amounts of wolf habitat. About 90 percent of packs in northern Wisconsin Zone 1, and northern portions of Zone 3 are located in ceded territory where Chippewa Bands have retained hunting and gathering rights.

In 2002, wolf numbers in Wisconsin alone surpassed the 1992 Revised Recovery Plan criterion for a second population within 100 miles of the Minnesota population (100 wolves for a minimum of 5 consecutive years (USFWS 1992, p. 4)). Furthermore, in 2004, Wisconsin wolf numbers

exceeded the 1992 recovery criterion of 200 animals for 6 successive late-winter surveys for an isolated wolf population (USFWS 1992, p. 4). Wisconsin population estimates for 1985 to 2010 increased from 15 to 690 wolves (see table 1 above) and from 4 to 181 packs (Wydeven *et al.* 2010, figure 3). This represents an annual population increase of 21 percent through 2000, and an average annual increase of 6 percent for the most recent 6 years. The slower rates of increase since 2000 are an indication that the State's wolf population growth and geographic expansion are beginning to level off.

Michigan Recovery

Except for Isle Royale, wolves were extirpated from Michigan as a reproducing species long before they were listed as endangered under the Act in 1974. Prior to 1989, the last known breeding population of wild Michigan wolves outside Isle Royale occurred in the mid-1950s. However, as wolves began to reoccupy northern Wisconsin, the Michigan Department of Natural Resources (MI DNR) began noting single wolves at various locations in the UP of Michigan. Wolf recovery in Michigan began with the documentation of three wolves traveling together and making territorial marks in the central UP during the fall of 1988; and the subsequent birth of pups in this territory during spring 1989 (Beyer *et al.* 2009, p. 73). Since that time, wolf packs have spread throughout the UP, with immigration occurring from Wisconsin on the west and possibly from Ontario on the east. Wolves now are found in every county of the UP, with the possible exception of Keweenaw County (Huntzinger *et al.* 2005, p. 6; Roell 2009, pers. comm.).

The MI DNR annually monitors the wolf population in the UP by conducting a winter survey. Roads and trails are searched intensively and extensively for wolf tracks and other wolf sign using trucks and snowmobiles (Potvin *et al.* 2005). Complete surveys conducted from 1999 to 2006 provided an opportunity to evaluate multiple sampling approaches (MI DNR 2008). Based on these evaluations, it was determined that a geographically stratified sampling protocol produced unbiased, precise estimates of wolf abundance (Potvin *et al.* 2005; Drummer, unpublished data). The sampling protocol implemented in 2007 allows trackers to spend more time in smaller areas (MI DNR 2008).

The UP is divided into 21 survey units from which a stratified random sample is drawn, covering roughly 50 percent of the UP every year (MI DNR 2008). Pack locations are derived from previous surveys, citizen reports, and extensive ground and aerial tracking of radio-collared wolves. During the winter of 2009–10, 557 wolves in 109 packs were resident in the UP (MI DNR in litt. 2010, Table 1). Surveys along the border of adjacent survey units are coordinated to avoid double counting of wolves and packs occupying those border areas. In areas with a high density of wolves, ground surveys by four to six surveyors with concurrent aerial tracking are used to accurately delineate territories of adjacent packs and count their members (Beyer *et al.* 2004, pp. 2–3; Huntzinger *et al.* 2005, pp. 3–6; Potvin *et al.* 2005, p. 1661). As with Wisconsin, the Michigan surveys likely miss lone wolves, thus underestimating the actual population.

Based on annual surveys in late winter, estimates of wolves in the UP increased from 57 wolves in 1994 to 557 in late winter 2009–10 (see table 1 above). Over the last 10 years, the annualized rate of increase has been about 12 percent (MI DNR in litt. 2010, table 1). This rate has varied from year to year, but there appear to be two distinct phases of population growth, with relatively rapid growth (25.8 percent average) from 1995 through 2000 and slower growth (10.1 percent average) from 2001 through 2010. In 2005, the number of wolves in the Michigan population alone surpassed the recovery criterion for an isolated wolf population of 200 animals for 6 successive late-winter surveys, as specified in the Revised Recovery Plan (USFWS 1992, pp. 24–26).

To date, no wolf packs are known to be primarily using Tribal-owned lands in Michigan (Roell 2011, pers. comm.). Native American Tribes in the UP of Michigan own small, scattered parcels of land relative to the size of wolf pack territories. Thus, no one Tribal property would likely support a wolf pack. However, as wolves occur in all counties in the UP and are wide-ranging, Tribal land is likely used periodically by wolves.

In October 2004, a coyote trapper mistakenly captured and killed a wolf in Presque Isle County in the northern Lower Peninsula (LP) of Michigan. This was the first verification of a wolf in the northern LP in at least 65 years (Roell *et al.* 2010, p. 4). This wolf had been trapped and radio-collared by the MI DNR the previous year (2003) while it was a member of an eastern UP pack. Since 2004, Michigan has surveyed the northern LP to determine whether wolves had successfully colonized the area. From 2005 through 2007, the survey had two components: A prioritized area search and a targeted area search based on citizen reports of wolves or wolf sign. USDA–Wildlife Services, Little Traverse Bay Band of Odawa Indians, and Central Michigan University worked cooperatively on the surveys. Nine units ranging in size from 200–400 sq mi (322–644 sq km) were surveyed; however, no wolf sign was found (Roell *et al.* 2010, p. 4). Beginning in 2008, a targeted search approach was used. The MI DNR issued a press release asking citizens to report any wolves or wolf sign; again, no wolves were detected in winters of 2008–10 (Roell *et al.* 2009, p. 5; Roell 2010, pers. comm.).

In the summer of 2009, video images of single wolves were recorded in two of the three northern LP counties nearest to the UP (Roell *et al.* 2010, p. 4). The videos, taken in Emmet County in May 19, 2009, and Presque Isle County in July 27, 2009, may have been of the same animal (Roell 2009, pers. comm.). In 2010, USDA Wildlife Services and MI DNR staff confirmed a single breeding pair with three pups in Cheboygan County in the northern LP (MI DNR 2010). This is the first time a wolf pack has been verified in the LP since the early 1900s. In 2008, the DNR recognized the likelihood that small numbers of wolves would eventually move into the northern LP and form persistent packs (Potvin 2003, pp. 29–30; Gehring and Potter 2005, p. 1242; Beyer *et al.* 2006, p. 35), and revised its Wolf Management Plan in part to incorporate provisions for wolf management in the northern LP (MI DNR 2008a, p. 46).

The wolf population of Isle Royale National Park, Michigan, is not considered to be an important factor in the recovery of wolves in the WGL. The Park population is small and isolated and lacks genetic uniqueness (Wayne *et al.* 1991, pp. 47–49). In addition, this island population probably has not had any contact with mainland wolf populations since its founding pair crossed the Lake Superior ice in the late 1940s (Peterson *et al.* 1998, p. 828). For genetic reasons and constraints on expansion due to the island's small size, this wolf population does not contribute significantly towards meeting numerical recovery criteria; however, long-term research on this wolf population has added a great deal to our knowledge of the species. The wolf population on Isle Royale has ranged from 12 to 50 wolves since 1959, and was 19 wolves in the winter of 2009–2010 (Vucetich and Peterson 2010, p. 5).

Summary for Wisconsin and Michigan

The two-State wolf population, excluding Isle Royale wolves, has

exceeded 100 wolves since late-winter 1993–94 and has exceeded 200 wolves since late-winter 1995–96. Therefore, the combined wolf population for Wisconsin and Michigan has exceeded the second recovery criterion of the 1992 Revised Recovery Plan for a nonisolated wolf population, since 1999. Furthermore, the two-State population has exceeded the recovery criterion for an isolated second population since 2001.

Other Areas In and Near the Proposed Western Great Lakes DPS

No surveys have been conducted to document the number of wolves present in North Dakota or South Dakota, but an increasing number of wolves has apparently been detected in the eastern portions of these States. The eastern boundaries of North Dakota and South Dakota are approximately 19 and 81 mi (30 and 130 km), respectively, from occupied habitat in Minnesota. Biologists who are familiar with wolves in these States, however, generally agree that the wolves found there are primarily lone dispersers, although there were reports of pups being seen in the Turtle Mountains of North Dakota, in 1994 (Collins in litt. 1998).

Other records include an adult male shot near Devil's Lake, North Dakota in 2002, another adult male shot in Richland County in extreme southeastern North Dakota in 2003 (Fain in litt. 2006), and a vehicle-killed adult male found near Sturgis, South Dakota, in 2006 (Larson in litt. 2006). In contrast to the other South Dakota wolves of the last 25 years, the animal found near Sturgis was genetically identified as having come from the Greater Yellowstone area (Fain in litt. 2006). Most recently, a wolf was shot in Roberts County, South Dakota in January 2009 (reportedly running with two or three other wolves) (Prieksat in litt. 2009), and another wolf was found dead in a foothold trap that was set as part of an ongoing USDA Wildlife Service's coyote control operation in southeastern Eddy County, North Dakota (Bicknell in litt. 2009). See *Delineating the Boundaries of the Proposed WGL Gray Wolf DPS* in this proposed rule for a detailed discussion of movement of wolves.

Wolf dispersal is expected to continue as wolves travel away from the more saturated habitats in the primary range into peripheral areas where wolves are extremely sparse or absent. Unless they return to the primary range and join or start a pack there, they are unlikely to contribute to long-term maintenance of WGL wolf populations.

Although it is possible for these dispersers to encounter and mate with a mature wolf outside the primary range, the lack of large expanses of unfragmented habitat make it unlikely that wolf packs will persist in these peripheral areas; lack of contiguous habitat is expected to seriously impede further expansion. The only exception is the northern LP of Michigan, where several studies indicate that a persistent wolf population may develop (Gehring and Potter 2005, p. 1242; Potvin 2003, pp. 29–30), albeit dependent on occasional to frequent immigration of UP wolves. Despite the constraints on further expansion described here, however, current wolf populations in Minnesota, Wisconsin, and the UP of Michigan have already greatly exceeded the recovery levels defined in the 1992 Revised Recovery Plan, and maintenance of these numbers is not contingent on recruitment of wolves from areas outside the primary range that has been established for the WGL.

*Summary of Wolf Recovery in the Western Great Lakes Region*

Wolves in the proposed WGL DPS greatly exceed the recovery criteria (USFWS 1992, pp. 24–26) for (1) a secure wolf population in Minnesota, and (2) a second population outside Minnesota and Isle Royale consisting of 100 wolves for 5 successive years. Based on the criteria set by the Eastern Wolf Recovery Team in 1992 and reaffirmed in 1997 and 1998 (Peterson in litt. 1997, in litt. 1998), the proposed DPS contains sufficient wolf numbers and distribution to ensure their long-term survival within the DPS.

The maintenance and expansion of the Minnesota wolf population has maximized the preservation of the genetic diversity that remained in the proposed WGL DPS when its wolves were first protected in 1974. Furthermore, the Wisconsin–Michigan wolf population has exceeded the numerical recovery criterion even for a completely isolated second population. Therefore, even in the unlikely event that this two-State population was to become totally isolated and wolf immigration from Minnesota and Ontario completely ceased, it would still remain a viable wolf population for the foreseeable future, as defined by the Revised Recovery Plan (USFWS 1992, pp. 25–26). Finally, each of the wolf populations in Wisconsin and Michigan has exceeded 200 animals for 11 and 10 years, respectively, so if either were somehow to become isolated, they would remain viable, and each State has committed to manage its wolf population at or above viable population levels. The wolf's numeric and distributional recovery criteria in the WGL have been met.

*Have the Wolves of the Western Great Lakes Region Been Restored?*

Leonard and Wayne (2008, p. 3) have stated that Great Lakes wolves have not been restored based on absence of certain historical mtDNA haplotypes from the current population, an estimated historical population size far greater than the current population size, and the admixture of coyote and western wolf haplotypes in the current population.

The spatial representativeness of both the historical and recent samples reported by Leonard and Wayne (2008) has been questioned by Mech (2009). For example, 16 recent but no historical samples from Minnesota were included in the study. Leonard and Wayne (2009) responded that they did not believe that genetic differences were likely to be pronounced at the geographic scale discussed by Mech and Paul (2008) and Mech (2009).

The current population of wolves in Minnesota, Wisconsin, and Michigan is derived from expansion of the remnant population in northeastern Minnesota (Fain *et al.* 2010, p. 12), which was likely to have included both *C. lupus* and *C. lycaon* (Mech and Frenzel 1971; Mech 2010, p. 135), and in the case of UP Michigan, with possible contributions from *C. lycaon* from southern Ontario (Fain *et al.* 2010, p. 12).

Subsequent studies with larger samples of the current wolf population find, despite acknowledged influence of western wolves, the current population is generally representative of the historical population (Fain *et al.* 2010, p. 14; Wheeldon *et al.* 2010). Koblmüller *et al.* (2009, pp. 10–11) found "comparatively slight" differentiation at autosomal microsatellite DNA loci between historical and current Great Lakes wolves. Wheeldon and White (2009, p. 4) present microsatellite DNA evidence that the hybridization processes noted by Leonard and Wayne (2008) were taking place over a century ago, so that the current population is comparable to the historical population with respect to admixture. Hybridization between eastern wolves and western wolves in the western Great Lakes region occurred prior to significant human effects on population size or habitat (Fain *et al.* 2010, p. 14). According to Fain *et al.* (2010, p. 14), the current population of wolves in the western Great Lakes "represents an ancient component of the northeast ecosystem and have been

established throughout the region for thousands of years."

The loss of mtDNA haplotypes found in historical but not the current western Great Lakes wolf population reported by Leonard and Wayne (2008, pp. 2–3) and the loss of allelic diversity (Fain *et al.* 2010, p. 11), indicate that a genetic bottleneck occurred when wolves were nearly extirpated from the western Great Lakes region and the period of slow recovery that immediately followed. Despite these "founder effects" on the genetic composition of the western Great Lakes population, various measures of genetic diversity remain comparable to other wolf populations (Koblmüller *et al.* 2009; Fain *et al.* 2010, p. 12; Wheeldon *et al.* 2010), at least partially owing to contributions from western wolves (*C. lupus*).

Wolves in the WGL region display a healthy level of heterozygosity (Fain *et al.* 2010, p. 12), and show no evidence of genetic bottlenecks (Koblmuller *et al.* 2009, p. 1). Schwartz and Vucetich (2009, p. 2) have stated that "By all accounts, the return of wolves to the Great Lakes region has been successful * * * they are doing superbly—both in terms of population viability and ecological function." Cronin and Mech (2009, p. 2) state, "We suggest that wolves in the [W]GL region can simply be called a wolf population with mixed ancestry." They further state that, "It is generally acknowledged that the Great Lakes wolf population is fit, with abundant genetic variation" (Cronin and Mech 2009, p. 2).

**Distinct Vertebrate Population Segment Policy Overview**

Pursuant to the Act, we consider whether information is sufficient to indicate that listing, reclassifying, or delisting any species, subspecies, or, for vertebrates, any DPS of these taxa may be warranted. To interpret and implement the DPS provision of the Act and congressional guidance, the Service and the National Marine Fisheries Service (NMFS) published a policy regarding the identification of distinct vertebrate population segments under the Act (Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act, 61 FR 4722, February 7, 1996) (hereafter DPS Policy). Under the DPS policy, two factors are considered in a decision regarding the potential identification of a DPS: (1) Discreteness of the population segment in relation to the remainder of the taxon, and (2) the significance of the population segment to the taxon to which it belongs. If a population meets both tests, it can be identified as a DPS. Then a third factor, the DPS's conservation status, is evaluated in relation to the Act's standards for listing, delisting, or reclassification, meaning that we undertake an analysis to determine whether the DPS is endangered or threatened or does not meet the criteria for listing. All three steps are necessary components of a complete DPS analysis.

**Past Practice and History of Using DPSs**

As of February 1, 2011, of the 392 native vertebrate listings, 85 are listed as less than an entire taxonomic species or subspecies (henceforth referred to in this discussion as populations) under one of several authorities, including the "distinct population segment" language in the Act's definition of species (section 3(16)). Thirty-three of these 85 populations, which span 52 different taxa, predate the 1996 DPS Policy; as such, the final listing determinations for these populations did not include formal policy-based analyses or expressly designate the listed entity as a DPS. In several instances, however, the Service and National Marine Fisheries Service (NMFS) have established a DPS and revised the List of Endangered and Threatened Wildlife in a single action, as shown in the following examples.

In February 1985, the Service delisted the brown pelican (*Pelecanus occidentalis*) in the southeastern United States and continued to identify it as endangered throughout the remainder of its range (50 FR 4938). In June 1994, NMFS revised the entry for the gray whale (*Eschrichtius robustus*) to remove the eastern North Pacific population from the List while retaining the western North Pacific population as endangered (59 FR 31094). In July 2003, the Service established two DPSs of the Columbian white-tailed deer (*Odocoileus virginianus leucurus*)—the Douglas County DPS and the Columbia River DPS—and delisted only the Douglas County DPS, while listing the Columbia River DPS (68 FR 43647). In March 2007, the Service established a DPS of the grizzly bear (*Ursus arctos horribilis*) for the Greater Yellowstone Area and surrounding area within the existing grizzly bear listing in the lower 48 States, and delisted this DPS (72 FR 14865). Also in March 2007, the Service identified the American crocodile (*Crocodylus acutus*) in Florida as a DPS within the existing endangered listing of the American crocodile in the United States and reclassified the Florida DPS from endangered to threatened (71 FR 13027). Revising and delisting the WGL DPS of wolves is consistent with the Service's past practice and does not represent a change in agency position.

**Proposed Western Great Lakes Distinct Population Segment**

In 1978, based on what was at that time the "best available biological data," the Service stated that there were two "species" of gray wolves in the conterminous United States: "For purposes of this rulemaking, the gray wolf (*Canis lupus*) group in Mexico and the 48 conterminous States of the United States, other than Minnesota, is being considered as one "species," and the gray wolf group in Minnesota is being considered as another "species." (43 FR 9607, 9610, March 9, 1978). The Service then assigned a different status under the Act to each of those two "species," finding the Minnesota gray wolf "species" to be threatened, while the other gray wolf "species" (the 48 conterminous States, except Minnesota, and in Mexico) to be endangered. The 1978 rule referred to the Minnesota listing as the listing of a "species" when, clearly, based on the information available at that time, the Minnesota wolves did not taxonomically constitute a separate species of wolf. Therefore, the 1978 listing either effectively established a Minnesota DPS or listed an entity in a portion of its broader range.

The DPS Policy (61 FR 4725, February 7, 1996) expressly provides for reexamining pre-policy DPS listings: "Any DPS of a vertebrate taxon that was listed prior to implementation of this policy will be reevaluated on a case-by-case basis as recommendations are made to change the listing status for that distinct population segment. The appropriate application of the policy will also be considered in the 5-year reviews of the status of listed species required by section 4(c)(2) of the Act." Based on this provision, we are, within this proposed rule, (1) recognizing that a Minnesota DPS was established in 1978, (2) reevaluating that DPS listing, and (3) proposing to revise that DPS to meet the criteria in the DPS policy and to reflect the "best available biological data."

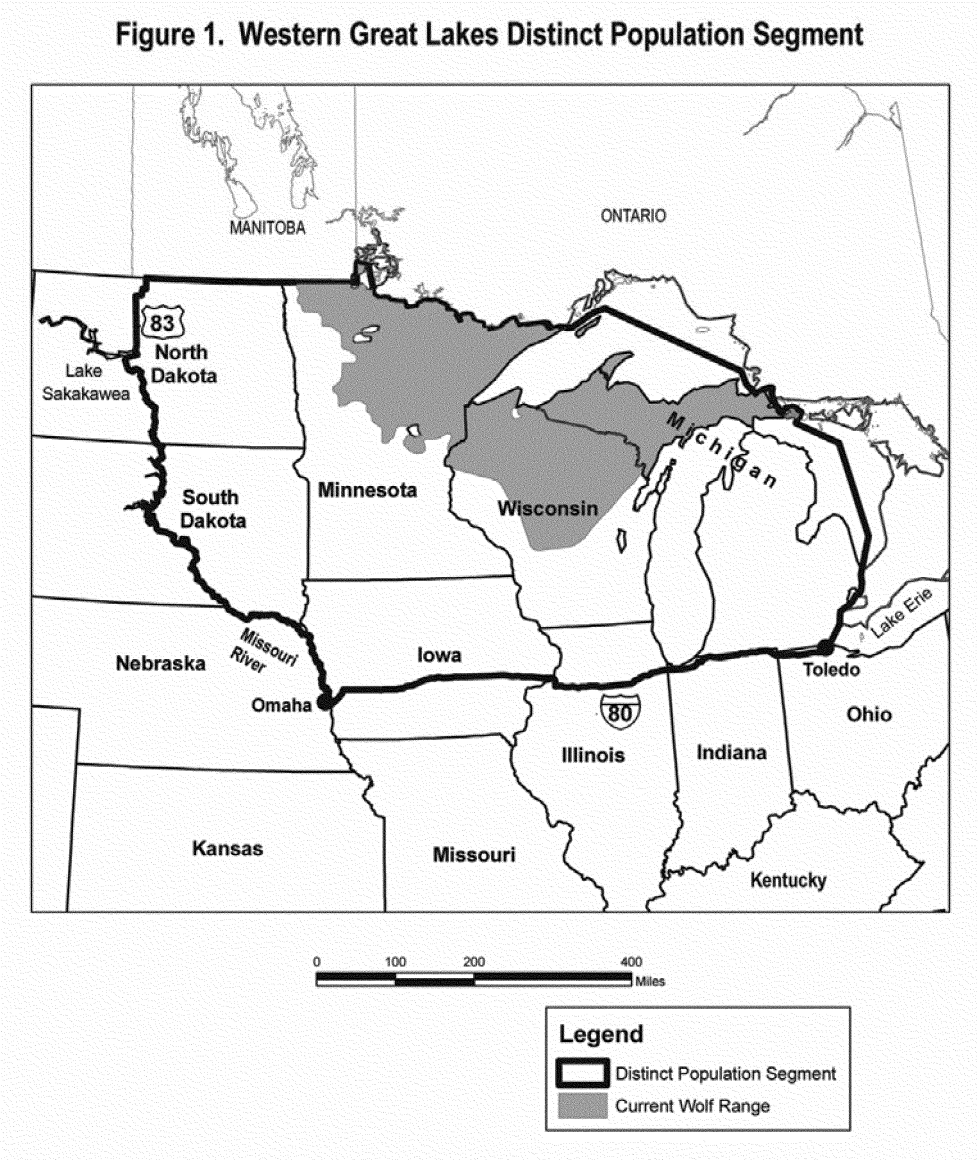
A gray wolf DPS that includes only Minnesota does not meet the criteria in the DPS policy because it is not discrete "* * * in relation to the remainder of the species to which it belongs" (61 FR 4725, February 7, 1996). The Minnesota wolf population has expanded beyond State boundaries and is connected to the wolf population in Wisconsin and Michigan, as evidenced by frequent movements of wolves among the States (Van Deelen 2009, p. 140; Treves *at al.* 2009, pp. 192–195) and genetic analyses

that demonstrate the Wisconsin and Michigan wolves are mostly from the same genetic mix as Minnesota wolves (Wheeldon and White 2009, p. 4; Fain *et al.* 2010). Therefore, we are proposing to revise the boundaries of the Minnesota DPS to meet the criteria in the DPS policy as discussed under the *Distinct Population Segment Analysis,* below.

*Geographical Area of the Proposed Western Great Lakes DPS*

The geographical area of the proposed WGL DPS is shown in figure 1, below, and is described as all of Minnesota, Wisconsin, and Michigan; the portion of North Dakota north and east of the Missouri River upstream to Lake Sakakawea and east of the centerline of Highway 83 from Lake Sakakawea to the Canadian border; the portion of South Dakota north and east of the Missouri River; the portions of Iowa, Illinois, and Indiana north of the centerline of Interstate Highway 80; and the portion of Ohio north of the centerline of Interstate Highway 80 and west of the Maumee River at Toledo.

BILLING CODE 4310–55–P




BILLING CODE 4310–55–C

*Distinct Population Segment Analysis*

Analysis for Discreteness

Under the 1996 DPS Policy (61 FR 4722), a population segment of a vertebrate taxon may be considered discrete if it satisfies either of the following conditions: (1) it is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation); or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act.

*Markedly Separated from Other Populations of the Same Taxon*—The western boundaries of the proposed WGL DPS are approximately 400 mi (644 km) from the nearest known gray wolf packs in Wyoming and Montana. The distance between those western packs and the nearest packs within the proposed WGL DPS is nearly 600 mi

(966 km). The area between Minnesota packs and northern Rocky Mountain (NRM) packs largely consists of unsuitable habitat, with only scattered islands of possibly suitable habitat, such as the Black Hills of eastern Wyoming and western South Dakota. There are no known populations of gray wolves to the south or east of the proposed WGL DPS within the United States.

As discussed in the previous section, wolves are known to disperse over vast distances, but straight line documented dispersals of 400 mi (644 km) or more are very rare. Although we cannot rule out the possibility of a WGL wolf traveling 600 mi (966 km) or more and joining or establishing a pack in the northern Rockies, such a movement has not been documented and is expected to happen very infrequently, if at all. Similar movements from the NRM wolf population into the proposed WGL DPS are unknown and are expected to happen infrequently. The 2006 Sturgis (South Dakota) wolf is the closest that an NRM wolf has come to entering the proposed WGL DPS (Fain in litt. 2006); however, the Sturgis wolf would still have had to travel over 300 mi (500 km) before encountering the nearest wolf pack in the proposed WGL DPS. As the discreteness criterion requires that the DPS be "markedly separated" from other populations of the taxon rather than requiring complete isolation, this high degree of physical separation between the WGL DPS and the northern Rocky Mountains satisfies the discreteness criterion.

*Delimited by International Boundaries with Significant Management Differences*—The DPS policy allows us to use international borders to delineate the boundaries of a DPS if there are differences in control of exploitation, conservation status, or regulatory mechanisms between the countries. The border between the United States and Canada has been used as the northern boundary of the listed entity since gray wolves were reclassified in the lower 48 States and Mexico in 1978. There remain significant cross-border differences in exploitation, management, conservation status, and regulatory mechanisms. About 52,000 to 60,000 wolves occur in Canada, where suitable habitat is abundant (Boitani 2003, p. 322). Because of this abundance, wolves in Canada are not protected by Federal laws and are only minimally protected in most Canadian provinces (Pletscher *et al.* 1991, p. 546). In the United States, unlike Canada, Federal protection and intensive management has been necessary to recover the wolf (Carbyn 1983).

In general, Canadian gray wolf populations are sufficiently large and healthy so that population regulation, rather than protection and close monitoring, is the management focus. There are an estimated 4,000 wolves in Manitoba (Manitoba Conservation undated). Hunting is allowed nearly province-wide, including in those provincial hunting zones adjoining northwestern Minnesota, with last year's season running from August 31, 2009, through March 31, 2010 (Manitoba Conservation 2009a). Trapping wolves is allowed province-wide, except in and immediately around Riding Mountain National Park (southwestern Manitoba), with last year's season running from October 14, 2008, through February 28 or March 31, 2009 (varies with trapping zone) (Manitoba Conservation 2009b).

The Ontario Ministry of Natural Resources estimates there are 8,850 wolves in the province, based on prey composition and abundance, topography, and climate and wolf numbers in most parts of the province are believed to be stable or increasing since about 1993 (Ontario MNR 2005a, pp. 7–9). In 2005, Ontario limited hunting and trapping of wolves by closing the season from April 1 through September 14 in central and northern Ontario (Ontario MNR 2005b). In southern Ontario, the portion of the province that is adjacent to the proposed WGL DPS, wolf hunting and trapping is permitted year round (Ontario MNR 2005c). If delisted, Minnesota, Wisconsin, and Michigan would carefully monitor and manage wolves to retain populations at or above the recovery goal (see Factor D). Therefore, even though biologically the WGL wolf population is simply a well-connected southern extension of wolves in Canada, we will continue to use the United States-Canada border to mark the northern boundary of the DPS due to the difference in control of exploitation, conservation status, and regulatory mechanisms between the two countries.

*Conclusion*—We find, based on our analysis of the best available scientific information, that the proposed WGL DPS is markedly separated from other United States populations of gray wolves and difference in control of exploitation, conservation status, and regulatory mechanisms justifies discreteness between United States and Canadian wolf populations. Therefore, the proposed WGL DPS meets the criterion for discreteness under the DPS policy.

Analysis for Significance

If we determine that a population segment is discrete, we next consider available scientific evidence of its significance to the taxon to which it belongs. Our DPS policy states that this consideration may include, but is not limited to, the following: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; and/or (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics. Factor 2 applies to the proposed WGL DPS and is included in our analysis for significance. Factors 1, 3, and 4 do not apply to the proposed WGL DPS and thus are not included in our analysis for significance.

*Significant Gap in the Range of the Taxon*—Wolves once lived throughout most of North America. Wolves have been extirpated from most of the southern portions of their historical North American range. The successful restoration of a viable wolf metapopulation to large parts of Minnesota, Wisconsin, and Michigan has filled a significant gap in the holarctic range of gray wolves in the United States, and it provides an important extension of the range of gray wolves in North America. The loss of the WGL wolf population would, therefore, represent a significant gap in the species' holarctic range in that the WGL wolf population is the only wolf population in the conterminous States east of the Rocky Mountains, except for the red wolves (a different species) being restored along the Atlantic Coast, and currently holds about 40 percent of North American gray wolves known to occur south of Canada.

*Finding*—We find, based on our analysis of the best available scientific information, that the proposed WGL DPS is significant to the taxon to which it belongs because its loss would result in a significant gap in the range of the taxon. Therefore, the proposed WGL DPS meets the criterion for significance under the DPS policy.

Discrete Vertebrate Population Segment Conclusion

We propose, based on our review of the best available scientific data, that the WGL DPS is discrete from other gray

wolf populations as a result of physical separation from other gray wolf populations in the United States and the international border with Canada. The DPS is significant to the taxon to which it belongs because it contains a wolf metapopulation that fills a large gap in the historical range of the taxon in the conterminous States. Therefore, we have determined that this population segment of wolves satisfies the discreteness and significance criteria required for a DPS. The evaluation of the appropriate conservation status for the proposed WGL DPS is found below.

*Delineating the Boundaries of the Proposed WGL Gray Wolf DPS*

In contrast to a species or a subspecies, a DPS is a biological population that is delineated by a boundary that is based on something other than established taxonomic distinctions. Therefore, the starting point for delineating a DPS is the biological population or metapopulation, and a geographical delineation of the DPS must reasonably represent the population or metapopulation and its biological characteristics and recovery needs.

To delineate the boundary of the proposed WGL DPS, we considered the current distribution of wolves in the Midwest and the characteristic movements of those wolves and of wolves elsewhere. We examined the best available scientific data on long-distance movements, including long-distance movements followed by return movements to the vicinity of the natal pack. We concluded that wolf behavior and the nature of wolf populations require that we include within the area of the DPS some subset of known long-distance movement locations. However, as explained below, wolf biology and common sense argue against including all known or potential long-distance movements within the DPS's boundaries.

The analysis detailed below resulted in the proposed boundaries of the WGL DPS that are shown in figure 1. This DPS has been delineated to include the core recovered wolf population plus a wolf movement zone around the core wolf populations. This geographic delineation is not intended to include all areas to which wolves have moved from the Great Lakes population. Rather, it includes the area currently occupied by wolf packs in Minnesota, Wisconsin, and Michigan; the nearby areas in these States in which wolf packs may become established in the foreseeable future; and a surrounding area into which Minnesota, Wisconsin, and Michigan wolves occasionally move but where persistent packs are not expected to be established because suitable habitat is rare and exists only as small patches. The area surrounding the core wolf populations includes the locations of most known dispersers from the core populations, especially the shorter and medium-distance movements from which wolves are most likely to return to the core areas and contribute to the wolf population. Therefore, the DPS encompasses the current range of the population, which is considered to be viable, including the primary range and the peripheral range.

The WGL areas that are regularly occupied by wolf packs are well documented in Minnesota (Erb and Benson 2004, p. 12, fig. 3; Erb and Don Carlos 2009, pp. 57–60), Wisconsin (Wydeven *et al.* 2006, p. 33, fig. 1; Wydeven *et al.* 2009c, pp. 93–98), and the UP of Michigan (Huntzinger *et al.* 2005, pp. 25–27, figs. 4–6; Beyer *et al.* 2009, pp. 73–75). Wolves have successfully colonized most, perhaps all, suitable habitat in Minnesota. Minnesota data from the winter of 2007–08 indicate that wolf numbers and density have stabilized since 1997–98, and there was no expansion of occupied range in the State (Erb 2008, pp. 5–7). Wisconsin wolves now occupy most habitat areas believed to have a high probability of wolf occurrence except for some areas of northeastern Wisconsin, and the State's wolf population continues to annually increase in numbers and, to a lesser degree, in area (Wydeven and Wiedenhoeft 2009, p. 2). The UP of Michigan has wolf packs throughout the peninsula. In the last 22 years, the wolf population in the UP has grown every year except 1997 and 2010 (Roell 2010, pers. comm.). Over the past 5 years, the average annual growth has been about 7 percent. While the population trend continues to increase, the rate of increase has slowed, consistent with any population expanding into and then filling available habitat. The population may continue to grow or remain steady; however, a small or even negative growth rate may occur any year and should be considered a natural fluctuation seen in any wildlife population.

When delineating the proposed WGL DPS, we had to consider the high degree of mobility shown by wolves. The dispersal of wolves from their natal packs and territories is a normal and important behavioral attribute of the species that facilitates the formation of new packs, the occupancy of vacant territories, and the expansion of occupied range by the "colonization" of vacant habitat. Data on wolf dispersal rates from numerous North American studies (summarized in Fuller *et al.* 2003, p. 179, Table. 6.6; Boyd and Pletscher 1999, p. 1102, Table 6) show dispersal rates of 13 to 48 percent of the individuals in a pack. Sometimes the movements are temporary, and the wolf returns to a location in or near its natal territory. In some cases, a wolf may continue its movement for scores or even hundreds of miles until it locates suitable habitat, where it may establish a territory or join an existing pack. In other cases, a wolf is found dead at a distance from its original territory, leaving unanswered the questions of how far it would have gone and whether it eventually would have returned to its natal area or population.

*Minnesota*—The current record for a documented movement by a wolf in North America is held by a Minnesota wolf that moved a minimum (that is, the straight-line distance from known starting point to most distant point) of at least 550 mi (886 km) northwest into Saskatchewan (Fritts 1983, pp. 166–167). Nineteen other primarily Minnesota movements summarized by Mech (in litt. 2005) averaged 154 mi (248 km). Their minimum distance of travel ranged from 32 to 532 mi (53–886 km) with the minimum dispersal distance shown by known returning wolves ranging from 54 mi (90 km) to 307 mi (494 km).

*Wisconsin*—In 2004, a wolf tagged in Michigan was killed by a vehicle in Rusk County in northwestern Wisconsin, 295 mi (475 km) west of his original capture location in the eastern UP (Wydeven *et al.* 2005b, p. 4). A north-central Wisconsin yearling female wolf traveled a similar distance (298 mi, 480 km) to the Rainy Lake region of Ontario during 1988–89 (Wydeven *et al.* 1995, p. 149).

*Michigan*—Drummer *et al.* (2002, pp. 14–15) reported 10 long-distance dispersal events involving UP wolves. One of these wolves moved to north-central Missouri and another to southeastern Wisconsin, both beyond the core wolf areas in the WGL. The average straight-line distance traveled by those two wolves was 377 mi (608 km), while the average straight-line distance for all 10 of these wolves was 232 mi (373 km). Their straight-line distances ranged from 41 to 468 mi (66 to 753 km).

*Illinois and Indiana*—In December 2002, a Marshall County (Illinois) wolf likely dispersed from the Wisconsin wolf population, nearly 200 mi (322 km) to the north (Great Lakes Directory 2003). The Randolph County (Indiana) wolf had traveled a minimum distance of at least 428 mi (689 km) to get around

Lake Michigan from its central Wisconsin birthplace; it likely traveled much farther than that unless it went through the city or suburbs of Chicago (Wydeven *et al.* 2004, pp. 10–11; Treves *et al.* 2009, p. 194). The Pike County (Illinois) wolf that was shot in late 2005 was about 300 mi (180 km) from the nearest wolf packs in central Wisconsin.

*North Dakota, South Dakota, and Nebraska*—Licht and Fritts (1994, p. 77) tabulated seven wolves found dead in North Dakota and South Dakota from 1981 through 1992 that are believed to have originated from Minnesota, based on skull morphometrics. Although none of these wolves were marked or radio-tracked, making it impossible to determine the point of initiation of their journey, a minimum travel distance for the seven can be determined from the nearest wolf breeding range in Minnesota. For the seven, the average distance to the nearest wolf breeding range was 160 mi (257 km) and ranged from 29 to 329 mi (46 to 530 km). One of these seven wolves moved west of the Missouri River before it died.

Genetic analysis of a wolf killed in Harding County, in extreme northwestern South Dakota, in 2001 indicated that it originated from the Minnesota-Wisconsin-Michigan wolf populations (Fain in litt. 2006). The straight-line travel distance to the nearest Minnesota wolf pack is nearly 400 mi (644 km).

The wolf from the Greater Yellowstone area that was killed by a vehicle on Interstate 90 near Sturgis, South Dakota, in March of 2006 traveled a minimum straight-line distance of about 270 mi (435 km) from the nearest known Greater Yellowstone pack before it died (USFWS *et al.* 2006, in USFWS Program Report, Figure 1).

A large canid was shot by a Boyd County (Nebraska) rancher in late 1994 or early 1995, likely after crossing the frozen Missouri River from South Dakota (Anschutz in litt. 2006, Jobman in litt. 1995). It was determined to be a wolf that originated from the Great Lakes wolf populations (Fain in litt. 2006), whose nearest pack would have been about 300 mi (480 km) away. A wolf illegally killed near Spalding, Nebraska, in December of 2002 also originated from the Minnesota-Wisconsin-Michigan wolf population, as determined by genetic analysis (Anschutz in litt. 2003, Fain in litt. 2006). The nearest Minnesota wolf pack is nearly 350 mi (563 km) from this location.

*Other notable extra-territorial movements*—The extra-territorial movements of several wolves were radio-tracked in sufficient detail to provide insight into their actual travel routes and total travel distances for each trek, rather than only documenting straight-line distance from beginning to end-point. Merrill and Mech (2000, pp. 429–431) reported on four such Minnesota wolves with documented travel distances ranging from 305 to 2,640 mi (490 to 4,251 km) and an average travel route length of 988 mi (1590 km). Wydeven (1994, pp. 20–22) described a Wisconsin wolf that moved from northwestern Wisconsin to the northern suburbs of St. Paul, Minnesota, for 2 weeks (apparently not seen or reported to authorities by the local residents), then moved back to north-central Wisconsin. The total travel distance was 278 mi (447km) from her natal pack into Minnesota and on to the north-central Wisconsin location where she settled down.

While investigating the origins of Scandinavian wolf populations, Linnell *et al.* (2005, p. 387) compiled wolf dispersal data from 21 published studies, including many cited separately here. Twenty-two of 298 compiled dispersals (7.4 percent) were over 300 km (186 mi). Eleven dispersals (3.7 percent) were over 500 km (311 mi). Because of the likelihood that many long-distance dispersers are never reported, they conclude that the proportion of long-distance dispersers is probably severely underestimated.

From these extra-territorial movement records, we conclude that wolf movements of over 200 mi (320 km) straight-line distance have been documented on numerous occasions, while shorter distance movements are more frequent. Movements of 300 mi (480 km) straight-line distance or more are less common, but include one Minnesota wolf that journeyed a straight-line distance of 300 mi (480 km) and a known minimum-travel distance of 2,640 mi (4,251 km) before it reversed direction, as determined by its satellite-tracked collar. This wolf ultimately returned to a spot only 24 mi (40 km) from its natal territory (Merrill and Mech 2000, p. 430). Although much longer movements have been documented, including some by midwestern wolves, return movements to the vicinity of natal territories have not been documented for extra-territorial movements beyond 300 mi (480 km).

Based on these extra-territorial movement data, we conclude that affiliation with the midwestern wolf population is diminished and essentially lost when dispersal takes a Midwest wolf a distance of 250 to 300 mi (400 to 480 km) beyond the outer edge of the areas that are continuously occupied by wolf packs. Although some WGL wolves will move beyond this distance, available data indicate that longer distance dispersers are unlikely to return to their natal population. Therefore, they have lost their functional connection with, and potential conservation value to, the WGL wolf population.

Wolves moving substantial distances outward from the core areas of Minnesota, Wisconsin, and Michigan will encounter landscape features that are at least partial barriers to further wolf movement and that may, if crossed, impede attempts of wolves to return toward the WGL core areas. If such partial barriers are in a location that has separate utility in delineating the biological extent of a wolf population, they can and should be used to delineate the DPS boundary. Such landscape features are the Missouri River in North Dakota and downstream to Omaha, Nebraska, and Interstate Highway 80 from Omaha eastward through Illinois, Indiana, and into Ohio, ending where this highway crosses the Maumee River in Toledo, Ohio. We do not believe these are absolute barriers to wolf movement. There is evidence that several Minnesota-origin wolves have crossed the Missouri River (Licht and Fritts 1994, pp. 75 & 77, Fig. 1 and Table 1; Anschutz in litt. 2003, 2006) and some Midwest wolves have crossed interstate highways (Merrill and Mech 2000, p. 430). There is also evidence that some wolves are hesitant to cross highways (Whittington *et al.* 2004, pp. 7, 9; Wydeven *et al.* 2005b, p. 5; but see Blanco *et al.* 2005, pp. 315–316, 319–320 and Kohn *et al.* 2000, p. 22). Interstate highways and smaller roads are a known mortality factor for wolves and, therefore, pose a partial barrier to wolf movements (Blanco *et al.* 2005, p. 320). The death of a NRM wolf near Sturgis in western South Dakota (Fain in litt. 2006) suggests that the area of the Dakotas west of the Missouri River may be traversed by a small number of wolves coming from both the NRM and WGL wolf populations, as well as wolves from Canada (Licht and Fritts 1994, pp. 75–77). Wolves in this area cannot be assumed to belong to the WGL wolf population, supporting our belief that the boundary should not be designed to include the locations of all known dispersers.

**Summary of Factors Affecting the Species**

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status.

"Species" is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). Once the "species" is identified, we then evaluate whether that species may be endangered or threatened because of one or more of the five factors described in section 4(a)(1) of the Act. We must consider these same five factors in delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered nor threatened because (1) the species is extinct, (2) the species has recovered and is no longer endangered or threatened, or (3) the original scientific data used at the time the species was classified were in error.

A recovered species is one that no longer meets the Act's definition of threatened or endangered. The analysis for a delisting due to recovery must be based on the five factors outlined in section 4(a)(1) of the Act. This analysis must include an evaluation of threats that existed at the time of listing, those that currently exist, and those that could potentially affect the species once the protections of the Act are removed.

In the context of the Act, the term "threatened species" means any species or subspecies or, for vertebrates, Distinct Population Segment (DPS) that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The term "endangered species" means any species that is in danger of extinction throughout all or a significant portion of its range. The Act does not define the term "foreseeable future." For the purpose of this proposal, we define the "foreseeable future" to be the extent to which, given the amount and substance of available data, we can anticipate events or effects, or reliably extrapolate threat trends that relate to the status of the WGL DPS. For the proposed WGL DPS, the foreseeable future differs for each factor potentially affecting the DPS.

It took a considerable length of time for public attitudes and regulations to result in a social climate that promoted and allowed for wolf recovery in the proposed WGL DPS. The length of time over which this shift occurred, and the ensuing stability in those attitudes, gives us confidence that this social climate will persist. Also, the States have had a solid history of cooperating and assisting in wolf recovery and have made a commitment, through legislative actions, to continue these activities. We believe this commitment will continue. When evaluating the available information, with respect to foreseeable future, we take into account reduced confidence as we forecast further into the future. As explained previously, our analysis of the factors affecting the WGL DPS refer to the gray wolf (*C. lupus*), because that is the named entity currently on the List of Endangered and Threatened Wildlife (see *Procedural Aspects of Proposal Applying to the Gray Wolf* above).

**A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range**

A common misconception is that wolves inhabit only remote pristine forests or mountainous areas, where human developments and other activities have produced negligible change to the natural landscape. Their extirpation south of Canada and Alaska, except for the heavily forested portions of northeastern Minnesota, reinforced this popular belief. However, the primary reason wolves survived in those areas was not because of habitat conditions, but, rather, because remote areas were sufficiently free of the human persecution that elsewhere killed wolves faster than the species could reproduce (Mech 1995a, p. 271).

In the western Great Lakes region, wolves in the densely forested northeastern corner of Minnesota have expanded into the more agricultural portions of central and northwestern Minnesota, northern and central Wisconsin, and the entire UP of Michigan. Habitats currently being used by wolves span the broad range from the mixed hardwood-coniferous forest wilderness area of northern Minnesota, through sparsely settled, but similar habitats in Michigan's UP and northern Wisconsin, and into more intensively cultivated and livestock-producing portions of central and northwestern Minnesota and central Wisconsin.

Wolf research and the expansion of wolf range over the last three decades have shown that wolves can successfully occupy a wide range of habitats, and they are not dependent on wilderness areas for their survival. In the past, for instance, wolf populations occupied nearly every type of habitat north of mid-Mexico that contained large ungulate prey species, including bison, elk, white-tailed deer, mule deer, moose, and woodland caribou; thus, wolves historically occupied the entire Midwest. Inadequate prey density or high levels of human-caused mortality appear to be the only factors that limit wolf distribution (Mech 1995a, p 271; 1995b, p. 544).

*Suitable Habitat Within the Proposed Western Great Lakes DPS*

Various researchers have investigated habitat suitability for wolves in the central and eastern portions of the United States. In recent years, most of these efforts have focused on using a combination of human density, density of agricultural lands, deer density or deer biomass, and road density, or have used road density alone to identify areas where wolf populations are likely to persist or become established (Mladenoff *et al.* 1995, pp. 284–285; 1997, pp. 23–27; 1998, pp. 1–8, 1999; pp. 39–43; Harrison and Chapin 1997, p. 3; 1998, p. 769–770; Wydeven *et al.* 2001a, pp. 110–113; Erb and Benson 2004, p. 2; Potvin *et al.* 2005, pp. 1661–1668; Mladenoff *et al.* 2009, pp. 132–135).

To a large extent, road density has been adopted as the best predictor of habitat suitability in the Midwest due to the connection between roads and human-related wolf mortality. Several studies demonstrated that wolves generally did not maintain breeding packs in areas with a road density greater than about 0.9 to 1.1 linear miles per sq mi (0.6 to 0.7 km per sq km) (Thiel 1985, pp. 404–406; Jensen *et al.* 1986, pp. 364–366; Mech *et al.* 1988, pp. 85–87; Fuller *et al.* 1992, pp. 48–51). Work by Mladenoff and associates indicated that colonizing wolves in Wisconsin preferred areas where road densities were less than 0.7 mi per sq mi (0.45 km per sq km) (Mladenoff *et al.* 1995, p. 289). However, recent work in the UP of Michigan indicates that, in some areas with low road densities, low deer density appears to limit wolf occupancy (Potvin *et al.* 2005, pp. 1667–1668) and may prevent recolonization of portions of the UP. In Minnesota, a combination of road density and human density is used by MN DNR to model suitable habitat. Areas with a human density up to 8 people per sq km are suitable if they also have a road density less than 0.5 km per sq km. Areas with a human density of less than 4 people per sq km are suitable if they have road densities up to 0.7 km per sq km (Erb and Benson 2004, Table 1).

Road density is a useful parameter because it is easily measured and mapped, and because it correlates directly and indirectly with various forms of other human-related wolf mortality factors. A rural area with more roads generally has a greater human density, more vehicular traffic, greater access by hunters and trappers, more farms and residences, and more domestic animals. As a result, there is

a greater likelihood that wolves in such an area will encounter humans, domestic animals, and various human activities. These encounters may result in wolves being hit by motor vehicles, being controlled by government agents after becoming involved in depredations on domestic animals, being shot intentionally by unauthorized individuals, being trapped or shot accidentally, or contracting diseases from domestic dogs (Mech *et al.* 1988, pp. 86–87; Mech and Goyal 1993, p. 332; Mladenoff *et al.* 1995, pp. 282, 291). Based on mortality data from radio-collared Wisconsin wolves from 1979 to 1999, natural causes of death predominate (57 percent of mortalities) in areas with road densities below 1.35 mi per sq mi (0.84 km per sq km), but human-related factors produced 71 percent of the wolf deaths in areas with higher road densities (Wydeven *et al.* 2001a, pp. 112–113).

Some researchers have used a road density of 1 mi per sq mi (0.6 km per sq km) of land area as an upper threshold for suitable wolf habitat. However, the common practice in more recent studies is to use road density to predict probabilities of persistent wolf pack presence in an area. Areas with road densities less than 0.7 mi per sq mi (0.45 km per sq km) are estimated to have a greater than 50 percent probability of wolf pack colonization and persistent presence, and areas where road density exceeded 1 mi per sq mi (0.6 km per sq km) have less than a 10 percent probability of occupancy (Mladenoff *et al.* 1995. pp. 288–289; Mladenoff and Sickley 1998, p. 5; Mladenoff *et al.* 1999, pp. 40–41). Wisconsin researchers view areas with greater than 50 percent probability as "primary wolf habitat," areas with 10 to 50 percent probability as '"secondary wolf habitat," and areas with less than 10 percent probability as unsuitable habitat (WI DNR 1997, pp. 47–48).

The territories of packs that do occur in areas of high road density, and hence with low expected probabilities of occupancy, are generally near broad areas of more suitable habitat that are likely serving as a source of wolves, thereby assisting in maintaining wolf presence in the higher road density and, therefore, less-suitable areas (Mech 1989, pp. 387–388; Wydeven *et al.* 2001a, p. 112). The predictive ability of this model was questioned (Mech 2006a, 2006b) and responded to (Mladenoff *et al.* 2006), and an updated analysis of Wisconsin pack locations and habitat has been completed (Mladenoff *et al.* 2009). This new model maintains that road density is still an important indicator of suitable wolf habitat; however, lack of agricultural land is also a strong predictor of habitat wolves occupy.

It appears that essentially all suitable habitat in Minnesota is now occupied, range expansion has slowed or possibly ceased, and the wolf population within the State has stabilized (Erb and Benson 2004, p. 7; Erb and Don Carlos 2009, pp. 57, 60). This suitable habitat closely matches the areas designated as Wolf Management Zones 1 through 4 in the Revised Recovery Plan (USFWS 1992, p. 72), which are identical in area to Minnesota Wolf Management Zone A (see Figure 2, below; MN DNR 2001, Appendix III).

Recent surveys for Wisconsin wolves and wolf packs show that wolves have now recolonized the areas predicted by habitat models to have high and moderate probability of occupancy (primary and secondary wolf habitat). The late-winter 2008–09 Wisconsin wolf survey identified packs occurring throughout the central Wisconsin forest area (Wolf Management Zone 2, Figure 3) and across the northern forest zone (Zone 1, Figure 3), with highest pack densities in the northwest and north-central forest; pack densities are lower, but increasing, in the northeastern corner of the State (Wydeven and Wiedenhoeft 2009, Figure 1).

Michigan wolf surveys in winter 2009–10 continue to show wolf pairs or packs (defined by Michigan DNR as two or more wolves traveling together) in every UP county except Keweenaw County (Huntzinger *et al.* 2005, p. 6; Roell 2011, pers. comm.), which probably lacks a suitable ungulate prey base during winter months (Potvin *et al.* 2005, p. 1665).

Habitat suitability studies in the Upper Midwest indicate that the only large areas of suitable or potentially suitable habitat areas that are currently unoccupied by wolves are located in the northern LP of Michigan (Mladenoff *et al.* 1997, p. 23; Mladenoff *et al.* 1999, p. 39; Potvin 2003, pp. 44–45; Gehring and Potter 2005, p. 1239). One published Michigan study (Gehring and Potter 2005, p. 1239) estimates that these areas could host 46 to 89 wolves; a graduate thesis estimates that 110–480 wolves could exist in the northern LP (Potvin 2003, p. 39). The northern LP is separated from the UP by the Straits of Mackinac, whose 4-mile (6.4-km) width freezes during mid- and late-winter in some years. In recent years there have been several documented occurrences of wolves in the northern LP, but until 2010, there had been no indication of persistence beyond several months. Prior to those occurrences, the last recorded wolf in the LP was in 1910.

In the first instance a radio-collared female wolf from the eastern UP was trapped and killed by a coyote trapper in Presque Isle County in late October 2004. In late November 2004, tracks from two wolves were verified in the same northern LP county. Follow-up winter surveys by the DNR in early 2005 failed to find additional wolf tracks in the northern LP (Huntzinger *et al.* 2005, p. 7); additional surveys conducted in 2006–10 also failed to find evidence of continued northern LP wolf presence (Roell *et al.* 2009, p. 5; Roell 2010, pers. comm.). A video of a single wolf was taken near Mackinac City in Cheboygan County in May 2009, and another trail-camera video-recorded a wolf in Presque Isle County in July 2009. These two sightings may have been the same animal (Roell 2009, pers. comm.). In 2010, USDA Wildlife Services and MI DNR staff confirmed a single breeding pair with pups in Cheboygan County in the northern LP (MI DNR 2010).

These northern LP patches of potentially suitable habitat contain a great deal of private land, are small in comparison to the occupied habitat on the UP and in Minnesota and Wisconsin, and are intermixed with agricultural and higher road density areas (Gehring and Potter 2005, p. 1240). Therefore, continuing wolf immigration from the UP may be necessary to maintain a future northern LP population. The Gehring and Potter study (2005, p. 1239) predicted 850 sq mi (2,198 sq km) of suitable habitat (areas with greater than a 50 percent probability of wolf occupancy) in the northern LP. Potvin (2003, p. 21), using deer density in addition to road density, believes there are about 3,090 sq mi (8,000 sq km) of suitable habitat in the northern LP. Gehring and Potter (2005, p. 1239) exclude from their calculations those northern LP low-road-density patches that are less than 19 sq mi (50 sq km), while Potvin (2003, pp. 10–15) does not limit habitat patch size in his calculations. Both of these area estimates are well below the minimum area described in the Revised Recovery Plan, which states that 10,000 sq mi (25,600 sq km) of contiguous suitable habitat is needed for a viable isolated gray wolf population, and half that area (5,000 sq mi or 12,800 sq km) is needed to maintain a viable wolf population that is subject to wolf immigration from a nearby population (USFWS 1992, pp. 25–26).

Based on the above-described studies and the guidance of the 1992 Revised Recovery Plan, the Service has concluded that suitable habitat for wolves in the proposed WGL DPS can be determined by considering four

factors: Road density, human density, prey base, and size. An adequate prey base is an absolute requirement, but in much of the proposed WGL DPS the white-tailed deer density is well above adequate levels, causing the other factors to become the determinants of suitable habitat. Prey base is primarily of concern in the UP where severe winter conditions cause deer to move away from some lakeshore areas, making otherwise suitable areas locally and seasonally unsuitable. Road density and human density frequently are highly correlated; therefore, road density is the best single predictor of habitat suitability. However, areas with higher road density may still be suitable if the human density is very low, so a consideration of both factors is sometimes useful (Erb and Benson 2004, p. 2).

Finally, although the territory of individual wolf packs can be relatively small, packs are not likely to persist as a viable population if they occupy a small isolated island of otherwise unsuitable habitat. The 1992 Revised Recovery Plan indicates that a wolf population needs to occupy at least 10,000 contiguous sq mi (25,600 sq km) to be considered viable if it is isolated from other wolf populations, and must occupy at least half that area if it is not isolated from another self-sustaining population (USFWS 1992, pp. 25–26).

Based on the information discussed above, we conclude that Minnesota Wolf Management Zone A (Federal Wolf Management Zones 1–4, Figure 2), Wisconsin Wolf Zones 1 and 2 (Figure 3), and the UP of Michigan contain a sufficient amount of suitable wolf habitat. The other areas within the DPS are unsuitable habitat, or are potentially habitat that is too small or too fragmented to be suitable for maintaining a viable wolf population.

*Wolf Populations on Federal Lands*

National forests, and the prey species found in their various habitats, have been important to wolf conservation and recovery in the core areas of the proposed WGL DPS. There are five national forests in Minnesota, Wisconsin, and Michigan (Superior, Chippewa, Chequamegon-Nicolet, Ottawa, and Hiawatha National Forests) with wolf packs that exclusively or partially reside on them. Their wolf populations range from approximately 484 on the Superior National Forest in northeastern Minnesota, to an estimated 182 on the UP's Ottawa National Forest, 164 on the Chequamegon–Nicolet National Forest in northeastern Wisconsin, and another estimated 49 on the Hiawatha National Forest in the eastern UP (Delphey 2009, pers. comm.; Eklund 2009, pers. comm.; Roell 2011, pers. comm., Wydeven 2011, pers. comm.).

Voyageurs National Park, along Minnesota's northern border, has a land base of nearly 340 sq mi (882 sq km). As of the last survey in 2008, there were 31 to 46 wolves within 7 to 9 packs that exclusively or partially reside within the park, and at least 5 packs are located wholly inside the Park boundaries (Ethier *et al.* 2008, p. 5). The 2008 estimates fall within the range of wolf estimates for the Park from the 1990s (Gogan *et al.* 2004) and early 2000s (Fox *et al.* 2001, pp. 6–7).

Within the boundaries of the proposed WGL DPS, we currently manage seven units within the National Wildlife Refuge System with significant wolf activity. Primary among these are Agassiz National Wildlife Refuge (NWR), Tamarac NWR, and Rice Lake NWR in Minnesota; Seney NWR in the UP of Michigan; and Necedah NWR in central Wisconsin. Agassiz NWR has had as many as 20 wolves in 2 to 3 packs in recent years. Although in 1999 mange and illegal shootings reduced them to a single pack of five wolves and a separate lone wolf, since 2001, two packs with a total of 10 to 12 wolves have been using the Refuge. About 60 percent of the packs' territories are located on the Refuge or on an adjacent State-owned wildlife management area (Huschle in litt. 2005).

Data collected by Agassiz NWR staff during winter wolf sign surveys conducted in cooperation with the MN DNR during both the winters of 2007–08 and 2008–09 support the above wolf totals. Winter track data from 2007–08 suggest that one pack on Agassiz had a minimum size of five and one had a minimum size of six. The following winter's survey information suggested a minimum pack size of five for both packs (Knutson 2009, pers. comm.). Two packs of wolves that currently include about eight and five members, respectively, use Tamarac NWR and the territory of a third occurs partly on the Refuge (Brininger 2009, pers. comm.). The size of the one pack using Rice Lake NWR, in Minnesota, has been reported at six to nine in previous years; in 2009 a maximum of three wolves were confirmed on the Refuge (McDowell 2009, pers. comm.), although total pack size may be greater.

Other single or paired wolves pass through the Refuge frequently (Stefanski 2004, pers. comm.; McDowell in litt. 2005). Seney NWR has three packs, representing 8–10 wolves, which partially reside on the Refuge (Roell 2010, pers. comm.). In 2010, two packs of six wolves each and at least one loner were detected on Necedah NWR (Wydeven *et al.* 2010, p. 41). Over the past 10 years, Sherburne and Crane Meadows NWR Complex in central Minnesota have had intermittent, but reliable, observations and signs of individual wolves each year. To date, no established packs have been documented on either of those Refuges. The closest established packs are within 15 mi (24 km) of Crane Meadows NWR at Camp Ripley Military Installation and 30 mi (48 km) north of Sherburne NWR at Mille Lacs State Wildlife Management Area (Berkley 2009, pers. comm.).

*Suitable Habitat Ownership and Protection*

In Minnesota, public lands, including national forests, a national park, national wildlife refuges, tax-forfeit lands (managed mostly by counties), State forests, State wildlife management areas, and State parks, encompass approximately 42 percent of current wolf range. American Indians and Tribes own 3 percent, an additional 1,535 sq mi (2,470 sq km), in Minnesota's wolf range (see Erb and Benson 2004, Table 1). In its 2001 Minnesota Wolf Management Plan, MN DNR states that it "will continue to identify and manage currently occupied and potential wolf habitat areas to benefit wolves and their prey on public and private land, in cooperation with landowners and other management agencies" (MN DNR 2001, p. 25). MN DNR will monitor deer and moose habitat and, when necessary and appropriate, improve habitat for these species. MN DNR maintains that several large public land units of State parks and State forests along the Wisconsin border will likely ensure that the connection between the two States' wolf populations will remain open to wolf movements. Nevertheless, MN DNR stated that it would cooperate with Wisconsin DNR to incorporate the effects of future development "into long-term viability analyses of wolf populations and dispersal in the interstate area" (MN DNR 2001, p. 27).

The MN DNR Divisions of Forestry and Wildlife directly administer approximately 5,330 sq mi (13,805 sq km) of land in Minnesota's wolf range. The DNR has set goals of enlarging and protecting its forested land base by, in part, "minimizing the loss and fragmentation of private forest lands" (MN DNR 2000, p. 20) and by connecting forest habitats with natural corridors (MN DNR 2000, p. 21). It plans to achieve these goals and objectives via several strategies, including the development of (Ecological) Subsection

Forest Resource Management Plans (SFRMP) and to expand its focus on corridor management and planning.

In 2005, the Forest Stewardship Council (FSC) certified that 4.84 million acres (1.96 million hectares) of State-administered forest land are "well managed" (FSC 2005); the Sustainable Forestry Initiative (SFI) also certified that MN DNR was managing these lands to meet its standards. For the FSC certification, independent certifiers assessed forest management against FSC's Lakes States Regional Standard, which includes a requirement to maximize habitat connectivity to the extent possible at the landscape level (FSC 2005, p. 22).

Efforts to maximize habitat connectivity in the range of wolves would complement measures the MN DNR described in its State wolf plan (MN DNR 2001, pp. 26–27). If the Service ultimately delists the DPS as proposed, the Service will review certification evaluation reports issued by FSC to assess MN DNR's ongoing efforts in this area as part of its post-delisting monitoring.

Counties manage approximately 3,860 sq mi (9,997 sq km) of tax forfeit land in Minnesota's wolf range (MN DNR unpublished data). We are aware of no specific measures that any county in Minnesota takes to conserve wolves. If most of the tax-forfeit lands are maintained for use as timber lands or natural areas, however, and if regional prey levels are maintained, management specifically for wolves on these lands will not be necessary. MN DNR manages ungulate populations "on a regional basis to ensure sustainable harvests for hunters, sufficient numbers for aesthetic and nonconsumptive use, and to minimize damage to natural communities and conflicts with humans such as depredation of agricultural crops" (MN DNR 2001, p. 17). Moreover, although counties may sell tax-forfeit lands subject to Minnesota State law, they generally manage these lands to ensure that they will retain their productivity as forests into the future. For example, Crow Wing County's mission for its forest lands includes the commitment to "sustain a healthy, diverse, and productive forest for future generations to come." In addition, at least four counties in Minnesota's wolf range—Beltrami, Carlton, Koochiching, and St. Louis—are certified by SFI, and four others (Aitkin, Cass, Itasca, and Lake) have been certified by FSC. About ten private companies with industrial forest lands in Minnesota's wolf range have also been certified by FSC.

There are no legal or regulatory requirements for the protection of wolf habitat, per se, on private lands in Minnesota. Land management activities such as timber harvest and prescribed burning carried out by public agencies and by private land owners in Minnesota's wolf range incidentally and significantly improves habitat for deer, the primary prey for wolves in the State. The impact of these measures is apparent from the continuing high deer densities in Minnesota's wolf range. The State's second largest deer harvest occurred in 2006, and approximately one-half of the Minnesota deer harvest is in the Forest Zone, which encompasses most of the occupied wolf range in the State (MN DNR 2009, Table 1).

Given the extensive public ownership and management of land within Minnesota's wolf range, as well as the beneficial habitat management expected from Tribal lands, we believe suitable habitat, and especially an adequate wild prey base, will remain available to the State's wolf population for the foreseeable future. Management of private lands for timber production will provide additional habitat suitable for wolves and white-tailed deer.

Similarly, current lands in northern and central Wisconsin that are judged to be primary and secondary wolf habitat are well protected from significant adverse development and habitat degradation due to public ownership or protective management that preserves the habitat and wolf prey base. Primary habitat (that is, areas with greater than 50 percent probability of wolf pack occupancy; Wydeven *et al.* 1999, pp. 47–48) totals 5,812 sq mi (15,053 sq km). The 1999 Wisconsin wolf plan listed land ownership of primary and secondary wolf habitat (Wydeven *et al.* 1999, p. 48). In 2006, Sickley (2006, pers. comm.) provided an update of the data with more accurate land ownership data. That data show that about 55 percent of primary habitat was in public land including, Federal, State, or county ownership, and 7 percent was on Tribal land. County lands, mostly county forests, comprised 29 percent of the primary habitat, and Federal lands mostly the Chequamegon–Nicolet National Forest, included another 17 percent.

Most Tribal land (7 percent of primary habitat), while not public land, will likely remain as suitable deer and wolf habitat for the foreseeable future. State forest ownership protects 10 percent. Private industrial forest lands comprised another 10 percent of the primary habitat, although some of these lands have been subdivided for second or vacation home sites, reducing this acreage in recent years. The remaining 29 percent is in other forms of private ownership and is vulnerable to loss from the primary habitat category to an unknown extent (Sickley in litt. 2006, unpublished data updating Table C2 of WI DNR 1999, p. 48).

Areas judged to be secondary wolf habitat by WI DNR (10 to 50 percent probability of occupancy by wolf packs; Wydeven *et al.* 1999, pp. 47–48) were somewhat more developed or fragmented habitats and were less well protected overall, because only 43 percent were in public ownership and 5 percent were in Native American reservations. Public land that maintained secure habitat included county (17 percent) and national (18 percent) forests ownership protecting the largest segments, and State land protected 7 percent. Private industrial forest ownership provided protection to 5 percent, and the remaining 47 percent was in other forms of private ownership (Sickley in litt. 2006).

County forest lands represent the single largest category of primary wolf habitat in Wisconsin. Wisconsin Statute 28.11 guides the administration of county forests, and directs management for production of forest products together with recreational opportunities, wildlife, watershed protection, and stabilization of stream flow. This Statute also provides a significant disincentive to conversion for other uses. Any proposed withdrawal of county forest lands for other uses must meet a standard of a higher and better use for the citizens of Wisconsin, and be approved by two-thirds of the County Board. As a result of this requirement, withdrawals are infrequent, and the county forest land base is actually increasing.

This analysis shows that nearly three-quarters of the primary habitat in Wisconsin receives substantial protection due to ownership or management for sustainable timber production. Over half of the secondary habitat is similarly protected. Portions of the primary habitat in northeastern Wisconsin remained sparsely populated with wolf packs until recently, but are filling in lately (Wydeven *et al.* 2010, Fig. 2, p. 66), although still allowing for some continuing wolf population expansion. In general, we believe this degree of habitat protection is more than adequate to support a viable wolf population in Wisconsin for the foreseeable future.

In the UP of Michigan, State and Federal ownership comprises 2.0 and 2.1 million acres respectively, representing 19.3 percent and 20.1 percent of the land surface of the UP. The Federal ownership is composed of

87 percent national forest, 8 percent national park, and 5 percent national wildlife refuge. The management of these three categories of Federal land is discussed elsewhere, but clearly will benefit wolves and their prey.

State lands on the UP are 94 percent State forest land, 6 percent State park, and less than 1 percent in fishing and boating access areas and State game areas. Part 525, Sustainable Forestry on State Forestlands, of the Michigan Natural Resources and Environmental Protection Act, 1994 PA 451, as amended, directs State forestland management in Michigan. It requires the MI DNR to manage the State forests in a manner consistent with sustainable forestry, to prepare and implement a management plan, and to seek and maintain a third party certification that the lands are managed in a sustainable fashion (MI DNR 2005c, p. 1).

Much of the private land on the UP is managed or protected in a manner that will maintain forest cover and provide suitable habitat for wolves and white-tailed deer. Nearly 1.9 million acres (0.8 million hectares) of large-tract industrial forest lands and another 1.9 million acres (0.8 million hectares) of smaller private forest land are enrolled in the Commercial Forest Act (CFA). These 3.7 million acres (1.5 million hectares) are managed for long-term sustainable timber production under forest management plans written by certified foresters; in return, the landowners benefit from a reduction in property taxes. In addition, nearly 37,000 acres on the UP are owned by The Nature Conservancy, and continue to be managed to restore and preserve native plant and animal communities. Therefore, these private land management practices currently are preserving an additional 36 percent of the UP as suitable habitat for wolves and their prey species.

In total, 39 percent of the UP is Federally and State-owned land whose management will benefit wolf conservation for the foreseeable future, and another 36 percent is private forest land that is being managed, largely under the incentives of the CFA, in a way that provides suitable habitat and prey for wolf populations. Therefore, a minimum of nearly three-quarters of the UP should continue to be suitable for wolf conservation, and we do not envision UP habitat loss or degradation as a problem for wolf population viability in the foreseeable future.

Hearne *et al.* (2003), determined that a viable wolf population (one having less than 10 percent chance of extinction over 100 years), should consist of at least 175 to 225 wolves (p. 170), and they modeled various likely scenarios of habitat conditions in the UP of Michigan and northern Wisconsin through the year 2020 to determine whether future conditions would support a wolf population of that size. Most scenarios of future habitat conditions resulted in viable wolf populations in each State through 2020. When the model analyzed the future conditions in the two States combined, all scenarios produced a viable wolf population through 2020. Their scenarios included increases in human population density, changes in land ownership that may result in decreased habitat suitability, and increased road density (pp. 101–151).

The large areas of unsuitable habitat in the eastern Dakotas; the northern portions of Iowa, Illinois, Indiana, and Ohio; and the southern areas of Minnesota, Wisconsin, and Michigan; as well as the relatively small areas of unoccupied potentially suitable habitat, will not contribute to the viability of wolves in the proposed WGL DPS. Therefore, we have determined that the existing and likely future threats to wolves outside the currently occupied areas, and especially to wolves outside of Minnesota, Wisconsin, and the UP, do not rise to the level that they threaten the long-term viability of wolf populations in Minnesota, Wisconsin, and the UP of Michigan.

In summary, wolves currently occupy the vast majority of the suitable habitat in the proposed WGL DPS, and that habitat is adequately protected for the foreseeable future. Unoccupied areas that have the characteristics of suitable habitat exist in small and fragmented parcels and are not likely to develop viable wolf populations. Threats to those habitat areas will not adversely impact the recovered wolf metapopulation in the DPS.

*Prey*

Wolf density is heavily dependent on prey availability (for example, expressed as ungulate biomass, Fuller *et al.* 2003, pp. 170–171), but prey availability is not likely to threaten wolves in the proposed WGL DPS. Conservation of primary wolf prey in the proposed WGL DPS, white-tailed deer and moose, is clearly a high priority for State conservation agencies. As Minnesota DNR points out in its wolf management plan (MN DNR 2001, p. 25), it manages ungulates to ensure a harvestable surplus for hunters, nonconsumptive users, and to minimize conflicts with humans. To ensure a harvestable surplus for hunters, MN DNR must account for all sources of natural mortality, including loss to wolves, and adjust hunter harvest levels when necessary. For example, after severe winters in the 1990's, MN DNR modified hunter harvest levels to allow for the recovery of the local deer population (MN DNR 2001, p. 25). In addition to regulation of human harvest of deer and moose, MN DNR also plans to continue to monitor and improve habitat for these species.

Land management carried out by other public agencies and by private land owners in Minnesota's wolf range, including timber harvest and prescribed fire, incidentally and significantly improves habitat for deer, the primary prey for wolves in the State. The success of these measures is apparent from the continuing high deer densities in the Forest Zone of Minnesota, and the fact that the State's five largest deer harvests have occurred in the last 6 years, with a deer harvest averaging 241,000 deer over the last 5 years. Approximately one-half of the Minnesota deer harvest is in the Forest Zone, which encompasses most of the occupied wolf range in the State (Cornicelli 2008, pp. 208–209). There is no indication that harvest of deer and moose or management of their habitat will significantly depress abundance of these species in Minnesota's core wolf range. Therefore, lack of prey availability is not likely to pose a threat to wolves in the foreseeable future in the State.

The deer populations in Wisconsin and the UP of Michigan declined somewhat from historically high levels in recent years. Wisconsin's preseason deer population has exceeded 1 million animals since 1984 (WI DNR undated a; Rolley 2007, p. 6; Rolley 2008, p. 6), and hunter harvest has exceeded 400,000 deer in 10 of the last 12 years (WI DNR 2010, p.57). Across northern Wisconsin wolf range (Zone 1), winter deer density in northern deer management units averaged from 22–30 deer per sq mi (8.5–11.6 deer per sq km) between 2001–07, but declined to 17–18 deer per sq mi (6.6–6.9 deer per sq km) in 2009 and 2010. In Central Forest wolf range (Zone 2), winter deer density in deer management units averaged 29–50 deer per sq mi (11.2–19.3 deer per sq km) from 2001 to 2007, and was 35 deer per sq mi (13.5 deer per sq km) in 2009, and 26 deer per sq mi (10.0 deer per sq km) in 2010 (WI DNR data).

Michigan's 2009 October forecast for the deer population was approximately 1.8 million deer, with about 312,800 residing in the UP; the 2010 estimates projected a slightly higher UP deer population (Doepker 2010, pers. comm.; Rudolph 2010, pers. comm.). Because of severe winter conditions (persistent, deep snow) in the UP, deer populations

can change dramatically from year to year. Recently (2010) the MI DNR finalized a new deer management plan, to address ecological, social, and regulatory shifts. An objective of this plan is to manage deer at the appropriate scale, considering impacts of deer on the landscape and on other species, in addition to population size (MI DNR 2010, p. 20). Additionally, the Michigan wolf management plan addresses maintaining a sustainable population of wolf prey (MI DNR 2008, p. 36). Short of a major, and unlikely, shift in deer management and harvest strategies, there will be no shortage of prey for Wisconsin and Michigan wolves for the foreseeable future.

*Summary of Factor A*

The wolf population in the proposed WGL DPS currently occupies all the suitable habitat area identified for recovery in the Midwest in the 1978 Recovery Plan and 1992 Revised Recovery Plan and most of the potentially suitable habitat in the WGL DPS. Viable wolf populations are unlikely to develop and persist in unsuitable habitat and the small fragmented areas of suitable habitat away from these core areas. Although they may have been historical habitat, many of these areas are no longer suitable for wolves and they have not been considered necessary for the recovery of the proposed DPS.

The wolf population in the proposed WGL DPS exceeds its numerical, temporal, and distributional goals for recovery. The amount of habitat likely to support a delisted wolf population is considered to be adequate for maintaining the WGL population at or above recovery levels for the foreseeable future. Because much important wolf habitat in the DPS is in public ownership, the States will likely continue to manage for high ungulate populations, and the States, Tribes, and Federal land management agencies will adequately regulate human-caused mortality of wolves and wolf prey. This will allow these States to easily support a recovered and viable wolf metapopulation into the foreseeable future. We conclude that wolves within this proposed DPS are not in danger of extinction now, or likely to be in danger of extinction in the foreseeable future, as a result of destruction, modification, or curtailment of the species' habitat or range.

**B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes**

Threats to wolves resulting from uses for scientific or educational purposes are not likely to increase substantially following delisting of the proposed WGL DPS, and any increased use for these purposes will be regulated and monitored by the States and Tribes in the core recovery areas. Since their listing under the Act, no wolves have been legally killed or removed from the wild in any of the nine States included in the proposed WGL DPS for either commercial or recreational purposes. Some wolves may have been illegally killed for commercial use of the pelts and other parts, but illegal commercial trafficking in wolf pelts or parts and illegal capture of wolves for commercial breeding purposes happens rarely. State wolf management plans for Minnesota, Wisconsin, and Michigan help ensure that wolves will not be killed for commercial or recreational purposes for many years following the proposed Federal delisting, so these forms of mortality will not likely emerge as new threats upon delisting. See Factor D for a detailed discussion of State wolf management plans, and for applicable regulations in States without wolf management plans.

We do not expect the use of wolves for scientific purposes to increase in proportion to total wolf numbers in the proposed WGL DPS after delisting. While listed, the intentional or incidental killing, or capture and permanent confinement, of endangered or threatened wolves for scientific purposes has only legally occurred under permits or subpermits issued by the Service (under section 10(a)(1)(A)) or by a State agency operating under a cooperative agreement with the Service pursuant to section 6 of the Act (50 CFR 17.21(c)(5) and 17.31(b)). Although exact figures are not available, throughout the conterminous 48 States, such permanent removals of wolves from the wild have been very limited and probably comprise an average of not more than two animals per year since the species was first listed as endangered. In the proposed WGL DPS, these animals were either taken from the Minnesota wolf population during long-term research activities (about 15 wolves) or were accidental takings as a result of research activities in Wisconsin (5 to 6 mortalities and 1 long-term confinement) and in Michigan (4 mortalities) (Berg in litt. 1998; Mech in litt. 1998; Roell in litt. 2004; Roell in litt. 2005a; Roell 2011, pers. comm.; Wydeven 2009, pers. comm.).

The Minnesota DNR plans to encourage the study of wolves with radio-telemetry after delisting, with an emphasis on areas where they expect wolf–human conflicts and where wolves are expanding their range (MN DNR 2001, p. 19). Similarly, Wisconsin and Michigan DNRs plan to continue to trap wolves for radio-collaring, examination, and health monitoring for the foreseeable future (WI DNR 1999, pp. 19–21; MI DNR 2008a, pp. 31–32; WI DNR 2006a, p. 14). The continued handling of wild wolves for research, including the administration of drugs, may result in some accidental deaths of wolves. We believe that capture and radio-telemetry-related injuries or mortalities will not increase significantly above the level observed to date in proportion to wolf abundance; adverse effects to wolves associated with such activities have been minimal and would not constitute a threat to wolves in the proposed WGL DPS.

No wolves have been legally removed from the wild for educational purposes in recent years. Wolves that have been used for such purposes are the captive-reared offspring of wolves that were already in captivity for other reasons, and this is not likely to change as a result of Federal delisting. We do not expect taking for educational purposes to constitute any threat to Midwest wolf populations in the proposed DPS for the foreseeable future.

See Factor E for a discussion of Taking of Wolves by Native Americans for Certain Purposes. See the Depredation Control Programs sections under Factor D for discussion of other past, current, and potential future forms of intentional and accidental take by humans, including depredation control, public safety, and under public harvest. While public harvest may include recreational harvest, it is likely that public harvest will also serve as a management tool, so it is discussed in Factor D.

*Summary of Factor B*

Taking wolves for scientific or educational purposes in the other States in the proposed WGL DPS may not be regulated or closely monitored in the future, but the threat to wolves in those States will not be significant to the long-term viability of the wolf population in the proposed WGL DPS. The potential limited commercial and recreational harvest that may occur in the DPS will be regulated by State and/or Tribal conservation agencies and is discussed under Factor D. Therefore, we conclude that overutilization for commercial, recreational, scientific, or educational purposes will not be a threat sufficient to cause wolves in the proposed WGL DPS to be in danger of extinction in the foreseeable future in all or a significant portion of the range within the proposed WGL DPS.

**C. Disease or Predation.**

*Disease*

Many diseases and parasites have been reported for the wolf, and several of them have had significant impacts during the recovery of the species in the 48 conterminous States (Brand *et al.* 1995, p. 419; WI DNR 1999, p. 61). If not monitored and controlled by States, these diseases and parasites, and perhaps others, may threaten wolf populations in the future. Thus, to avoid a future decline caused by diseases or parasites, States and their partners will have to diligently monitor the prevalence of these pathogens in order to effectively respond to significant outbreaks.

Canine parvovirus (CPV) is a relatively new disease that infects wolves, domestic dogs, foxes, coyotes, skunks, and raccoons. Recognized in the United States in 1977 in domestic dogs, it appeared in Minnesota wolves (based upon retrospective serologic evidence) live-trapped as early as 1977 (Mech *et al.* 1986, p. 105). Minnesota wolves, however, may have been exposed to the virus as early as 1973 (Mech and Goyal 1995, p. 568). Serologic evidence of wolf exposure to CPV peaked at 95 percent for a group of Minnesota wolves live-trapped in 1989 (Mech and Goyal 1993, p. 331). In a captive colony of Minnesota wolves, pup and yearling mortality from CPV was 92 percent of the animals that showed indications of active CPV infections in 1983 (Mech and Fritts 1987, p. 6), demonstrating the substantial impacts this disease can have on young wolves. It is believed that the population impacts of CPV occur via diarrhea-induced dehydration leading to abnormally high pup mortality (WI DNR 1999, p. 61). CPV has been detected in nearly every wolf population in North America including Alaska (Bailey *et al.* 1995, p. 443) and exposure in wolves is now believed to be almost universal.

There is no evidence that CPV has caused a population decline or has had a significant impact on the recovery of the Minnesota wolf population. Mech and Goyal (1995, p. 566, Table 1, p. 568, Fig. 3), however, found that high CPV prevalence in the wolves of the Superior National Forest in Minnesota occurred during the same years in which wolf pup numbers were low. Because the wolf population did not decline during the study period, they concluded that CPV-caused pup mortality was compensatory, that is, it replaced deaths that would have occurred from other causes, especially starvation of pups. They theorized that CPV prevalence affects the amount of population increase and that a wolf population will decline when 76 percent of the adult wolves consistently test positive for CPV exposure. Their data indicate that CPV prevalence in adult wolves in their study area increased by an annual average of 4 percent during 1979–93 and was at least 80 percent during the last 5 years of their study (Mech and Goyal 1995, pp. 566, 568).

Additional data gathered since 1995 suggests that CPV reduced pup survival both in the Superior National Forest and statewide, between 1984 and 2004; however, statewide there is some evidence of a slight increase in pup survival since about 1995. These conclusions are based on an inverse relationship between pup numbers in summer captures and seroprevalence of CPV antibodies in summer-captured adult wolves (Mech *et al.* 2008, pp. 827–830).

In a more recent study, Mech and Goyal (2010) looked more specifically at CPV influence on the Superior National Forest population by evaluating five 7-year periods to determine when CPV had its greatest effects. They found the strongest effect on wolf pup survival was from 1981 to 1993, and that after that time, little effect was seen despite the continued seroprevalence of CPV antibodies (Mech and Goyal 2010, pp. 6–7). They conclude that after CPV became endemic in the population, the population developed immunity and was able to withstand severe effects from the disease (Mech and Goyal 2010, p. 7). The observed population effects in the Superior National Forest population are consistent with results for studies in smaller, isolated populations in Wisconsin and on Isle Royale, Michigan (Wydeven *et al.* 1995; Peterson *et al.* 1998), but indicate that CPV also had only a temporary population effect in a larger population.

The WI DNR and the WI DNR Wildlife Health, in conjunction with the U.S. Geological Survey National Wildlife Health Center in Madison, Wisconsin, (formerly the National Wildlife Health Laboratory) have an extensive dataset on the incidence of wolf diseases, beginning in 1981. Canine parvovirus exposure was evident in 5 of 6 wolves tested in 1981, and probably stalled wolf population growth in Wisconsin during the early and mid-1980s when numbers there declined or were static; at that time 75 percent of 32 wolves tested positive for CPV. During the following years of population increase (1988–96), only 35 percent of the 63 wolves tested positive for CPV (WI DNR 1999, p. 62). More recent exposure rates for CPV continue to be high in Wisconsin wolves, with annual rates ranging from 60 to 100 percent among wild wolves handled from 2001 through mid-2006. Part of the reason for high exposure percentages is likely an increased emphasis in sampling pups and Central Forest wolves starting in 2001, so comparisons of post- and pre-2001 data are of limited value.

CPV appears not to be a significant cause of mortality, as only a single wolf (male pup) is known to have died from CPV during this period (Wydeven and Wiedenhoeft 2002, p. 8 Table 4; 2003a, pp. 11–12 Table 4; 2004a, pp. 11–12 Table 5; 2005, pp. 19–20 Table 4; 2006, pp. 23–25 Table 4; 2009, Table 2; Wydeven *et al.* 2007, pp. 12–14; 2008, pp. 19–21). While the difficulty of discovering CPV-killed pups must be considered, and it is possible that CPV-caused pup mortality is being underestimated, the continuing increase of the Wisconsin wolf population indicates that CPV mortality is no longer impeding wolf population growth in the State. It may be that many Wisconsin wolves have developed some degree of resistance to CPV, and this disease is no longer a significant threat in the State.

Similar to Wisconsin wolves, serological testing of Michigan wolves captured from 1992 through 2001 (most recent available data) shows that the majority of UP wolves have been exposed to CPV. Fifty-six percent of 16 wolves captured from 1992 to 1999 and 83 percent of 23 wolves captured in 2001 showed antibody titers at levels established as indicative of previous CPV exposure that may provide protection from future infection from CPV (Beheler in litt. undated, in litt. 2004). There are no data showing any CPV-caused wolf mortality or population impacts to the wolf population on the UP, but few wolf pups are handled in the UP (Hammill in litt. 2002, Beyer in litt. 2006a), so low levels of CPV-caused pup mortality may go undetected there. Mortality data are primarily collected from collared wolves, which until 2004 received CPV inoculations. Therefore, mortality data for the UP should be interpreted cautiously.

Sarcoptic mange is caused by a mite (*Sarcoptes scabiei*) infection of the skin. The irritation caused by the feeding and burrowing mites results in scratching and then severe fur loss, which in turn can lead to mortality from exposure during severe winter weather. The mites are spread from wolf to wolf by direct body contact or by common use of "rubs" by infested and uninfested animals. Thus, mange is frequently passed from infested females to their young pups, and from older pack members to their pack mates. In a long-

term Alberta, Canada, wolf study, higher wolf densities were correlated with increased incidence of mange, and pup survival decreased as the incidence of mange increased (Brand *et al.* 1995, p. 428).

From 1991 to 1996, 27 percent of live-trapped Wisconsin wolves exhibited symptoms of mange. During the winter of 1992–93, 58 percent showed symptoms, and a concurrent decline in the Wisconsin wolf population was attributed to mange-induced mortality (WI DNR 1999, p. 61). Seven Wisconsin wolves died from mange from 1993 through October 15, 1998, and severe fur loss affected five other wolves that died from other causes. During that period, mange was the third largest cause of death in Wisconsin wolves, behind trauma (usually vehicle collisions) and shooting (Thomas in litt. 1998). Largely as a result of mange, pup survival was only 16 percent in 1993, compared to a normal 30 percent survival rate from birth to one year of age (WI DNR 1999, p. 61).

Mange continues to occur on wolves in Wisconsin. From 2003 through 2007, 25 percent of live-trapped wolves showed signs of mange, but that declined to 11 percent of wolves handled in 2009 and 2010. Mortality data from closely monitored radio-collared wolves provides a relatively unbiased estimate of mortality factors, especially those linked to disease or illegal actions, because nearly all carcasses are located within a few days of deaths. Diseased wolves suffering from hypothermia or nearing death generally crawl into dense cover and may go undiscovered if they are not radio-tracked (Wydeven *et al.* 2001b, p. 14). Data from those closely monitored radio-collared wolves show that mange mortality ranged from 22 percent of deaths in 2006 and 12 percent in 2007 to 21 percent of deaths in 2008 (Wydeven in litt. 2009), 15 percent in 2009 (Wydeven *et al.* 2010, p. 13), and 6 percent in 2010 (Wydeven *et al.* 2011, p. 2).

Mange mortality does appear to be stabilizing or perhaps declining in Wisconsin. Not all mangy wolves succumb; other observations showed that some mangy wolves are able to survive the winter (Wydeven *et al.* 2001b, p. 14). Mange has been detected in Wisconsin wolves every year since 1991 when 45 to 52 wolves occurred in the State, and may have slowed the growth of the wolf population in the early 1990s (Wydeven *et al.* 2009c), but despite its constant presence as an occasional mortality factor, the wolf population grew to its present (2010) level of 690 or more wolves.

The survival of pups during their first winter is believed to be strongly affected by mange. The highest to date wolf mortality (30 percent of radio-collared wolves; Wydeven and Wiedenhoeft 2004a, p. 12) from mange in Wisconsin in 2003 may have had more severe effects on pup survival than in previous years. The prevalence of the disease may have contributed to the relatively small population increase in 2003 (2.4 percent in 2003 as compared to the average 18 percent to that point since 1985). However, mange has not caused a decline in the State's wolf population, and even though the rate of population increase has slowed in recent years, the wolf population continues to increase despite the continued prevalence of mange in Wisconsin wolves. Although mange mortality may not be the primary limiting factor for wolf population growth in the State, the impacts of mange in Wisconsin need to be closely monitored, as identified and addressed in the Wisconsin wolf management plan (WI DNR 1999, p. 21; 2006a, p. 14).

Disease monitoring in Wisconsin has identified a second form of mange in the wild wolf population—demodectic mange (Wydeven and Wiedenhoeft 2008, p. 8). Demodectic mange mites are relatively common in domestic dogs, where symptoms are often minor. The WI DNR is closely monitoring wolf pups and examining all dead wolves to determine if this becomes a significant new cause of wolf mortality.

Seven Michigan wolves died from mange during 1993–97, making it responsible for 21 percent of all mortalities, and all disease-caused deaths, during that period (MI DNR 1997, p. 39). During bioyears (mid-April to mid-April) 1999–2009, mange-induced hypothermia killed 18 radio-collared Michigan wolves, representing 15 percent of the total mortality during those years. Since 2004, 11 radio-collared wolves are known to have died from mange in the State (Roell 2010, pers. comm.). Before 2004, MI DNR treated all captured wolves with Ivermectin if they showed signs of mange. In addition, MI DNR vaccinated all captured wolves against CPV and canine distemper virus (CDV). These inoculations were discontinued in 2004 to provide more natural biotic conditions and to provide biologists with an unbiased estimate of disease-caused mortality rates in the population (Roell in litt. 2005b).

Wisconsin wolves similarly had been treated with Ivermectin and vaccinated for CPV and CDV when captured, but the practice was stopped in 1995 to allow the wolf population to experience more natural biotic conditions. Since that time, Ivermectin has been administered only to captured wolves with severe cases of mange. In the future, Ivermectin and vaccines will be used sparingly on Wisconsin wolves, but will be used to counter significant disease outbreaks (Wydeven in litt. 1998).

Among Minnesota wolves, mange may always have been present at low levels and may currently infect less than 10 percent of the State's wolves. Of the 407 wolves trapped by Wildlife Services during 2006–08 in response to depredation complaints, 52 (13 percent) exhibited signs of mange (Hart 2009, pers. comm.); the proportion of wolves with signs of mange decreased from 17 percent in 2006 to 10 percent in 2008. During the previous 3-year period (2003–05), the proportion of trapped wolves with signs of mange was also about 13 percent, suggesting that mange has not increased in prevalence among wolves in Minnesota since 2003. The incidence of mange among wolves targeted by Wildlife Services is likely not representative of the prevalence of the disease in the statewide wolf population; wolves targeted for depredation control appear to be more likely to carry the disease (Hart 2009, pers. comm.).

In a separate study, mortality data from 12 years (1994–05) of monitoring radio-collared wolves in 7 to 9 packs in north-central Minnesota show that 11 percent died from mange (DelGiudice in litt. 2005). However, the sample size (17 total mortalities, 2 from mange in 1998 and 2004) is far too small to deduce trends in mange mortality over time. Furthermore, these data are from mange mortalities, while the Wildlife Services' data are based on mange symptoms, not mortalities.

It is hypothesized that the current incidence of mange is more widespread than it would have otherwise been, because the WGL wolf range has experienced a series of mild winters beginning with the winter of 1997–98 (Van Deelen 2005, Fig. 2). Mange-induced mortality is chiefly a result of winter hypothermia, thus the less severe winters resulted in higher survival of mangy wolves, and increased spread of mange to additional wolves during the following spring and summer. The high wolf population, and especially higher wolf density on the landscape, may also be contributing to the increasing occurrence of mange in the WGL wolf population.

Lyme disease, caused by the spirochete *Borrelia burgdorferi,* is another relatively recently recognized disease, first documented in New England in 1975, although it may have

occurred in Wisconsin as early as 1969. It is spread by ticks that pass the infection to their hosts when feeding. Host species include humans, horses, dogs, white-tailed deer, white-footed mice, eastern chipmunks, coyotes, and wolves. The prevalence of Lyme disease exposure in Wisconsin wolves averaged 70 percent of live-trapped animals in 1988–91, dropped to 37 percent during 1992–97 and was back up to 56 percent (32 of 57 tested) in 2002–04 (Wydeven and Wiedenhoeft 2004b, pp. 23–24 Table 7; 2005, pp. 23–24 Table 7). Clinical symptoms have not been reported in wolves, but infected dogs can experience debilitating conditions, and abortion and fetal mortality have been reported in infected humans and horses. It is possible that individual wolves may be debilitated by Lyme disease, perhaps contributing to their mortality; however, Lyme disease is not believed to be a significant factor affecting wolf populations (Kreeger 2003, p. 212).

The dog louse (*Trichodectes canis*) has been detected in wolves in Ontario, Saskatchewan, Alaska, Minnesota, and Wisconsin (Mech *et al* 1985, pp. 404–405; Kreeger 2003, p. 208; Paul in litt. 2005). Dogs are probably the source of the initial infections, and subsequently wild canids transfer lice by direct contact with other wolves, particularly between females and pups. Severe infestations result in irritated and raw skin, substantial hair loss, particularly in the groin. However, in contrast to mange, lice infestations generally result in loss of guard hairs but not the insulating under fur, thus, hypothermia is less likely to occur and much less likely to be fatal (Brand *et al.* 1995, p. 426). Even though observed in nearly 4 percent in a sample of 391 Minnesota wolves in 2003–05 (Paul in litt. 2005), dog lice infestations have not been confirmed as a cause of wolf mortality, and are not expected to have a significant impact even at a local scale.

Canine distemper virus (CDV) is an acute disease of carnivores that has been known in Europe since the sixteenth century and is now infecting dogs worldwide (Kreeger 2003, p. 209). CDV generally infects dog pups when they are only a few months old, so mortality in wild wolf populations might be difficult to detect (Brand *et al* 1995, pp. 420–421). CDV mortality among wild wolves has been documented only in two littermate pups in Manitoba (Carbyn 1982, pp. 111–112), in two Alaskan yearling wolves (Peterson *et al.* 1984, p. 31), and in two Wisconsin wolves (an adult in 1985 and a pup in 2002 (Thomas in litt. 2006; Wydeven and Wiedenhoeft 2003b, p. 20). Carbyn (1982, pp. 113–116) concluded that CDV was a contributor to a 50 percent decline of the wolf population in Riding Mountain National Park (Manitoba, Canada) in the mid-1970s. Serological evidence indicates that exposure to CDV is high among some Midwest wolves—29 percent in northern Wisconsin wolves and 79 percent in central Wisconsin wolves in 2002–04 (Wydeven and Wiedenhoeft 2004b, pp. 23–24 Table 7; 2005, pp. 23–24 Table 7). However, the continued strong recruitment in Wisconsin and elsewhere in North American wolf populations indicates that distemper is not likely a significant cause of mortality (Brand *et al.* 1995, p. 421).

Other diseases and parasites, including rabies, canine heartworm, blastomycosis, bacterial myocarditis, granulomatous pneumonia, brucellosis, leptospirosis, bovine tuberculosis, hookworm, coccidiosis, and canine hepatitis have been documented in wild wolves, but their impacts on future wild wolf populations are not likely to be significant (Brand *et al.* 1995, pp. 419–429; Hassett in litt. 2003; Johnson 1995, pp. 431, 436–438; Mech and Kurtz 1999, pp. 305–306; Thomas in litt. 1998, Thomas in litt. 2006, WI DNR 1999, p. 61; Kreeger 2003, pp. 202–214). Continuing wolf range expansion, however, likely will provide new avenues for exposure to several of these diseases, especially canine heartworm, raccoon rabies, and bovine tuberculosis (Thomas in litt. 2000, in litt. 2006), further emphasizing the need for disease monitoring programs.

In addition, the possibility of new diseases developing and existing diseases, such as chronic wasting disease (CWD), West Nile Virus (WNV) and canine influenza (Crawford *et al.* 2005, 482–485), moving across species barriers or spreading from domestic dogs to wolves must all be taken into account, and monitoring programs will need to address such threats. Currently there is no evidence that CWD can directly affect canids (Thomas in litt. 2006). Wisconsin wolves have been tested for WNV at necropsy since the first spread of the virus across the State: To date, all results have been negative. Although experimental infection of dogs produced no ill effects, WNV is reported to have killed two captive wolf pups, so young wolves may be at some risk (Thomas in litt. 2006).

In aggregate, diseases and parasites were the cause of 21 percent of the diagnosed mortalities of radio-collared wolves in Michigan from 1999 through 2004 (Beyer 2005, unpublished data) and 27 percent of the diagnosed mortalities of radio-collared wolves in Wisconsin from October 1979 through December 2009 (Wydeven *et al.* 2010, p. 45). In recent years (2006–10), disease has been the cause of death for 14 percent (10 of 70 dead wolves) of the diagnosed mortalities of radio-collared wolves in Wisconsin and 3 to 7 percent of all wolves (radio-collared and not collared) found dead in the State (72 to 94 wolves). During that time period, disease was the cause of death of 12 percent (5 of 43) of the diagnosed mortalities of radio-collared wolves in Michigan, and of 3 percent (6 of 199) of the total known wolf mortalities in Minnesota.

Many of the diseases and parasites are known to be spread by wolf-to-wolf contact. Therefore, the incidence of mange, CPV, CDV, and canine heartworm may increase as wolf densities increase in the more recently colonized areas (Thomas in litt. 2006). Because wolf densities generally are relatively stable following the first few years of colonization, wolf-to-wolf contacts will not likely lead to a continuing increase in disease prevalence in areas that have been occupied for several years or more and are largely saturated with wolf packs (Mech in litt. 1998).

Disease and parasite impacts may increase because several wolf diseases and parasites are carried and spread by domestic dogs. This transfer of pathogens from domestic dogs to wild wolves may increase as wolves continue to colonize non-wilderness areas (Mech in litt. 1998). Heartworm, CPV, and rabies are the main concerns (Thomas in litt. 1998) but dogs may become significant vectors for other diseases with potentially serious impacts on wolves in the future (Crawford *et al.* 2005, pp. 482–485). However, to date wolf populations in Wisconsin and Michigan have continued their expansion into areas with increased contacts with dogs and have shown no adverse pathogen impacts since the mid-1980s impacts from CPV.

Disease and parasite impacts are a recognized concern of the Minnesota, Michigan, and Wisconsin DNRs. The Michigan Gray Wolf Recovery and Management Plan states that necropsies will be conducted on all dead wolves, and that all live wolves that are handled will be examined, with blood, skin, and fecal samples taken to provide disease information. The Michigan Plan states that the Michigan DNR will continue to monitor the prevalence and impact of disease on wolf health following Federal delisting (MI DNR 2008, pp. 32, 40–42).

Similarly, the Wisconsin Wolf Management Plan states that as long as the wolf is State-listed as a threatened

or endangered species, the WI DNR will conduct necropsies of dead wolves and test a sample of live-captured wolves for diseases and parasites, with a goal of screening 10 percent of the State wolf population for diseases annually. However, the plan anticipates that since State delisting (which occurred on March 24, 2004), disease monitoring will be scaled back because the percentage of the wolf population that is live-trapped each year will decline. Disease monitoring of captured wolves currently is focusing on diseases known to be causing noteworthy mortality, such as mange, and other diseases for which data are judged to be sparse, such as Lyme disease and ehrlichiosis (Wydeven and Wiedenhoeft 2006, p. 8). The State will continue to test for disease and parasite loads through periodic necropsy and scat analyses. The 2006 update to the 1999 plan also recommends that all wolves live-trapped for other studies should have their health monitored and reported to the WI DNR wildlife health specialists (WI DNR 1999, p. 21; 2006c, p. 14). Furthermore, the 2006 update identifies a need for "continued health monitoring to document significant disease events that may impact the wolf population and to identify new diseases in the population * * *." (WI DNR 2006a, p. 24).

The Minnesota Wolf Management Plan states that MN DNR "will collaborate with other investigators and continue monitoring disease incidence, where necessary, by examination of wolf carcasses obtained through depredation control programs, and also through blood or tissue physiology work conducted by the MN DNR and the U.S. Geological Survey. The DNR will also keep records of documented and suspected incidence of sarcoptic mange (MN DNR 2001, p. 32)." In addition, it will initiate "(R)egular collection of pertinent tissues of live captured or dead wolves" and periodically assess wolf health "when circumstances indicate that diseases or parasites may be adversely affecting portions of the wolf population (MN DNR 2001, p. 19)." Unlike Michigan and Wisconsin, Minnesota has not established minimum goals for the proportion of its wolves that will be assessed for disease nor does it plan to treat any wolves, although it does not rule out these measures. Minnesota's less intensive approach to disease monitoring and management seems warranted in light of its much greater abundance of wolves than in the other two States.

In areas within the proposed WGL DPS, but outside Minnesota, Wisconsin, and Michigan, we lack data on the incidence of diseases or parasites in transient wolves. However, the boundary of the proposed WGL DPS is laid out in a manner such that the vast majority of, and perhaps all, wolves that will occur in the DPS in the foreseeable future will have originated from the Minnesota–Wisconsin–Michigan wolf metapopulation. Therefore, they will be carrying the "normal" complement of Midwest wolf parasites, diseases, and disease resistance with them. For this reason, any new pairs, packs, or populations that develop within the DPS are likely to experience the same low to moderate adverse impacts from pathogens that have been occurring in the core recovery areas.

The most likely exceptions to this generalization would arise from exposure to sources of novel diseases or more virulent forms that are being spread by other canid species that might be encountered by wolves dispersing into currently unoccupied areas of the DPS. To increase the likelihood of detecting such novel or more virulent diseases and thereby reduce the risk that they might pose to the core meta-population after delisting, we will encourage these States and Tribes to provide wolf carcasses or suitable tissue, as appropriate, to the USGS Madison Wildlife Health Center or the Service's National Wildlife Forensics Laboratory for necropsy. This practice should provide an early indication of new or increasing pathogen threats before they reach the core metapopulation or impact future transient wolves to those areas.

Disease Summary

We believe that several diseases have had noticeable impacts on wolf population growth in the Great Lakes region in the past. These impacts have been both direct, resulting in mortality of individual wolves, and indirect, by reducing longevity and fecundity of individuals or entire packs or populations. Canine parvovirus stalled wolf population growth in Wisconsin in the early and mid-1980s and has been implicated in the decline in the mid-1980s of the isolated Isle Royale wolf population in Michigan, and in attenuating wolf population growth in Minnesota (Mech in litt. 2006). Sarcoptic mange has affected wolf recovery in Michigan's UP and in Wisconsin over the last 12 years, and it is recognized as a continuing issue.

Despite these and other diseases and parasites, the overall trend for wolf populations in the proposed WGL DPS continues to be upward. Wolf management plans for Minnesota, Michigan, and Wisconsin include disease monitoring components that we expect will identify future disease and parasite problems in time to allow corrective action to avoid a significant decline in overall population viability. We conclude that diseases and parasites will not prevent continued population growth or the maintenance of viable wolf populations in the DPS. Delisting of wolves in the proposed WGL DPS will not significantly change the incidence or impacts of disease and parasites on these wolves. Furthermore, we conclude that diseases and parasites will not be threats sufficient to cause wolves in the proposed WGL DPS to be likely to become endangered in the foreseeable future in all or a significant portion of the range within the proposed WGL DPS.

*Natural Predation*

No wild animals habitually prey on wolves. Large prey such as deer, elk, or moose (Mech and Nelson 1989, pp. 207–208; Smith *et al.* 2001, p. 3), or other predators, such as mountain lions (*Felis concolor*) or grizzly bears (*Ursus arctos horribilis*) where they are extant (USFWS 2005, p. 3), occasionally kill wolves, but this has only been rarely documented. This very small component of wolf mortality will not increase with delisting.

Wolves frequently are killed by other wolves, most commonly when packs encounter and attack a dispersing wolf as an intruder or when two packs encounter each other along a territorial boundary (Mech 1994, p. 201). This form of mortality is likely to increase as more of the available wolf habitat becomes saturated with wolf pack territories, as is the case in northeastern Minnesota, but such a trend is not yet evident from Wisconsin or Michigan data. From October 1979 through June 1998, 7 (12 percent) of the mortalities of radio-collared Wisconsin wolves resulted from wolves killing wolves, and 8 of 73 (11 percent) mortalities were from this cause during 2000–05 (Wydeven 1998, p. 16 Table 4; Wydeven and Wiedenhoeft 2001, p. 8 Table 5; 2002, pp. 8–9 Table 4; 2003a, pp. 11–12 Table 4; 2004a, pp. 11–12 Table 5, 2005, p. 21 Table 5).

Among radio-collared wolves dying from known causes between October 1979 and December 2009, overall rate of intraspecific strife was similar at 17 of 151 mortalities or 11 percent (Wydeven *et al.* 2010, p. 45). Gogan *et al.* (2004, p. 7) studied 31 radio-collared wolves in northern Minnesota from 1987 to 1991 and found that 4 (13 percent) were killed by other wolves, representing 29 percent of the total mortality of radio-collared wolves. Intra-specific strife

caused 50 percent of mortality within Voyageurs National Park and 20 percent of the mortality of wolves adjacent to the Park (Gogan *et al.* 2004, p. 22). The DelGiudice data (in litt. 2005) show a 17 percent mortality rate from other wolves in another study area in north-central Minnesota from 1994 to 2005. This behavior is normal in healthy wolf populations and is an expected outcome of dispersal conflicts and territorial defense, as well as occasional intra-pack strife. This form of mortality is something with which the species has evolved and it should not pose a threat to wolf populations in the proposed WGL DPS if this DPS is delisted.

*Human Predation*

Because our concern about human predation is its overall effect on wolf mortality, the following discussion addresses the major human causes of wolf mortality, including illegal killing, depredation control, and vehicle collisions.

Humans have functioned as highly effective predators of the wolf in North America for several hundred years. European settlers in the Midwest attempted to eliminate the wolf entirely in earlier times, and the U.S. Congress passed a wolf bounty that covered the Northwest Territories in 1817. Bounties on wolves subsequently became the norm for States across the species' range. In Michigan, an 1838 wolf bounty became the ninth law passed by the First Michigan Legislature; this bounty remained in place until 1960. A Wisconsin bounty was instituted in 1865 and was repealed about the time wolves were extirpated from the State in 1957. Minnesota maintained a wolf bounty until 1965.

Subsequent to the gray wolf's listing as a Federally endangered species, the Act and State endangered species statutes prohibited the killing of wolves except under very limited circumstances, such as in defense of human life, for scientific or conservation purposes, or under special regulations intended to reduce wolf depredations of livestock or other domestic animals. The resultant reduction in human-caused wolf mortality is the main cause of the wolf's reestablishment in large parts of its historical range. It is clear, however, that illegal killing of wolves has continued in the form of intentional mortality and incidental deaths.

Illegal killing of wolves occurs for a number of reasons. Some of these killings are accidental (for example, wolves are hit by vehicles, mistaken for coyotes and shot, or caught in traps set for other animals); some of these accidental killings are reported to State, Tribal, and Federal authorities. It is likely that most illegal killings, however, are intentional and are never reported to government authorities. Because they generally occur in remote locations and the evidence is easily concealed, we lack reliable estimates of annual rates of intentional illegal killings.

In Wisconsin, all forms of human-caused mortality accounted for 56 percent of the diagnosed deaths of radio-collared wolves from October 1979 through December 2009 (Wydeven *et al.* 2010, p. 45). Thirty-four percent of the diagnosed mortalities, and 62 percent of the human-caused mortalities, were from illegal killing (mainly shootings). Another 9 percent of all the diagnosed mortalities (15 percent of the human-caused mortalities) resulted from vehicle collisions. (These percentages and those in the following paragraphs exclude seven radio-collared Wisconsin wolves that were killed in depredation control actions by USDA–APHIS—Wildlife Services. The wolf depredation control programs in the Midwest are discussed separately under Depredation Control, below.) Data from 2006 through 2010 (68 diagnosed mortalities of radio-collared wolves) show the mortality percentages for disease to be slightly lower and illegal kills to be similar, with 14 percent of the mortalities resulting from mange or disease and 35 percent from being illegally killed. The mortality percentage for vehicle collisions during this time period remained constant (13 percent) (Wydeven *et al.* 2007, p. 10; and Wydeven and Wiedenhoeft 2008, Summary). Most recently for 2010, mortality data from actively monitored wolves show that of wolves that died, 38 percent were killed illegally (all shootings); 12 percent were euthanized for human safety concerns; 6 percent of the deaths were disease related; 6 percent died from apparent old age, 6 percent from intraspecific strife, and 12 percent from vehicle collisions; and the causes for 19 percent of the deaths were unknown (Wydeven *et al.* 2011, p. 2).

During the periods that wolves were Federally delisted (from March 2007 through September 2008 and from April through early July 2009), 92 wolves were killed for depredation control, including 8 legally shot by private landowners (Wydeven and Wiedenhoeft 2008, p. 8; Wydeven *et al.* 2009b, p. 6; Wydeven *et al.* 2010, p. 13).

As the Wisconsin population has increased in numbers and range, vehicle collisions have increased as a percentage of radio-collared wolf mortalities. During the October 1979 through June 1992 period, only 1 of 27 (4 percent) known mortalities was from that cause; but from July 1992 through June 1998, 5 of the 26 (19 percent) known mortalities resulted from vehicle collisions (Wydeven 1998, p. 6). From 2002 through 2004, 7 of 45 (16 percent) known mortalities were from that cause (Wydeven and Wiedenhoeft 2003a, pp. 11–12 Table 4; 2004a, pp. 11–12 Table 5; 2005, pp. 19–20 Table 4); and from 2005 through 2009, 126 of 459 (27 percent) known mortalities were from that cause (Wydeven and Wiedenhoeft 2005, p. 20; Wydeven and Wiedenhoeft 2006, p. 20; Wydeven *et al.* 2007a, p. 7; Wydeven *et al.* 2007b, p. 10; Wydeven and Wiedenhoeft 2008, p. 7; Wydeven *et al.* 2009a, pp. 19–21; Wydeven and Wiedenhoeft 2009, Table 3; Wydeven *et al.* 2010, Table 7).

A comparison over time for diagnosed mortalities of radio-collared Wisconsin wolves shows that 18 of 57 (32 percent) were illegally killed from October 1979 through 1998, while 12 of 42 (29 percent) were illegally killed from 2002 through 2004 and 24 of 72 (33 percent) were illegally killed from 2005 to March 2007 (WI DNR 1999, p. 63; Wydeven and Wiedenhoeft 2003a, pp. 11–12 Table 4; 2004a, pp. 11–12 Table 4; 2005. pp. 19–20 Table 4; Wydeven *et al.* 2006a, p. 6; 2006b, p. 8; 2007, pp. 6–7; 2008a, p. 10). In 2006, prior to the Federal delisting the following year, 17 of 72 wolves found dead in the state were killed illegally. Among nine radio-collared wolves that had died in 2006, six (67 percent) were illegally killed. In 2007, after Federal delisting, 10 of 90 dead wolves found in the State were illegally killed, and 3 (19 percent) of the radio-collared wolves found dead were illegally killed. In 2008, 14 of 94 dead wolves found in Wisconsin were illegally killed, and 4 (28 percent) of 14 radio-collared wolves found dead were illegal kills. In 2009, when wolves were again Federally listed for most of the year, 20 of the 72 dead wolves found in Wisconsin were illegally killed, and 8 (62 percent) of 13 radio-collared wolves found dead were illegal kills. In 2010, when wolves continued to be Federally listed, 14 of 72 dead wolves were illegally killed, and 6 (38 percent) of 16 radio-collared wolves were illegally killed.

Thus the number of known illegally killed wolves declined slightly from 17 in 2006, to 10 in 2007 and 14 in 2008, increased to 20 in 2009, and declined to 14 in 2010. Among radio-collared wolves found dead, illegal killing represented 67 percent of all mortality in 2006, 19 percent in 2007, 23 percent in 2008, 62 percent in 2009, and 38

percent in 2010 (Wydeven *et al.* 2010, p. 13; Wydeven *et al.* 2011, p. 2).

In the UP of Michigan, human-caused mortalities accounted for 75 percent of the diagnosed mortalities, based upon 34 wolves recovered from 1960 to 1997, including mostly non-radio-collared wolves. Twenty-eight percent of all the diagnosed mortalities and 38 percent of the human-caused mortalities were from shooting. In the UP during that period, about one-third of all the known mortalities were from vehicle collisions (MI DNR 1997, pp. 5–6). During the 1998 Michigan deer hunting season, three radio-collared wolves were shot and killed, resulting in one arrest and conviction (Hammill in litt. 1999, Michigan DNR 1999). During the subsequent 3 years, eight additional wolves were killed in Michigan by gunshot, and the cut-off radio-collar from a ninth animal was located, but the animal was never found. These incidents resulted in six guilty pleas, with three cases remaining open.

Data collected from radio-collared wolves from the 1999 to 2009 bioyears (mid-April to mid-April) show that human-caused mortalities still account for the majority of the wolf mortalities (66 percent) in Michigan. Deaths from vehicular collisions were about 18 percent of total mortality (27 percent of the human-caused mortality) and showed no trend over this 11-year period. Deaths from illegal killing constituted 39 percent of all mortalities (60 percent of the human-caused mortality) over the period. From 1999 through 2001, illegal killings were 31 percent of the mortalities, but this increased to 42 percent during the 2002 through 2004 bioyears and to 40 percent during bioyears 2005 through 2010 (Roell 2010, pers. comm.).

Most Michigan residents place a high priority on wolf management actions that address public concerns for human safety (Beyer *et al.* 2006). Quick and professional responses to wolf conflicts have been important for wolf recovery (Ruid *et al.* 2009, p. 280). In most cases, people can take simple, sensible measures to avoid those situations and protect themselves against harm. Other cases may warrant higher levels of concern and professional assistance. Michigan DNR solved most wolf-human conflicts using nonlethal methods (Roell 2010, pers. comm.). However, in a few incidents lethal control was warranted and carried out under Federal regulations (50 CFR 17.21, which allows the take of an endangered species when there is a "demonstrable but nonimmediate threat" to protect human safety, or to euthanize a sick or injured wolf, but only if it is not reasonably possible to translocate the animal alive), or while wolves were not Federally protected (Roell 2010 *et al.,* p. 9). Since 2004 the Michigan DNR and USDA–Wildlife Services have killed 13 animals (12 involving human safety and 1 sick wolf) under the authority of this regulation (Roell 2010 *et al.,* p. 9). Two others were killed for human safety concerns while wolves were Federally delisted (Roell 2010, pers. comm.).

North-central Minnesota data from 16 diagnosed mortalities of radio-collared wolves over a 12-year period (1994–2005) show that human-causes resulted in 69 percent of the diagnosed mortalities. This includes 1 wolf accidentally snared, 2 vehicle collisions, and 8 (50 percent of all diagnosed mortalities) that were shot (DelGiudice in litt. 2005). However, this data set of only 16 mortalities over 12 years is too small for reliable comparison to Wisconsin and Michigan data.

A smaller mortality dataset is available from a 1987–91 study of wolves in, and adjacent to, Minnesota's Voyageurs National Park, along the Canadian border. Of 10 diagnosed mortalities, illegal killing outside the Park was responsible for a minimum of 60 percent of the deaths (Gogan *et al.* 2004, p. 22).

Two Minnesota studies provide some limited insight into the extent of human-caused wolf mortality before and after the species' listing. On the basis of bounty data from a period that predated wolf protection under the Act by 20 years, Stenlund (1955, p. 33) found an annual human-caused mortality rate of 41 percent. Fuller (1989, pp. 23–24) provided 1980–86 data from a north-central Minnesota study area and found an annual human-caused mortality rate of 29 percent, a figure that includes 2 percent mortality from legal depredation control actions. Drawing conclusions from comparisons of these two studies, however, is difficult due to the confounding effects of habitat quality, exposure to humans, prey density, differing time periods, and vast differences in study design. Although these figures provide support for the contention that human-caused mortality decreased after the wolf's protection under the Act, it is not possible at this time to determine if human-caused mortality (apart from mortalities from depredation control) has significantly changed over the nearly 35-year period that the gray wolf has been listed as threatened or endangered.

Wolves were largely eliminated from the Dakotas in the 1920s and 1930s and were rarely reported from the mid-1940s through the late 1970s. Ten wolves were killed in these two States from 1981 to 1992 (Licht and Fritts 1994, pp. 76–77). Seven more were killed in North Dakota since 1992, with four of these mortalities occurring in 2002 and 2003; in 2001, one wolf was killed in Harding County in extreme northwestern South Dakota. The number of reported sightings of wolves in North Dakota is increasing. From 1993 to 1998, six wolf depredation reports were investigated in North Dakota, and adequate signs were found to verify the presence of wolves in two of the cases. A den with pups was also documented in extreme north-central North Dakota near the Canadian border in 1994. From 1999 to 2003, residents of North Dakota reported 16 wolf sightings or depredation incidents to USDA–APHIS–Wildlife Services, and 9 of these incidents were verified. Additionally, one North Dakota wolf sighting was confirmed in early 2004, two wolf depredation incidents were verified north of Garrison in late 2005, and one wolf was found dead in Eddy County in 2009. USDA–APHIS–Wildlife Services also confirmed a wolf sighting along the Minnesota border near Gary, South Dakota, in 1996, and a trapper with the South Dakota Game, Fish, and Parks Department sighted a lone wolf in the western Black Hills in 2002.

Several other unconfirmed sightings have been reported from these States, including two reports in South Dakota in 2003. Wolves killed in North and South Dakota were most often shot by hunters after being mistaken for coyotes, or were killed by vehicles. The 2001 mortality in South Dakota and one of the 2003 mortalities in North Dakota were caused by M–44 devices that had been legally set in response to complaints about coyotes.

In and around the core recovery areas in the Midwest, a continuing increase in wolf mortalities from vehicle collisions, both in actual numbers and as a percent of total diagnosed mortalities, is expected as wolves continue their colonization of areas with more human developments and a denser network of roads and vehicle traffic. In addition, the growing wolf populations in Wisconsin and Michigan are producing greater numbers of dispersing individuals each year, and this also will contribute to increasing numbers of wolf-vehicle collisions. This increase in accidental deaths would be unaffected by a removal of wolves in the proposed WGL DPS from the protections of the Act.

In those areas of the proposed WGL DPS that are beyond the areas currently occupied by wolf packs in Minnesota, Wisconsin, and Michigan, we expect that human-caused wolf mortality in the form of vehicle collisions, shooting, and

trapping have been removing all, or nearly all, the wolves that disperse into these areas. We expect this to continue after Federal delisting. Road densities are high in these areas, with numerous interstate highways and other freeways and high-speed thoroughfares that are extremely hazardous to wolves attempting to move across them. Shooting and trapping of wolves also is likely to continue as a threat to wolves in these areas for several reasons. Especially outside of Minnesota, Wisconsin, and Michigan, hunters will not expect to encounter wolves, and may easily mistake them for coyotes from a distance, resulting in unintentional shootings.

It is important to note that, despite the difficulty in measuring the extent of illegal killing of wolves, all sources of wolf mortality, including legal (for example, depredation control) and illegal human-caused mortality, have not been of sufficient magnitude to stop the continuing growth of the wolf population in Wisconsin and Michigan, nor to cause a wolf population decline in Minnesota. This indicates that total wolf mortality does not threaten the continued viability of the wolf population in these three States, or in the proposed WGL DPS.

Human Predation Summary

The high reproductive potential of wolves allows wolf populations to withstand relatively high mortality rates, including human-caused mortality. The principle of compensatory mortality is believed to occur in wolf populations. This means that human-caused mortality is not simply added to "natural" mortality, but rather replaces a portion of it. For example, some of the wolves that are killed during depredation control actions would have otherwise died during that year from disease, intraspecific strife, or starvation. Thus, the addition of intentional killing of wolves to a wolf population will reduce the mortality rates from other causes on the population. Based on 19 studies by other wolf researchers, Fuller *et al.* (2003, pp. 182–186) concludes that human-caused mortality can replace about 70 percent of other forms of mortality.

Fuller *et al.* (2003, p. 182 Table 6.8) has summarized the work of various researchers in estimating mortality rates, especially human harvest, that would result in wolf population stability or decline. They provide a number of human-caused and total mortality rate estimates and the observed population effects in wolf populations in the United States and Canada. While variability is apparent, in general, wolf populations increased if their total average annual mortality was 30 percent or less, and populations decreased if their total average annual mortality was 40 percent or more. Four of the cited studies showed wolf population stability or increases with human-caused mortality rates of 24 to 30 percent. The clear conclusion is that a wolf population with high pup productivity—the normal situation in a wolf population—can withstand levels of overall and of human-caused mortality without suffering a long-term decline in numbers.

The wolf populations in Minnesota, Wisconsin, and Michigan will stop growing when they have saturated the suitable habitat and are curtailed in less suitable areas by natural mortality (disease, starvation, and intraspecific aggression), depredation management, incidental mortality (for example, road kill), illegal killing, and other means. At that time, we should expect to see population declines in some years followed by short-term increases in other years, resulting from fluctuations in birth and mortality rates. Adequate wolf monitoring programs, however, as described in the Michigan, Wisconsin, and Minnesota wolf management plans, are likely to identify high mortality rates or low birth rates that warrant corrective action by the management agencies (see Regulatory Mechanisms in Minnesota, Wisconsin, and Michigan, below). The goals of all three State wolf management plans are to maintain wolf populations well above the numbers recommended in the Recovery Plan for the Eastern Timber Wolf to ensure long-term viable wolf populations. The State management plans recommend a minimum wolf population of 1,600 in Minnesota, 350 in Wisconsin, and 200 in Michigan.

Despite human-caused mortalities of wolves in Minnesota, Wisconsin, and Michigan, these wolf populations have continued to increase in both numbers and range. If wolves in the proposed WGL DPS are delisted, as long as other mortality factors do not increase significantly and monitoring is adequate to document, and if necessary counteract (see Post-Delisting Monitoring, below), the effects of excessive human-caused mortality should that occur, the Minnesota–Wisconsin–Michigan wolf population will not decline to nonviable levels in the foreseeable future as a result of human-caused killing or other forms of predation. Therefore, we conclude that predation, including all forms of human-caused mortality, will not be a sufficient future threat to cause wolves in the proposed WGL DPS to be likely to become endangered in the foreseeable future in all or a significant portion of the range within the proposed WGL DPS.

**D. The Inadequacy of Existing Regulatory Mechanisms**

The inadequacy of existing regulatory mechanisms is one of five factors that, under the Endangered Species Act (Act), may result in a determination as to whether a species should be listed or not. In analyzing whether the existing regulatory mechanisms are adequate, the Service reviews relevant Federal, state, and Tribal laws, plans, regulations, Memorandum of Understandings, Cooperative Agreements and other such factors that influence conservation of the species in question, including analyzing the extent those mechanism can be relied upon. Other examples include State governmental actions enforced under a State statute or constitution, or Federal action under statute.

Strongest weight is given to statutes and their implementing regulations, and management direction that stems from those laws and regulations. Some other agreements are more voluntary in nature; in those cases we analyze the specific facts to determine the extent to which it can be relied on in the future, including how it addresses threats to the species. We consider all pertinent information, including the efforts and conservation practices of State governments, whether or not these are enforceable by law. Regulatory mechanisms, if they exist, may preclude the need for listing if such mechanisms are judged to adequately address the threat to the species such that listing is not warranted. Conversely, threats on the landscape are exacerbated when not addressed by existing regulatory mechanisms, or when the existing mechanisms are not adequate (or not adequately implemented or enforced).

The following sections discuss the adequacy of regulatory mechanisms that would be implemented if the WGL DPS were delisted, that is, removed from the List of Endangered and Threatened Wildlife. For the reasons described in the following section, the Service has determined that, if delisted, adequate regulatory mechanisms would be in place to ensure that this DPS of wolves is neither threatened nor endangered.

*Regulatory Mechanisms in Minnesota, Wisconsin, and Michigan*

State Wolf Management Planning

During the 2000 legislative session, the Minnesota Legislature passed wolf

management provisions addressing wolf protection, taking of wolves, and directing MN DNR to prepare a wolf management plan. The MN DNR revised a 1999 draft wolf management plan to reflect the legislative action of 2000, and completed the Minnesota Wolf Management Plan (MN Plan) in early 2001 (MN DNR 2001, pp. 8–9).

The Wisconsin Natural Resources Board (NRB) approved the Wisconsin Wolf Management Plan in October 1999 (WI Plan). In 2004 and 2005 the Wisconsin Wolf Science Advisory Committee and the Wisconsin Wolf Stakeholders group reviewed the 1999 Plan, and the Science Advisory Committee subsequently developed updates and recommended modifications to the 1999 Plan. The WI DNR presented the Plan updates and modifications to the Wisconsin NRB on June 28, 2006, and the NRB approved them at that time, with the understanding that some numbers would be updated and an additional reference document would be added (Holtz in litt. 2006). The updates were completed and received final NRB approval on November 28, 2006 (WI DNR 2006a, p. 1).

In late 1997, the Michigan Wolf Recovery and Management Plan (MI Plan) was completed and received the necessary State approvals. It primarily focused on wolf recovery, rather than long-term management of a large wolf population and the conflicts that result as a consequence of successful wolf restoration. In 2006 the MI DNR convened a Michigan Wolf Management Roundtable committee (Roundtable) to provide guiding principles to the DNR on changes and revisions to the 1997 Plan and to guide management of Michigan wolves and wolf-related issues following Federal delisting of the species. The MI DNR relied heavily on those guiding principles as it drafted a new wolf management plan. The Roundtable was composed of representatives from 20 Michigan stakeholder interests in wolf recovery and management, and its membership is roughly equal in numbers from the UP and the LP. During 2006, the Roundtable provided its "Recommended Guiding Principles for Wolf Management in Michigan" to the DNR in November (Michigan Wolf Management Roundtable 2006. p. 2). Based on those Roundtable recommendations, a revised Michigan Wolf Management Plan was completed in July 2008 (MI DNR 2008a). The complete text of the Wisconsin, Michigan, and Minnesota wolf plans can be found on our Web site (see **FOR FURTHER INFORMATION CONTACT**).

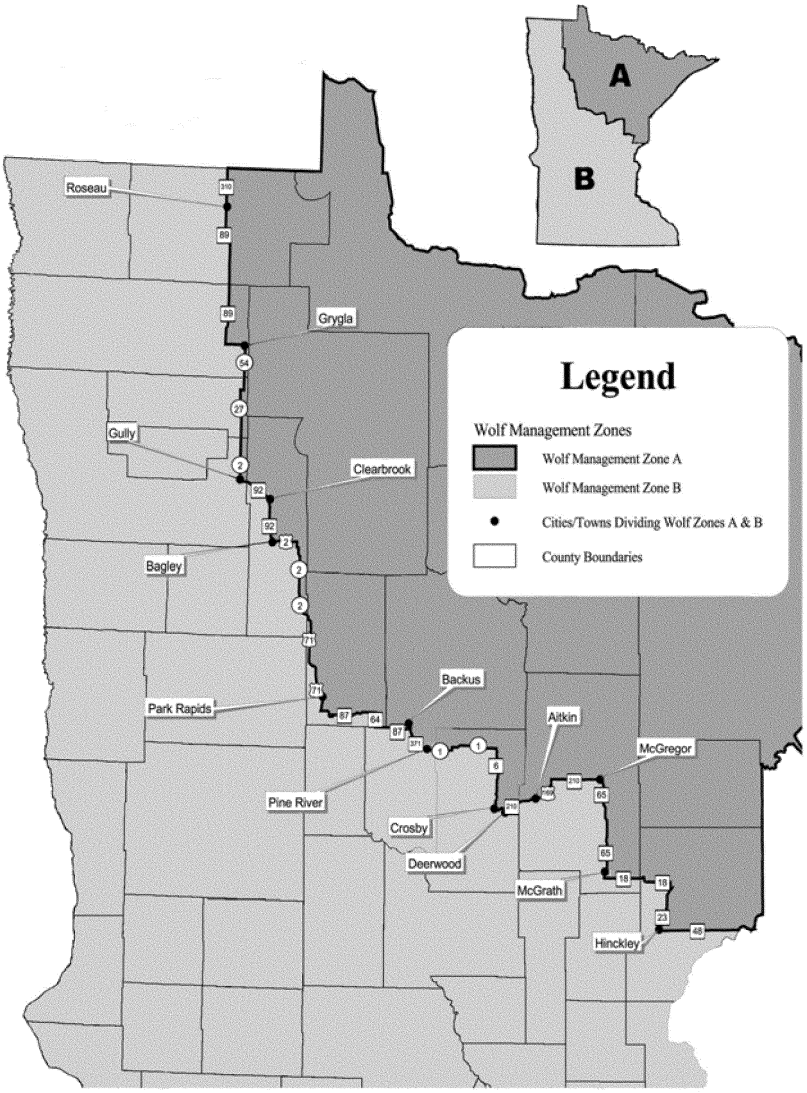
The Minnesota Wolf Management Plan

The Minnesota Plan is based, in part, on the recommendations of a State wolf management roundtable (MN DNR 2001, Appendix V) and on a State wolf management law enacted in 2000 (MN DNR 2001, Appendix I). This law and the Minnesota Game and Fish Laws constitute the basis of the State's authority to manage wolves. The Plan's stated goal is "to ensure the long-term survival of wolves in Minnesota while addressing wolf-human conflicts that inevitably result when wolves and people live in the same vicinity" (MN DNR 2001, p. 2). It establishes a minimum goal of 1,600 wolves in the State. Key components of the plan are population monitoring and management, management of wolf depredation of domestic animals, management of wolf prey, enforcement of laws regulating take of wolves, public education, and increased staffing to accomplish these actions. Following the proposed delisting, Minnesota DNR's management of wolves would differ from their current management while listed as threatened under the Act. Most of these differences deal with the control of wolves that attack or threaten domestic animals.

The Minnesota Plan divides the State into two wolf management zones—Zones A and B (see Figure 2 below). Zone A corresponds to Federal Wolf Management Zones 1 through 4 (approximately 30,000 sq mi (48,000 sq km) in northeastern Minnesota) in the Service's Recovery Plan for the Eastern Timber Wolf, whereas Zone B constitutes Zone 5 in that recovery plan (MN DNR 2001, pp. 19–20 and Appendix III; USFWS 1992, p. 72). Within Zone A, wolves would receive strong protection by the State, unless they were involved in attacks on domestic animals. The rules governing the take of wolves to protect domestic animals in Zone B would be less protective than in Zone A (see Post-delisting Depredation Control in Minnesota below).

BILLING CODE 4310–55–P

Figure 2. Minnesota wolf management zones.




Copyright February 2001, Minnesota Department of Natural Resources, Division of Wildlife

BILLING CODE 4310–55–C

The MN DNR plans to allow wolf numbers and distribution to naturally expand, with no maximum population goal, and if any winter population estimate is below 1,600 wolves, it would take actions to "assure recovery" to 1,600 wolves (MN DNR 2001 p. 19). The MN DNR plans to continue to monitor wolves in Minnesota to determine whether such intervention is necessary. The MN DNR plans to conduct another statewide population survey in the winter of 2012–13 and at subsequent 5-year intervals. In addition to these statewide population surveys, MN DNR annually reviews data on depredation incident frequency and locations provided by Wildlife Services and winter track survey indices (see Erb 2008) to help ascertain annual trends in wolf population or range (MN DNR 2001, pp. 18–19). The agency is currently evaluating alternatives to its current methodology with the potential to improve the efficiency and accuracy of its statewide population estimates (Stark 2009a, pers. comm.).

Minnesota (MN DNR 2001, pp. 21–24, 27–28) plans to reduce or control illegal mortality of wolves through education, increased enforcement of the State's wolf laws and regulations, discouraging new road access in some areas, and maintaining a depredation control program that includes compensation for livestock losses. The MN DNR plans to use a variety of methods to encourage and support education of the public about the effects of wolves on livestock, wild ungulate populations, and human activities and the history and ecology of wolves in the State (MN DNR 2001, pp. 29–30). These are all measures that have been in effect for years in Minnesota, although increased enforcement of State laws against take of wolves would replace enforcement of the Act's take prohibitions. Financial compensation for livestock losses has increased to the full market value of the animal, replacing previous caps of $400 and $750 per animal (MN DNR 2001, p. 24). We do not expect the State's efforts to result in the reduction of illegal take of wolves from existing levels, but we believe these measures will be crucial in ensuring that illegal mortality does not significantly increase if this proposed delisting is finalized.

The likelihood of illegal take increases in relation to road density and human population density, but

changing attitudes towards wolves may allow them to survive in areas where road and human densities were previously thought to be too high (Fuller *et al.* 2003, p. 181). The MN DNR does not plan to reduce current levels of road access, but would encourage managers of land areas large enough to sustain one or more wolf packs to "be cautious about adding new road access that could exceed a density of one mile of road per square mile of land, without considering the potential effect on wolves" (MN DNR 2001, pp. 27–28).

Under Minnesota law, the illegal killing of a wolf is a gross misdemeanor and is punishable by a maximum fine of $3,000 and imprisonment for up to one year. The restitution value of an illegally killed wolf is $2,000 (MN DNR 2001, p. 29). The MN DNR acknowledges that increased enforcement of the State's wolf laws and regulations would be dependent on increases in staff and resources, additional cross-deputization of Tribal law enforcement officers, and continued cooperation with Federal law enforcement officers. Minnesota DNR has designated three conservation officers who are stationed in the State's wolf range as the lead officers for implementing the wolf management plan (MN DNR 2001, pp. 29, 32; Stark 2009a, pers. comm.).

Minnesota DNR will consider wolf population management measures, including public hunting and trapping seasons and other methods, in the future. However, State law and the Minnesota Plan state that such consideration will occur no sooner than 5 years after Federal delisting, and there would be opportunity for full public comment on such possible changes at that time (Minnesota Statutes 97B.645 Subdiv. 9, see MN DNR 2001 Appendix 1, p. 6; MN DNR 2001, p. 20). The Minnesota Plan requires that these population management measures be implemented in such a way to maintain a statewide late-winter wolf population of at least 1,600 animals (MN DNR 2001, pp. 19–20), well above the planning goal of 1,251 to 1,400 wolves for the State in the Revised Recovery Plan (USFWS 1992, p. 28), therefore, implementing such management measures under that requirement would ensure the wolf's continued survival in Minnesota.

*Depredation Control in Minnesota*—Although Federally protected as a threatened species in Minnesota (since their 1978 reclassification), wolves that have attacked domestic animals have been killed by designated government employees under the authority of a special regulation (50 CFR 17.40(d)) under section 4(d) of the Act. However, no control of depredating wolves was allowed in Federal Wolf Management Zone 1, comprising about 4,500 sq mi (7,200 sq km) in extreme northeastern Minnesota (USFWS 1992, p. 72). In Federal Wolf Management Zones 2 through 5, employees or agents of the Service (including USDA–APHIS–Wildlife Services) have taken wolves in response to depredations of domestic animals within one-half mile of the depredation site. Young-of-the-year captured on or before August 1 must be released. The regulations that allow for this take (50 CFR 17.40(d)(2)(i)(B)(4)) do not specify a maximum duration for depredation control, but Wildlife Services personnel have followed internal guidelines under which they trap for no more than 10–15 days, except at sites with repeated or chronic depredation, where they may trap for up to 30 days (Paul 2004, pers. comm.).

During the period 1980–2009, the Federal Minnesota wolf depredation control program euthanized from 20 (in 1982) to 216 (in 1997) wolves annually. Annual averages (and percentage of statewide population) were 30 (2.2 percent) wolves killed from 1980 to 1984, 49 (3.0 percent) from 1985 to 1989, 115 (6.0 percent) from 1990 to 1994, 152 (6.7 percent) from 1995 to 1999, and 128 wolves (4.2 percent) from 2000 to 2005. During 2006–10 an average of 157 wolves were killed each year—approximately 5.4 percent of wolves in the State (Erb 2008; USDA–Wildlife Services 2010, p. 3). Since 1980, the lowest annual percentage of Minnesota wolves killed under this program was 1.5 percent in 1982; the highest percentage was 9.4 in 1997 (Paul 2004, pp. 2–7; 2006, p. 1). Following the return of wolves in Minnesota to the list of threatened species in 2009, 195 and 192 wolves were killed in 2009 and 2010, respectively, in response to depredation of domestic animals in Minnesota. This is the highest 22-year consecutive total since authorization to control depredating wolves was allowed by special regulation under section 4(d) of the Act while wolves were Federally listed.

This level of wolf removal for depredation control has not interfered with wolf recovery in Minnesota, although it may have slowed the increase in wolf numbers in the State, especially since the late-1980s, and may be contributing to the possibly stabilized Minnesota wolf population suggested by the 2003–04 and 2007–08 estimates (see additional information in Minnesota Recovery). Minnesota wolf numbers grew at an average annual rate of nearly 4 percent between 1989 and 1998 while the depredation control program was taking its highest percentages of wolves (Paul 2004, pp. 2–7).

Under a Minnesota statute, the Minnesota Department of Agriculture (MDA) compensates livestock owners for full market value of livestock that wolves have killed or severely injured. An authorized investigator must confirm that wolves were responsible for the depredation. The Minnesota statute also requires MDA to periodically update its Best Management Practices (BMPs) to incorporate new practices that it finds would reduce wolf depredation (Minnesota Statutes 2010, Section 3.737, subdivision 5).

*Post-delisting Depredation Control in Minnesota*—If the WGL DPS is delisted, depredation control will be authorized under Minnesota State law and conducted in conformance with the Minnesota Wolf Management Plan (MN DNR 2001). The Minnesota Plan divides the State into Wolf Management Zones A and B. Zone A is composed of Federal Wolf Management Zones 1–4, covering 30,728 sq mi (49,452 sq km), approximately the northeastern third of the State. Zone B is identical to the current Federal Wolf Management Zone 5, and contains the 54,603 sq mi (87,875 sq km.) that make up the rest of the State (MN DNR 2001, pp. 19–20 and Appendix III; USFWS 1992, p. 72). The statewide survey conducted during the winter of 2003–04 estimated that there were approximately 2,570 wolves in Zone A and 450 in Zone B (Erb in litt. 2005). As discussed in *Recovery Criteria above,* the Federal planning goal is 1,251–1,400 wolves for Zones 1–4 and no wolves in Zone 5 (USFWS 1992, p. 28).

In Zone A wolf depredation control is limited to situations of (1) immediate threat and (2) following verified loss of domestic animals. In this zone, if the DNR verifies that a wolf destroyed any livestock, domestic animal, or pet, and if the owner requests wolf control be implemented, trained and certified predator controllers may take wolves (specific number to be determined on a case-by-case basis) within a 1-mile radius of the depredation site (depredation control area) for up to 60 days. In contrast, in Zone B, predator controllers may take wolves (specific number to be determined on a case-by-case basis) for up to 214 days after MN DNR opens a depredation control area, depending on the time of year. Under State law, the DNR may open a control area in Zone B anytime within 5 years of a verified depredation loss upon request of the landowner, thereby providing more of a preventative approach than is allowed in Zone A, in

order to head off repeat depredation incidents (MN DNR 2001, p. 22).

State law and the Minnesota Plan will also allow for private wolf depredation control throughout the State. Persons may shoot or destroy a wolf that poses "an immediate threat" to their livestock, guard animals, or domestic animals on lands that they own, lease, or occupy. Immediate threat is defined as "in the act of stalking, attacking, or killing." This does not include trapping because traps cannot be placed in a manner such that they trap only wolves in the act of stalking, attacking, or killing. Owners of domestic pets may also kill wolves posing an immediate threat to pets under their supervision on lands that they do not own or lease, although such actions are subject to local ordinances, trespass law, and other applicable restrictions. The MN DNR will investigate any private taking of wolves in Zone A (MN DNR 2001, p. 23).

To protect their domestic animals in Zone B, individuals do not have to wait for an immediate threat or a depredation incident in order to take wolves. At any time in Zone B, persons who own, lease, or manage lands may shoot wolves on those lands to protect livestock, domestic animals, or pets. They may also employ a predator controller to trap a wolf on their land or within 1 mile of their land (with permission of the landowner) to protect their livestock, domestic animals, or pets (MN DNR 2001, p. 23–24).

The Minnesota Plan will also allow persons to harass wolves anywhere in the State within 500 yards of "people, buildings, dogs, livestock, or other domestic pets or animals." Harassment may not include physical injury to a wolf.

Depredation control will be allowed throughout Zone A, which includes an area (Federal Wolf Management Zone 1) where such control has not been permitted under the Act's protection. Depredation in Zone 1, however, has been limited to 2 to 4 reported incidents per year, mostly of wolves killing dogs, although Wildlife Services received one livestock depredation complaint in Zone 1 in 2008 (Hart pers. comm. 2009), and some dog kills in this zone probably go unreported. In 2009, there was one probable and one verified depredation of a dog near Ely, Minnesota, and in 2010 Wildlife Services confirmed three dogs killed by wolves in Zone 1 (USDA–Wildlife Services 2009, p. 3; USDA–Wildlife Services 2010, p. 3). There are few livestock in Zone 1; therefore, the number of verified future depredation incidents in that Zone is expected to be low, resulting in a correspondingly low number of depredating wolves being killed there after delisting.

The final change in Zone A is the ability for owners or lessees to respond to situations of immediate threat by shooting wolves in the act of stalking, attacking, or killing livestock or other domestic animals. We believe this is not likely to result in the killing of many additional wolves, as opportunities to shoot wolves "in the act" will likely be few and difficult to successfully accomplish, a belief shared by the most experienced wolf depredation agent in the lower 48 States (Paul in litt. 2006, p. 5). It is also possible that illegal killing of wolves in Minnesota will decrease, because the expanded options for legal control of problem wolves may lead to an increase in public tolerance for wolves (Paul in litt. 2006, p. 5).

Within Zone B, State law and the Minnesota Plan provide broad authority to landowners and land managers to shoot wolves at any time to protect their livestock, pets, or other domestic animals on land owned, leased, or managed by the individual. Such takings can occur in the absence of wolf attacks on the domestic animals. Thus, the estimated 450 wolves in Zone B could be subject to substantial reduction in numbers, and at the extreme, wolves could be eliminated from Zone B. However, there is no way to reasonably evaluate in advance the extent to which residents of Zone B will use this new authority, nor how vulnerable Zone B wolves will be. While wolves were under State management in 2007–08, landowners in Zone B shot six wolves under this authority. One additional wolf was trapped and euthanized in Zone B by a State certified predator controller in 2009 (Stark 2009b, pers. comm.).

The limitation of this broad take authority to Zone B is fully consistent with the Recovery Plan for the Eastern Timber Wolf's advice that wolves should be restored to the rest of Minnesota but not to Zone B (Federal Zone 5) because that area "is not suitable for wolves" (USFWS 1992, p. 20). The Recovery Plan for the Eastern Timber Wolf envisioned that the Minnesota numerical planning goal would be achieved solely in Zone A (Federal Zones 1–4) (USFWS 1992, p. 28), and that has occurred. Wolves outside of Zone A are not necessary to the establishment and long-term viability of a self-sustaining wolf population in the State, and therefore there is no need to establish or maintain a wolf population in Zone B. Accordingly, there is no need to maintain significant protection for wolves in Zone B in order to maintain a Minnesota wolf population that continues to satisfy the Federal recovery criteria after Federal delisting.

This expansion of depredation control activities will not threaten the continued survival of wolves in the State or the long-term viability of the wolf population in Zone A, the large part of wolf range in Minnesota. Significant changes in wolf depredation control under State management will primarily be restricted to Zone B, which is outside of the area necessary for wolf recovery (USFWS 1992, pp. 20, 28). Furthermore, wolves may still persist in Zone B despite the likely increased take there. The Eastern Timber Wolf Recovery Team concluded that the changes in wolf management in the State's Zone A would be "minor" and would not likely result in "significant change in overall wolf numbers in Zone A." They found that, despite an expansion of the individual depredation control areas and an extension of the control period to 60 days, depredation control will remain "very localized" in Zone A. The requirement that such depredation control activities be conducted only in response to verified wolf depredation in Zone A played a key role in the team's evaluation (Peterson in litt. 2001). While wolves were under State management in 2007 and 2008, the number of wolves killed for depredation control (133 wolves in 2007 and 143 wolves in 2008) remained consistent with those killed under the special regulation under section 4(d) of the Act while wolves were Federally listed (105, in 2004; 134, in 2005; and 122, in 2006).

Minnesota will continue to monitor wolf populations throughout the State and will also monitor all depredation control activities in Zone A (MN DNR 2001, p. 18). These and other activities contained in their plan will be essential in meeting their population goal of a minimum statewide winter population of 1,600 wolves, well above the planning goal of 1,251 to 1,400 wolves that the Revised Recovery Plan identifies as sufficient to ensure the wolf's continued survival in Minnesota (USFWS 1992, p. 28).

The Wisconsin Wolf Management Plan

Both the Wisconsin and Michigan Wolf Management Plans are designed to manage and ensure the existence of wolf populations in the States as if they are isolated populations and are not dependent upon immigration of wolves from an adjacent State or Canada, while still maintaining connections to those other populations. We support this approach and believe it provides strong assurances that the wolf in both States

will remain a viable component of the proposed WGL DPS for the foreseeable future.

The WI Plan allows for differing levels of protection and management within four separate management zones (see figure 3). The Northern Forest Zone (Zone 1) and the Central Forest Zone (Zone 2) now contain most of the State's wolf population, with approximately 6 percent of the Wisconsin wolves in Zones 3 and 4 (Wydeven and Wiedenhoeft 2009, Table 1). Zones 1 and 2 contain all the larger unfragmented areas of suitable habitat (see Wolf Range Ownership and Protection, above), so most of the State's wolf packs will continue to inhabit those parts of Wisconsin for the foreseeable future. At the time the Wisconsin Wolf Management Plan was completed, it recommended immediate reclassification from State-endangered to State-threatened status, because Wisconsin's wolf population had already exceeded its reclassification criterion of 80 wolves for 3 years. That state reclassification occurred in 1999, after the population exceeded that level for 5 years.

The Wisconsin Plan further recommends that the State manage for a wolf population of 350 wolves outside of Native American reservations, and specifies that the species should be delisted by the State once the population reaches 250 animals outside of reservations. The species was proposed for State delisting in late 2003, and the State delisting process was completed in 2004. Upon State delisting, the species was classified as a "protected nongame species," a designation that continues State prohibitions on sport hunting and trapping of the species (Wydeven and Jurewicz 2005, p. 1; WI DNR 2006b, p. 71). The Wisconsin Plan includes criteria that would trigger State relisting to threatened (a decline to fewer than 250 wolves for 3 years) or endangered status (a decline to fewer than 80 wolves for 1 year). The Wisconsin Plan will be reviewed annually by the Wisconsin Wolf Advisory Committee and will be reviewed by the public every 5 years. Recently the WI DNR began work on updating the State's wolf management plan, which may include increasing the State management goal (Wydeven and Wiedenhoeft 2009, p. 3).

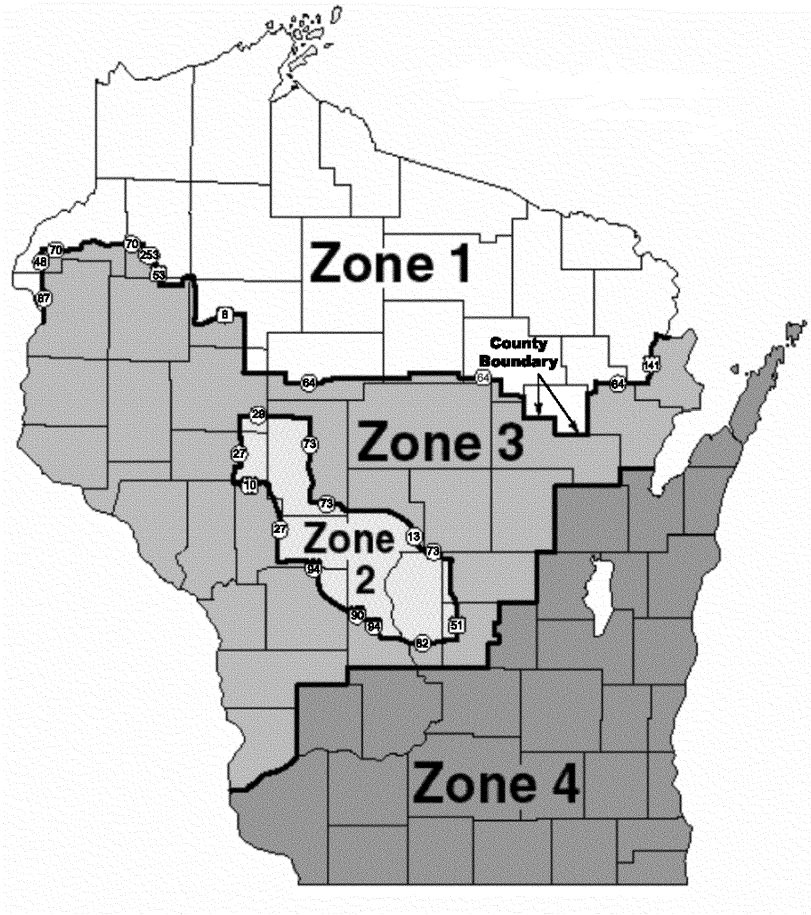
The WI Plan was updated during 2004–06 to reflect current wolf numbers, additional knowledge, and issues that have arisen since its 1999 completion. This update is in the form of text changes, revisions to two appendices, and the addition of a new appendix to the 1999 plan, rather than as a major revision to the plan. Several components of the plan that are key to our delisting evaluation are unchanged. The State wolf management goal of 350 animals and the boundaries of the four wolf management zones remain the same as in the 1999 Plan. The updated 2006 Plan continues access management on public lands and the protection of active den sites. Protection of pack rendezvous sites, however, is no longer considered to be needed in areas where wolves have become well established, due to the transient nature of these sites and the larger wolf population. The updated Plan states that rendezvous sites may need protection in areas where wolf colonization is still underway or where pup survival is extremely poor, such as in northeastern Wisconsin (WI DNR 2006a, p. 17). The guidelines for the wolf depredation control program did not undergo significant alteration during the update process. The only substantive change to depredation control practices is to expand the area of depredation control trapping in Zones 1 and 2 to 1 mi (1.6 km) outward from the depredation site, replacing the previous 0.5 mi (0.8 km) radius trapping zone (WI DNR 2006a, pp. 3–4).

An important component of the WI Plan is the annual monitoring of wolf populations by radio collars and winter track surveys in order to provide comparable annual data to assess population size and growth for at least 5 years after Federal delisting. This monitoring will include health monitoring of captured wolves and necropsies of dead wolves that are found. Wolf scat will be collected and analyzed to monitor for canine viruses and parasites. Health monitoring will be part of the capture protocol for all studies that involve the live capture of Wisconsin wolves (WI DNR 2006a, p. 14).

Cooperative habitat management will be promoted with public and private landowners to maintain existing road densities in Zones 1 and 2, protect wolf dispersal corridors, and manage forests for deer and beaver (WI DNR 1999, pp. 4, 22–23; 2006a, pp. 15–17). Furthermore, in Zone 1, a year-round prohibition on tree harvest within 330 feet (100 m) of den sites, and seasonal restrictions to reduce disturbance within one-half mile of dens, will be WI DNR policy on public lands and will be encouraged on private lands (WI DNR 1999, p. 23; 2006a, p. 17).

BILLING CODE 4310–55–P

**Figure 3. Wisconsin wolf management zones.**




BILLING CODE 4310–55–C

The 1999 WI Plan contains, and the 2006 update retains, other recommendations that will provide protection to assist in maintenance of a viable wolf population in the State: (1) Continue the protection of the species as a "protected wild animal" with penalties similar to those for unlawfully killing large game species (fines of $1,000–$2,000, loss of hunting privileges for 3–5 years, and a possible 6-month jail sentence), (2) maintain closure zones where coyotes cannot be shot during deer hunting season in Zone 1, (3) legally protect wolf dens under the Wisconsin Administrative Code, (4) require State permits to possess a wolf or wolf-dog hybrid, and (5) establish a restitution value to be levied in addition to fines and other penalties for wolves that are illegally killed (WI DNR 1999, pp. 21, 27–28, 30–31; 2006a, pp. 3–4).

The 2006 update of the WI Plan continues to emphasize the need for public education efforts that focus on living with a recovered wolf population, ways to manage wolves and wolf-human conflicts, and the ecosystem role of wolves. The Plan continues the State reimbursement for depredation losses (including dogs and missing calves), citizen stakeholder involvement in the wolf management program, and coordination with the Tribes in wolf management and investigation of illegal killings (WI DNR 1999, pp. 24, 28–29; 2006a, pp. 22–23).

Given the decline and ultimate termination in Federal funding for wolf monitoring that would occur upon delisting, Wisconsin and Michigan DNRs are seeking an effective, yet cost-efficient, method for detecting wolf population changes to replace the current labor-intensive and expensive monitoring protocols. Both DNRs have considered implementing a "Minnesota-type" wolf survey. Such methodology is less expensive for larger wolf populations than the intensive radio monitoring and track survey methods currently used by the two States, and if the wolf population continues to grow there will be increased need to develop and implement a less expensive method. However, each State conducted independent field testing of the Minnesota method several years ago and found that method to be unsuitable for both States' lower wolf population density and uneven pack distribution. In both States the application of that method resulted in an overestimate of wolf abundance, possibly due to the more patchy distribution of wolves and packs in these States and the difficulty in accurately delineating occupied wolf range in areas where wolf pack density is relatively low in comparison to Minnesota and where agricultural lands are interspersed with forested areas (Wiedenhoeft 2005, pp. 11–12; Beyer in litt. 2006b).

Both States remain interested in developing accurate but less costly alternate survey methods. WI DNR might test other methods following any Federal delisting, but the State will not replace its traditional radio tracking/snow tracking surveys during the 5 year post-delisting monitoring period (Wydeven in litt. 2006b). The 2006 update to the Wisconsin Wolf Management Plan has not changed the

WI DNR's commitment to annual wolf population monitoring in a manner that ensures accurate and comparable data (WI DNR 1999, pp.19–20), and we are confident that adequate annual monitoring will continue for the foreseeable future.

*Depredation Control in Wisconsin*—The rapidly expanding Wisconsin wolf population has resulted in an increased need for depredation control. From 1979 through 1989, there were only five cases (an average of 0.4 per year) of verified wolf depredations in Wisconsin. Between 1990 and 1997, there were 27 verified depredation incidents in the State (an average of 3.4 per year), and 82 incidents (an average of 16.4 per year) occurred from 1998 to 2002. Depredation incidents increased to 23 cases (including 50 domestic animals killed and 4 injured) in 2003, 35 cases (53 domestic animals killed, 3 injured, and 6 missing) in 2004, and to 45 cases (53 domestic animals killed and 11 injured) in 2005 (Wydeven and Wiedenhoeft 2004a, pp. 2–3, 7–8 Table 3; Wydeven *et al.* 2005b, p. 7; Wydeven *et al.* 2006b, p. 7). From 2005 to 2008, depredation incidents continued to increase, with 52 cases (92 domestic animals killed (includes 50 chickens) and 16 injured) in 2006, 60 cases (51 domestic animals killed, 18 injured, and 14 missing) in 2007, and 57 cases (67 domestic animals killed and 10 injured) in 2008 (Wydeven *et al.* 2007a, p. 7; Wydeven and Wiedenhoeft 2008, pp. 8, 25–32; Wydeven *et al.* 2009a, p. 6). Similar levels of depredations continued to occur in 2009, with 55 cases (65 domestic animals killed and 11 injured), but increased again to 81 cases (99 domestic animals killed and 20 injured) in 2010 (Wydeven *et al.* 2010, pp. 9–10; Wydeven *et al.* 2011, p. 3).

The number of farms experiencing wolf depredations has increased from 5 farms in 2000, to 28–32 farms from 2007 to 2009, and to 47 farms in 2010, a nearly ten-fold increase in the number of farms experiencing depredations during the last decade. The number of counties with wolf depredations on farms also grew during that time period from 5 to 17 counties, indicating that wolf depredation problems on farms are continuing to expand (Wydeven in litt. 2009; Wydeven *et al.* 2009a, p. 23; Wydeven *et al.* 2011, p.3). Between 1995 and 2002, an average of 7 percent of packs in Wisconsin were involved in livestock depredations (Wydeven *et al.* 2004, p.36), and between 2002 and 2010, an average of 13 percent (from 7 to 17) of the State's packs were involved in livestock depredation (WI DNR data). More aggressive lethal controls possible in 2007 and 2008 through State management following a temporary period of Federal delisting appear to have started to stabilize levels of livestock depredation in 2007–09, but loss of those control methods allowed major increases in levels of depredation in 2010.

A significant portion of depredation incidents in Wisconsin involve attacks on dogs, primarily those engaged in bear hunting activities or dogs being trained in the field for hunting. In most cases, these have been hunting dogs that were being used for, or being trained for, hunting bears, bobcats, coyotes, and snowshoe hare (Ruid *et al.* 2009, pp. 285–286). It is believed that the dogs entered the territory of a wolf pack and may have been close to a den, rendezvous site, or feeding location, thus triggering an attack by wolves defending their territory or pups. The frequency of attacks on hunting dogs has increased as the State's wolf population has grown. Between 1986 and 2010, 206 dogs were killed and 80 were injured by wolves in Wisconsin (WI DNR data files and summary of wolf survey reports). Generally about 90 percent of dogs killed were hunting hounds and about 50 percent of dogs injured were pet dogs attacked near homes (Ruid *et al.* 2009).

More than 80 percent of the dog kills occurred since 2001, with an average of 17.2 dogs killed annually (range 6 to 25 dogs killed per year), and 6.8 injured each year (range 1 to 14 dogs) during the period 2001–10 (WI DNR files). Data on recent depredations in 2009 and 2010 show a continued increase in wolf attacks on dogs, with 23 dogs killed and 11 injured by 20 wolf packs (12 percent of Wisconsin packs) in 2009, and 24 dogs killed and 14 injured by 21 wolf packs in 2010 (Wydeven *et al.* 2010, pp. 51–52; Wydeven *et al.* 2011 p.3). While the WI DNR compensates dog owners for mortalities and injuries to their dogs, the DNR takes no action against the depredating pack unless the attack was on a dog that was leashed, confined, or under the owner's control on the owner's land. Instead, the DNR issues press releases to warn bear hunters and bear dog trainers of the areas where wolf packs have been attacking bear dogs (WI DNR 2008, p. 5) and provides maps and advice to hunters on the WI DNR Web site (see *http://www.dnr.state.wi.us/org/land/er/mammals/wolf/dogdepred.htm*). In 2010, 14 wolf attacks on dogs had occurred near homes, which was the highest level seen of this type of depredation (Wydeven *et al.* 2011, p.3).

*Post-delisting Depredation Control in Wisconsin*—Following the proposed Federal delisting, wolf depredation control in Wisconsin will be carried out according to the 2006 Updated Wisconsin Wolf Management Plan (WI DNR 2006a, pp. 19–23), Guidelines for Conducting Depredation Control on Wolves in Wisconsin Following Federal Delisting (WI DNR 2008), and any Tribal wolf management plans or guidelines that may be developed for reservations in occupied wolf range. The 2006 updates have not significantly changed the 1999 State Plan, and the State wolf management goal of 350 wolves outside of Indian reservations (WI DNR 2006a, p. 3) is unchanged. Verification of wolf depredation incidents will continue to be conducted by USDA–APHIS–Wildlife Services, working under a cooperative agreement with WI DNR, or at the request of a Tribe, depending on the location of the suspected depredation incident. If determined to be a confirmed or probable depredation by a wolf or wolves, one or more of several options will be implemented to address the depredation problem. These options include technical assistance, loss compensation to landowners, translocating or euthanizing problem wolves, and private landowner control of problem wolves in some circumstances (WI DNR 2006a, pp. 3– 4, 20–22).

Technical assistance, consisting of advice or recommendations to prevent or reduce further wolf conflicts, will be provided. This may also include providing to the landowner various forms of noninjurious behavior modification materials, such as flashing lights, noise makers, temporary fencing, and fladry (a string of flags used to contain or exclude wild animals). Monetary compensation is also provided for all verified and probable losses of domestic animals and for a portion of documented missing calves (WI DNR 2006a, pp. 22–23).

The WI DNR compensates livestock and pet owners for confirmed losses to depredating wolves. The compensation is made at full market value of the animal (up to a limit of $2,500 for dogs) and can include veterinarian fees for the treatment of injured animals (WI DNR 2006c 12.54). Compensation costs have been funded from the endangered resources tax check-off and sales of the endangered resources license plates. Current Wisconsin law requires the continuation of the compensation payment for wolf depredation regardless of Federal listing or delisting of the species (WI DNR 2006c 12.50). In recent years annual depredation compensation payments have ranged from $68,907.88 (2007) to $203,943.51 (2010). From 1985 through December 24, 2010, the WI DNR had spent $1,083,162.62 on

reimbursement for damage caused by wolves in the State, with 82 percent of that total spent since 2000 (*http://dnr.wi.gov/org/land/er/mammals/wolf/pdfs/wolf_damage_payments_2010.pdf*).

For depredation incidents in Wisconsin Zones 1 through 3, where all wolf packs currently reside, wolves may be trapped by Wildlife Services or WI DNR personnel and, if feasible, translocated and released at a point distant from the depredation site. If wolves are captured adjacent to an Indian reservation or a large block of public land, the animals may be translocated locally to that area. As noted above, long-distance translocating of depredating wolves has become increasingly difficult in Wisconsin and is likely to be used infrequently in the future as long as the off-reservation wolf population is above 350 animals. In most wolf depredation cases where technical assistance and nonlethal methods of behavior modification are judged to be ineffective, wolves will be shot or trapped and euthanized by Wildlife Services or DNR personnel. Trapping and euthanizing will be conducted within a 1-mi (1.6-km) radius of the depredation in Zones 1 and 2, and within a 5-mi (8-km) radius in Zone 3. There is no distance limitation for depredation control trapping in Zone 4, and all wolves trapped in Zone 4 will be euthanized, rather than translocated (WI DNR 2006a, pp. 22–23).

Following the proposed Federal delisting, Wisconsin landowners who have had a verified wolf depredation will be able to obtain limited-duration permits from WI DNR to kill a limited number of depredating wolves on land they own or lease, based on the size of the pack causing the local depredations (WI DNR 2008, p. 8). Such permits would be issued to: (1) Landowners with verified permits on their property within the last 2 years; (2) landowners within 1 mile of properties with verified wolf depredations during the calendar year; (3) landowners with vulnerable livestock within WI DNR-designated proactive control areas; (4) landowners with human safety concerns on their property, and (5) landowners with verified harassment of livestock on their property (WI DNR 2008, p. 8). Limit on number of wolves to control will be based on estimated number of wolves in the pack causing depredation problems. In addition, landowners and lessees of land statewide will be allowed to kill a wolf without obtaining a permit "in the act of killing, wounding, or biting a domestic animal," the incident must be reported to a conservation warden within 24 hours and the landowners are required to turn any dead wolves over to the WI DNR (WI DNR 2006a, pp. 22–23; WI DNR 2008, p. 6). During the 19 months wolves were Federally delisted in 2007 and 2008, 5 wolves were shot in the act of depredations on domestic animals, and 2 wolves were shot by one landowner out of 67 permits issued. One wolf was shot in the act of attack on domestic animals during 2 months when wolves were delisted in 2009.

The updated Wisconsin Plan also envisions the possibility of intensive control management actions in sub-zones of the larger wolf management zones (WI DNR 2006a, pp. 22–23). Triggering actions and type of controls planned for these "proactive control areas" are listed in recent versions of the WI DNR depredation control guidelines (WI DNR 2008, pp. 7–9). Controls on these actions would be considered on a case-by-case basis to address specific problems, and would likely be carried out only in areas that lack suitable habitat, have extensive agricultural lands with little forest interspersion, in urban or suburban settings, and only when the State wolf population is well above the management goal of 350 wolves outside Indian reservations in late-winter surveys. The use of intensive population management in small areas will be adapted as experience is gained with implementing and evaluating localized control actions (Wydeven 2006, pers. comm.).

We have evaluated future lethal depredation control based upon verified depredation incidents over the last decade and the impacts of the implementation of similar lethal control of depredating wolves under 50 CFR 17.40(d) for Minnesota, § 17.40(o) for Wisconsin and Michigan, and section 10(a)(1)(A) of the Act for Wisconsin and Michigan. Under those authorities, WI DNR and Wildlife Services trapped and euthanized 17 wolves in 2003, 24 in 2004, 29 in 2005, 18 in 2006, 37 in 2007, 39 in 2008, 9 in 2009, and 16 in 2010 (WI DNR 2006a, p. 32; Wydeven *et al.* 2008, pp. 8–9; Wydeven *et al.* 2009, pp. 6–7; Wydeven *et al.* 2010, p. 15; Wydeven *et al.* 2011, p. 3). Although these lethal control authorities applied to Wisconsin and Michigan DNRs for only a portion of 2003 (April through December) and 2005 (all of January for both States; April 1 and April 19, for Wisconsin and Michigan respectively, through September 13), they covered nearly all of the verified wolf depredations during 2003–05, and thus provide a reasonable measure of annual lethal depredation control. Lethal control authority only occurred for about 3.5 months in 2006.

For 2003, 2004, and 2005, this represents 5.1 percent, 6.4 percent, 7.4 percent (including the several possible wolf-dog hybrids), respectively, of the late-winter population of Wisconsin wolves during the previous winter. Note that some of the wolves euthanized after August 1 were young-of-the-year who were not present during the late-winter survey, so the cited percentages are overestimates.

This level of lethal depredation control was followed by a wolf population increase of 11 percent from 2003 to 2004, 17 percent from 2004 to 2005, and 7 percent from 2005 to 2006 (Wydeven and Jurewicz 2005, p. 5; Wydeven *et al.* 2006a, p. 10). Limited lethal control authority was granted to WI DNR in 2006 by a section 10 permit resulting in removal of 18 wolves (3.9 percent of winter wolf population), and this permit remained in effect for 3.5 months (Wydeven *et al.* 2007, p. 7). Lethal depredation control was again authorized in the State while wolves were delisted in 2007 (9.5 months) and 2008 (9 months). During those times, 40 and 43 wolves, respectively, were killed for depredation control (by Wildlife Services or by legal landowner action), representing 7 and 8 percent of the late-winter population of Wisconsin wolves during the previous year.

This level of lethal depredation control was followed by a wolf population increase of 0.5 percent from 2007 to 2008, and 12 percent from 2008 to 2009, (Wydeven and Wiedenhoeft 2008, pp. 19–22; Wydeven *et al.* 2009a, p. 6). Authority for lethal control on depredating wolves only occurred for 2 months in 2009. During that time, eight wolves were euthanized for depredation control by USDA–WS, and one wolf was shot by a landowner; additionally a wolf was captured and euthanized by USDA–WS for human safety concerns later in 2009 after relisting (Wydeven *et al.* 2010, p. 15). Thus in 2009, 10 wolves, or 2 percent of the winter wolf population, were removed in control activities.

The Wisconsin wolf population in winter 2010 grew to 690 wolves, an increase of 8 percent from the wolf population in 2009 (Wydeven *et al.* 2010, pp. 12–13). In 2010, authority for lethal control of wolves depredating livestock was not available in Wisconsin, but 16 wolves or 2 percent of the winter population were removed for human safety concerns (Wydeven *et al.* 2011, p. 3). This provides strong evidence that this form and magnitude of depredation control will not adversely impact the viability of the Wisconsin wolf population. The locations of depredation incidents provide additional evidence that lethal control will not have an adverse impact

on the State's wolf population. Most livestock depredations are caused by packs near the northern forest-farm land interface. Few depredations occur in core wolf range and in large blocks of public land. Thus, lethal depredation control actions will not impact most of the Wisconsin wolf population (WI DNR 2006a, p. 30).

Control actions in Wisconsin also resulted in removal of wolf-dog hybrids from the wild that had begun associating with packs. Wolf-dog hybrid removal in depredation control activity by USDA–WS included 3 in 2005, 1 in 2007, 2 in 2008, and 1 in 2010 (WI DNR files).

One substantive change to lethal control that will result from the proposed Federal delisting is the ability of a small number of private landowners, whose farms have a history of recurring wolf depredation, to obtain DNR permits to kill depredating wolves (WI DNR 2006a, p. 23; WI DNR 2008, p. 8). During the time wolves were Federally delisted from March 12, 2007 through September 29, 2008, the DNR issued 67 such permits, resulting in 2 wolves being killed. Some landowners received permits more than once and permits were issued for up to 90 days at a time and restricted to specific calendar years. During that same time period, under Wisconsin depredation management guidelines, landowners were allowed to shoot wolves in the act of attacks on domestic animals on private land without a permit; under that authority, landowners killed a total of five wolves. The death of these seven additional wolves—only one percent of the State's wolves in 2008—did not affect the viability of the population. Another substantive change after the proposed delisting may be potential proactive trapping or "intensive control" of wolves in limited areas as described above. We are confident that the number of wolves killed by these actions will not impact the long-term viability of the Wisconsin wolf population, because generally less than 15 percent of packs cause depredations that would initiate such controls, and "proactive" controls will be carried out only if the State's late-winter wolf population exceeds 350 animals outside Indian reservations.

The State's current guidelines for conducting depredation control actions say that no control trapping will be conducted on wolves that kill "dogs that are free-roaming, roaming at large, hunting, or training on public lands, and all other lands except land owned or leased by the dog owner" (WI DNR 2008, p. 5). Controls would be applied on wolves depredating pet dogs attacked near homes and wolves attacking livestock, which in 2010 included 25 packs attacking livestock (23 packs that were also documented in the previous winter surveys), 8 packs attacking dogs at homes, and 5 packs attacking both livestock and dogs. Thus control would have been applied to 31 packs (17 percent of State packs) previously detected and 2 new packs. Because of these state-imposed limitations, we believe that lethal control of wolves depredating on hunting dogs will be rare and, therefore, will not be a significant additional source of mortality in Wisconsin.

Lethal control of wolves that attack captive deer is included in the WI DNR depredation control program, because farm-raised deer are considered to be livestock under Wisconsin law (WI DNR 2008, pp. 5–6; 2006c, 12.52). However, Wisconsin regulations for deer farm fencing have been strengthened, and it is unlikely that more than an occasional wolf will need to be killed to end wolf depredations inside deer farms in the foreseeable future. Claims for wolf depredation compensation are rejected if the claimant is not in compliance with regulations regarding farm-raised deer fencing or livestock carcass disposal (Wisconsin Statutes 90.20 & 90.21, WI DNR 2006c 12.54).

Data from verified wolf depredations in recent years indicate that depredation on livestock is likely to increase as long as the Wisconsin wolf population increases in numbers and range. Wolf packs establishing in more marginal habitat with high acreage of pasture land are more likely to become depredators (Treves *et al.* 2004, p. 121–122). Most large areas of forest land and public lands are included in Wisconsin Wolf Management Zones 1 and 2, and they have already been colonized by wolves. Therefore, new areas likely to be colonized by wolves in the future will be in Zones 3 and 4, where they will be exposed to much higher densities of farms, livestock, and residences. During 2008, of farms experiencing wolf depredation, 25 percent (8 of 32) were in Zone 3, yet only 4 percent of the State wolf population occurs in this zone (Wydeven *et al.* 2009a, p. 23). Further expansion of wolves into Zone 3 would likely lead to an increase in depredation incidents and an increase in lethal control actions against Zone 3 wolves. However, these Zone 3 mortalities will have no impact on wolf population viability in Wisconsin because of the much larger wolf populations in Zones 1 and 2.

For the foreseeable future, the wolf population in Zones 1 and 2 will continue to greatly exceed the recovery goal in the Recovery Plan for the Eastern Timber Wolf of 200 late-winter wolves for an isolated population and 100 wolves for a subpopulation connected to the larger Minnesota population, regardless of the extent of wolf mortality from all causes in Zones 3 and 4. Ongoing annual wolf population monitoring by WI DNR will provide timely and accurate data to evaluate the effects of wolf management under the Wisconsin Plan.

The possibility of a public harvest of wolves is acknowledged in the Wisconsin Wolf Management Plan and in plan updates (WI DNR 1999, Appendix D; 2006c, p. 23). However, the question of whether a public harvest will be initiated and the details of such a harvest are far from resolved. Public attitudes toward a wolf population in excess of 350 would have to be fully evaluated, as would the impacts from other mortalities, before a public harvest could be initiated.

The Wisconsin Conservation Congress, a group that advises the WI DNR on issues of fishing and hunting regulations, held hearings in 2008 (while wolves were Federally delisted in the WGL) to gather information on the public's attitudes toward a public harvest of wolves in the State. Of the people attending those meetings, 86 percent recommended that efforts begin to develop public harvest regulations for wolves in the State, indicating a strong interest among hunters and anglers to begin such development. Establishing a public harvest, however, would be preceded by extensive public input, including public hearings, and would require legislative authorization and approval by the Wisconsin Natural Resources Board. Because of the steps that must precede a public harvest of wolves and the uncertainty regarding the possibility of, and the details of, any such program, we consider public harvest of Wisconsin wolves to be highly speculative at this time. The Service will closely monitor any steps taken by States and Tribes within the proposed WGL DPS to establish any public harvest of wolves during our post-delisting monitoring program.

Future updates for the Wisconsin wolf management and conservation plan will likely contain more specific language on any potential public harvest for the State. The WI DNR is committed to maintaining a wolf population at 350 wolves outside of Indian reservations, which translates to a statewide population of 361 to 385 wolves in late winter. No harvest would be considered if the wolf population fell below this goal (WI DNR 1999, pp. 15, 16). Any harvest would consist of limited permits

on limited portions of the wolf range to reduce wolf-human conflict, and extensive areas in wolf range would be closed to harvest of wolves (WI DNR 1999, p. 21). Also, the fact that the Wisconsin Plan calls for State relisting of the wolf as a threatened species if the population falls to fewer than 250 for 3 years provides a strong assurance that any future public harvest is not likely to threaten the persistence of the population (WI DNR 1999, pp. 15–17). Based on wolf population data, the current Wisconsin Plan and the 2006 updates, we believe that any public harvest plan would continue to maintain the State wolf population well above the recovery goal of 200 wolves in late winter.

The Michigan Wolf Management Plan

In 1997, the Michigan DNR finalized the Michigan Gray Wolf Recovery and Management Plan (MI DNR 1997). That plan was developed when the number of wolves in the State was relatively small, and focused on recovery. In 2001, the MI DNR began reevaluating the 1997 Plan and appointed a committee to evaluate wolf recovery and management in the State. As a result of that evaluation, MI DNR concluded that the 1997 Plan needed revising, which prompted a more formal review, including extensive stakeholder input. Recognizing that wolf recovery had been achieved in Michigan, additional scientific knowledge had been gained, and new social issues had arisen since the 1997 Plan was drafted, the focus of the revised plan shifted from a recovery plan to a wolf management plan. To assist in this endeavor, the DNR convened a Michigan Wolf Management Roundtable, composed of a diverse group of citizens spanning the spectrum of those interested in, and impacted by, wolf recovery and management in Michigan, including Tribal entities and organizations focused on agriculture, hunting and trapping, the environment, animal protection, law enforcement and public safety, and tourism.

The Roundtable was asked to review the 1997 wolf management goal, to set priorities for management issues, and to recommend strategic goals or policies the DNR should use in addressing the management issues. The Roundtable provided "guiding principles" for managing wolves and wolf-related issues following Federal delisting (Michigan Wolf Management Roundtable 2006, pp. 6–7). Those guiding principles strongly influenced the 2008 Michigan Wolf Management Plan (MI Plan) (MI DNR 2008a).

The 2008 MI Plan describes the wolf recovery goals and management actions needed to maintain a viable wolf population in the UP of Michigan, while facilitating wolf-related benefits and minimizing conflicts. The four principal goals are to "1) maintain a viable Michigan wolf population above a level that would warrant its classification as threatened or endangered; 2) facilitate wolf-related benefits; 3) minimize wolf-related conflicts; and 4) conduct science-based wolf management with socially acceptable methods" (MI DNR 2008a, p. 22). The Michigan Plan details wolf management actions, including public education and outreach activities, annual wolf population and health monitoring, research, depredation control, ensuring adequate legal protection for wolves, and prey and habitat management. It does not address the potential need for wolf recovery or management in the Lower Peninsula, nor wolf management within Isle Royale National Park (where the wolf population is fully protected by the National Park Service).

As with the WI Plan, the MI DNR has chosen to manage the State's wolves as though they are an isolated population that receives no genetic or demographic benefits from immigrating wolves, even though their population will continue to be connected with populations in Minnesota, Wisconsin, and Canada. The Michigan wolf population must exceed 200 wolves in order to achieve the Plan's first goal of maintaining a viable wolf population in the UP. This number is consistent with the Federal Recovery Plan for the Eastern Timber Wolf's definition of a viable, isolated wolf population (USFWS 1992, p. 25). The MI Plan, however, clearly states that 200 wolves is not the target population size, and that a larger population may be necessary to meet the other goals of the Plan. Therefore, the State will maintain a wolf population that will "provide all of the ecological and social benefits valued by the public" while "minimizing and resolving conflicts where they occur" (MI DNR 2008a, pp. 22–23). We strongly support this approach, as it provides assurance that a viable wolf population will remain in the UP regardless of the future fate of wolves in Wisconsin or Ontario.

The 2008 Michigan Plan identifies wolf population monitoring as a priority activity, and specifically states that the WI DNR will monitor wolf abundance annually for at least 5 years post-delisting (MI DNR 2008a, pp. 31–32). This includes monitoring to assess wolf presence in the northern Lower Peninsula. As discussed previously, the size of the wolf population in Michigan is determined by extensive radio and snow tracking surveys. Recently the MI DNR also conducted a field evaluation of a less expensive "Minnesota-type" wolf survey. However, similar to WI DNR's experience, the evaluation concluded that the method overestimated wolf numbers, and is not suitable for use on the State's wolf population as it currently is distributed (Beyer in litt. 2006b).

From 1989 through 2006, the WI DNR attempted to count wolves throughout the entire UP. As the wolf population increased, this method became more difficult. In the winter of 2006–07, the MI DNR implemented a new sampling approach based on an analysis by Potvin *et al.* (2005, p. 1668) to increase the efficiency of the State survey. The new approach is based on a geographically based stratified random sample and produces an unbiased, regional estimate of wolf abundance. The UP was stratified into three sampling areas, and within each stratum the DNR intensively surveys roughly 40 to 50 percent of the wolf habitat area annually. Computer simulations have shown that such a geographically stratified monitoring program will produce unbiased and precise estimates of the total wolf population which can be statistically compared to estimates derived from the previous method to detect significant changes in the UP wolf population (Beyer in litt 2006b, see attachment by Drummer; Lederle in litt. 2006; Roell *et al.* 2009, p. 3).

Another component of wolf population monitoring is monitoring wolf health. The MI DNR will continue to monitor the impact of parasites and disease on the viability of wolf populations in the State through necropsies of dead wolves and analyzing biological samples from captured live wolves. Prior to 2004, MI DNR vaccinated all captured wolves for canine distemper and parvovirus and treated them for mange. These inoculations were discontinued to provide more natural biotic conditions and to provide biologists with an unbiased estimate of disease-caused mortality rates in the population (Roell in litt. 2005b). Since diseases and parasites are not currently a significant threat to the Michigan wolf population, the MI DNR is continuing the practice of not actively managing disease. If monitoring indicates that diseases or parasites may pose a threat to the wolf population, the MI DNR will again consider more active management similar to that conducted prior to 2004.

The 2008 Plan includes maintaining habitat and prey necessary to sustain a viable wolf population in the State as a management component. This includes maintaining prey populations required

for a viable wolf population while providing for sustainable human uses, maintaining habitat linkages to allow for wolf dispersal, and minimizing disturbance at known, active wolf dens (MI DNR 2008a, pp. 36–41).

The Plan does not determine whether a public harvest will be used as a management strategy in Michigan, but it discusses developing a "socially and biologically responsible policy regarding public harvest" (MI DNR 2008a, p. 65). Instituting public harvest during a regulated season would first require that the wolf be classified as a "game animal" in the State. Game-animal status in Michigan may be designated only by the State Legislature and, additionally, only the State Legislature could authorize the first harvest season. If such designation and authorization were conferred, the Michigan Natural Resources Commission would then need to enact regulations pertaining to the methods of a public harvest.

To minimize illegal take, the 2008 Plan calls for enacting and enforcing regulations to ensure adequate legal protection for wolves in the State. Under State regulations, wolves could be classified as threatened, endangered, game, or protected animal, all of which prohibit killing (or harming) the species except under a permit, license, or specific conditions. As discussed above, designating a species as a "game animal" would require action by the State Legislature. Michigan reclassified wolves from endangered to threatened in June 2002, and in April 2009, removed gray wolves from the State's Threatened and Endangered species list and amended the Wildlife Conservation Order to grant "protected animal" status to the gray wolf in the State (Roell 2009, pers. comm.). A person who commits a violation regarding the possession or taking of most wildlife species with the four legal designations (threatened, endangered, game, or protected animal) in Michigan is guilty of a misdemeanor punishable by imprisonment for not more than 90 days, or a fine of not less than $100 or more than $1,000, or both. Penalties may also include costs of prosecution, loss of hunting privileges, and reimbursing the value of the animal ($1,500 for a threatened or endangered species, $100 to $500 for most game species, and $100 for protected animals) (MI DNR 2008a, p. 35).

The 2008 Plan emphasizes the need for public education efforts that focus on living with a recovered wolf population and ways to manage wolves and wolf-human interaction (both positive and negative). The Plan recommends continuing reimbursement for depredation losses, citizen stakeholder involvement in the wolf management program, continuing important research efforts, and minimizing the impacts of captive wolves and wolf-dog hybrids on the wild wolf population (MI DNR 2008a, pp. 31, 59, 61, and 66).

The 2008 Michigan Plan calls for establishing a wolf management advisory group that would meet annually to monitor the progress made toward implementing the Plan. Furthermore, the Plan will be reviewed and updated at 5-year intervals, to address "ecological, social, and regulatory" changes (MI DNR 2008a, p. 66). The plan also addresses currently available and potential new sources of funding to offset costs associated with wolf management.

The MI DNR has long been an innovative leader in wolf recovery efforts, exemplified by its initiation of the nation's first attempt to reintroduce wild wolves to vacant historical wolf habitat in 1974 (Weise *et al.* 1975). The MI DNR's history of leadership in wolf recovery and its repeated written commitments to ensure the continued viability of a Michigan wolf population above a level that would trigger State or Federal listing as threatened or endangered further reinforces that the revised 2008 Michigan Wolf Management Plan will provide adequate regulatory mechanisms for Michigan wolves. The DNR's primary goal remains to conduct management to maintain the wolf population in Michigan above the minimum size that is biologically required for a viable, isolated population and to provide for ecological and social benefits valued by the public while resolving conflicts where they occur (MI DNR 2008a, p. 22).

Depredation Control in Michigan—Data from Michigan show a general increase in confirmed events of wolf depredations on livestock (Table 2). These livestock depredations occurred at 59 different UP farms (approximately 7 percent of the existing farms); 16 (27 percent) of those 59 farms have experienced more than one depredation event. Over 80 percent of the depredation events were on cattle, with the rest on sheep, poultry, rabbits, and captive cervids (Roell *et al.* 2009, pp. 9, 11). In 2010, 26 (57 percent) of the depredation events occurred on a single farm. The relationship between the number of wolves and the number of depredation events suggests that for every 100 additional wolves in the population there will be about 3 additional livestock depredation events per year (Roell *et al.* 2010, p. 6).

TABLE 2—NUMBER OF VERIFIED LIVESTOCK DEPREDATION EVENTS BY WOLVES IN MICHIGAN BY YEAR

| Year | Number of animals killed |
|---|---|
| 1998 | 3 |
| 1999 | 1 |
| 2000 | 5 |
| 2001 | 3 |
| 2002 | 5 |
| 2003 | 13 |
| 2004 | 11 |
| 2005 | 5 |
| 2006 | 10 |
| 2007 | 14 |
| 2008 | 14 |
| 2009 | 12 |
| 2010 | 46 |

Michigan has not experienced as high a level of attacks on dogs by wolves as Wisconsin, although a slight increase in such attacks has occurred over the last decade. Yearly losses vary and actions of a single pack of wolves can be an important influence. In Michigan, there is not a strong relationship between wolf depredation on dogs and wolf abundance (Roell *et al.* 2010, p. 7). The number of dogs killed in the State between 1996 and 2010 was 34; 12 additional dogs were injured in wolf attacks during that same period. Of the 34 wolf-related dog deaths during that time, 50 percent involved hounds used to hunt bears (Roell 2010, pers. comm.). Similar to Wisconsin, MI DNR has guidelines for its depredation control program, stating that lethal control will not be used when wolves kill dogs that are free-roaming, hunting, or training on public lands. Lethal control of wolves, however, would be considered if wolves have killed confined pets and remain in the area where more pets are being held (MI DNR 2005a, p. 6). However, in 2008, the Michigan Legislature passed a law that would allow dog owners or their designated agents to remove, capture, or, if deemed necessary, use lethal means to destroy a gray wolf that is in the act of preying upon the owner's dog, which includes dogs free-roaming or hunting on public lands.

During the several years that lethal control of depredating wolves had been conducted in Michigan, there is no evidence of resulting adverse impacts to the maintenance of a viable wolf population in the UP. A total of 41 wolves were killed by the MI DNR and USDA –Wildlife Services in response to depredation events during the time period when permits or special rules were in effect or while wolves were not on the Federal list of threatened and endangered species (Roell *et al.* 2010, p. 8). Four, five, two, seven, fourteen, eight, and one wolves, respectively,

were euthanized in 2003, 2004, 2005, 2006, 2007, 2008, and 2009 (2 months) (Beyer *et al.* 2006, p. 88; Roell in litt. 2006, p. 1; Roell *et al.* 2010, p. 19; Roell 2010, pers. comm.). This represents 1.2 percent, 1.7 percent, 0.5 percent, 1.6 percent, 2.7 percent, 2.5 percent, and 0.2 percent, respectively, of the UP's late-winter population of wolves during the previous winter. Following this level of lethal depredation control, the UP wolf population increased 12 percent from 2003 to 2004, 13 percent from 2004 to 2005, 7 percent from 2005 to 2006, 17 percent from 2006 to 2007, 2 percent from 2007 to 2008, and 11 percent from 2008 to 2009, demonstrating that the wolf population continues to increase at a healthy rate (Huntzinger *et al.* 2005, p. 6; MI DNR 2006a, Roell *et al.* 2009, p. 4). Lethal control of wolves during livestock depredation was not available in 2010.

*Post-delisting Depredation Control in Michigan*—Following the proposed Federal delisting, wolf depredation control in Michigan would be carried out according to the 2008 Michigan Wolf Recovery and Management Plan (MI DNR 2008) and any Tribal wolf management plans that may be developed in the future for reservations in occupied wolf range.

To provide depredation control guidance when lethal control is an option, MI DNR has developed detailed instructions for incident investigation and response (MI DNR 2005a). Verification of wolf depredation incidents will be conducted by MI DNR or USDA–APHIS—Wildlife Services personnel (working under a cooperative agreement with MI DNR or at the request of a Tribe, depending on the location) who have been trained in depredation investigation techniques. The MI DNR specifies that the verification process will use the investigative techniques that have been developed and successfully used in Minnesota by Wildlife Services (MI DNR 2005a, Append. B, pp. 9–10). Following verification, one or more of several options will be implemented to address the depredation problem. Technical assistance, consisting of advice or recommendations to reduce wolf conflicts, will be provided. Technical assistance may also include providing to the landowner various forms of noninjurious behavior modification materials, such as flashing lights, noise makers, temporary fencing, and fladry.

Trapping and translocating depredating wolves has been used in the past, resulting in the translocation of 23 UP wolves during 1998–2003 (Beyer *et al.* 2006, p. 88), but as with Wisconsin, suitable relocation sites are becoming rarer, and there is local opposition to the release of translocated depredators. Furthermore, none of the past translocated depredators have remained near their release sites, making this a questionable method to end the depredation behaviors of these wolves (MI DNR 2005a, pp. 3–4). Therefore, reducing depredation problems by relocation is no longer recommended as a management tool in Michigan (MI DNR 2008a, p. 57).

Lethal control of depredating wolves is likely to be the most common future response in situations when improved livestock husbandry and wolf behavior modification techniques (for example, flashing lights, noise-making devices) are judged to be inadequate. As wolf numbers continue to increase on the UP, the number of verified depredations will also increase, and will probably do so at a rate that exceeds the rate of wolf population increase. This will occur as wolves increasingly disperse into and occupy areas of the UP with more livestock and more human residences, leading to additional exposure to domestic animals. In a previous application for a lethal take permit under section 10(a)(1)(A) of the Act, MI DNR requested authority to euthanize up to 10 percent of the late-winter wolf population annually (MI DNR 2005b, p. 1). However, based on 2003–05 and 2007–09 depredation data, it is likely that significantly less than 10 percent lethal control will be needed over the next several years.

The MI Plan provides recommendations to guide management of various conflicts caused by wolf recovery, including depredation on livestock and pets, human safety, and public concerns regarding wolf impacts on other wildlife. We view the MI Plan's depredation and conflict control strategies to be conservative, in that they commit to nonlethal depredation management whenever possible, oppose preventative wolf removal where problems have not yet occurred, encourage incentives for best management practices that decrease wolf-livestock conflicts without impacting wolves, and support closely monitored and enforced take by landowners of wolves "in the act of livestock depredation" or under limited permits if depredation is confirmed and nonlethal methods are determined to be ineffective. Based on these components of the revised MI Plan and the stated goal for maintaining wolf populations at or above recovery goals, the Service believes any wolf management changes implemented following the proposed delisting would not be implemented in a manner that results in significant reductions in Michigan wolf populations. The MI DNR remains committed to ensuring a viable wolf population above a level that would trigger relisting as either threatened or endangered in the future (MI DNR 2008a, p. 9).

Similar to Wisconsin, Michigan livestock owners are compensated when they lose livestock as a result of a confirmed wolf depredation. Currently there are two complementary compensation programs in Michigan, one funded by the MI DNR and implemented by Michigan Department of Agriculture (MI DA) and another set up through donations (from Defenders of Wildlife and private citizens) and administered by the International Wolf Center (IWC), a nonprofit organization. From the inception of the program to 2000, MI DA has paid 90 percent of full market value of depredated livestock at the time of loss. The IWC account was used to pay the remaining 10 percent from 2000 to 2002 when MI DA began paying 100 percent of the full market value of depredated livestock. The IWC account continues to be used to pay the difference between value at time of loss and the full fall market value for depredated young-of-the-year livestock, and together the two funds have provided nearly $38,000 in livestock loss compensation through 2008 (Roell *et al.,* p. 15). Neither of these programs provides compensation for pets or for veterinary costs to treat wolf-inflicted livestock injuries. The MI DNR plans to continue cooperating with MI DA and other organizations to maintain the wolf depredation compensation program (MI DNR 2008a, pp. 59–60).

In 2009, Michigan passed two House Bills that would become effective after Federal delisting. Those bills authorized a livestock or dog owner (or a designated agent) to "remove, capture, or use lethal means to destroy a wolf that is in the act of preying upon" the owner's livestock or dog. During the 2 months that wolves were Federally and State delisted in 2009, no wolves were killed under these authorizations. We are confident that the limited number of wolves expected to be taken under these Bills would not affect the viability of the Michigan wolf population.

*Regulatory Mechanisms in Other States and Tribal Areas Within the Proposed WGL DPS*

North Dakota and South Dakota

North Dakota lacks a State endangered species law or regulation. Any wolves in the State currently are classified as furbearers, with a closed season. North

Dakota Game and Fish Department is unlikely to change the species' State classification immediately following the proposed Federal delisting. Wolves are included in the State's Wildlife Action Plan as a "Level 3" Species of Conservation Priority. Level 3 species are those "having a moderate level of conservation priority, but are believed to be peripheral or do not breed in North Dakota." Placement on this list gives species greater access to conservation funding, but does not afford any additional regulatory or legislative protection (Bicknell in litt. 2009).

Currently any wolves that may be in South Dakota are not State listed as threatened or endangered, nor is there a hunting or trapping season for them. Upon the effective date of any Federal delisting, gray wolves in eastern South Dakota will fall under general protections afforded all State wildlife. These protections require specific provisions—seasons and regulations—be established prior to initiating any form of legal take. Thus, the State could choose to implement a hunting or trapping season for wolves east of the Missouri River; however, absent some definitive action to establish a season, wolves would remain protected. Following the proposed Federal delisting, any verified depredating wolves east of the Missouri will likely be trapped and killed by the USDA–APHIS–Wildlife Services program (Larson in litt. 2005). Non-depredating wolves in North and South Dakota not on the Federal list will continue to receive protection by the States' wildlife protection statutes unless specific action is taken to open a hunting or trapping season or otherwise remove existing protections.

*Post-delisting Depredation Control in North and South Dakota*—Since 1993, five incidents of verified wolf depredation have occurred in North Dakota, with one in September 2003 and two more in December 2005. There have been no verified wolf depredations in South Dakota in recent decades. Following the proposed Federal delisting we assume that lethal control of a small number of depredating wolves will occur in one or both of these States. Lethal control of depredating wolves may have adverse impacts on the ability of wolves to occupy any small areas of suitable or marginally suitable habitat that may exist in the States. However, lethal control of depredating wolves in these two States will have no adverse effects on the long-term viability of wolf populations in the proposed WGL DPS as a whole, because the existence of a wolf or a wolf population in the Dakotas will not make a meaningful contribution to the maintenance of the current viable, self-sustaining, and representative metapopulation of wolves in the proposed WGL DPS.

Other States in the Western Great Lakes DPS

The proposed DPS includes the portion of Iowa that is north of Interstate Highway 80, which is approximately 60 percent of the State. The Iowa Natural Resource Commission currently lists wolves as furbearers, with a closed season (Howell in litt. 2005). If the State retains this listing following the proposed Federal delisting of the DPS, wolves dispersing into northern Iowa will be protected by State law.

The portion of Illinois that is north of Interstate Highway 80, less than one-fifth of the State, is included in the DPS, and is part of the geographic area where wolves are proposed for removal from Federal protection. Gray wolves are currently protected in Illinois as a threatened species under the Illinois Endangered Species Protection Act (520 ILCS 10). Thus, following the proposed Federal delisting, wolves dispersing into northern Illinois would continue to be protected from human take by State law.

The extreme northern portions of Indiana and northwestern Ohio are included within the proposed DPS. If this proposal is made final, any wolves that are found in this area would no longer be Federally protected under the Act. The State of Ohio classifies the gray wolf as "extirpated," and there are no plans to reintroduce or recover the species in the State. The species lacks State protection, but State action is likely to apply some form of protection if wolves begin to disperse into the State (Caldwell in litt. 2005). Indiana DNR lists the gray wolf as extirpated in the State, and the species would receive no State protection under this classification following any Federal delisting. The only means to provide State protection would be to list them as State-endangered, but that is not likely to occur unless wolves become resident in Indiana (Johnson in litt. 2005, in litt. 2006). Thus, if this proposal is made final, Federally delisted wolves that might disperse into Indiana and Ohio would lack State protection there, unless these two States take specific action to provide new protections.

Because the portions of Iowa, Illinois, Indiana, and Ohio within the proposed WGL DPS do not contain suitable habitat or currently established packs, depredation control in these States would not have any significant impact on the continued viability of wolf populations in the proposed WGL DPS.

Tribal Management and Protection of Wolves

Native American Tribes and inter-Tribal resource management organizations have indicated to the Service that they will continue to conserve wolves on most, and probably all, Native American reservations in the core recovery areas of the proposed WGL DPS. The wolf retains great cultural significance and traditional value to many Tribes and their members (additional discussion is found in Factor E), and to retain and strengthen cultural connections, many Tribes oppose unnecessary killing of wolves on reservations and on ceded lands, even following any Federal delisting (Hunt in litt. 1998; Schrage in litt. 1998a; Schlender in litt. 1998). Some Native Americans view wolves as competitors for deer and moose, whereas others are interested in harvesting wolves as furbearers (Schrage in litt. 1998a). Many Tribes intend to sustainably manage their natural resources, wolves among them, to ensure that they are available to their descendants. Traditional natural resource harvest practices, however, often include only a minimum amount of regulation by the Tribal governments (Hunt in litt. 1998).

Although not all Tribes with wolves that visit or reside on their reservations have completed management plans specific to the wolf, several Tribes have informed us that they have no plans or intentions to allow commercial or recreational hunting or trapping of the species on their lands after the proposed Federal delisting. The Red Lake Band of Chippewa Indians (Minnesota) and the Little Traverse Bay Band of Odawa Indians (Michigan) have developed wolf monitoring and/or management plans. The Service has also awarded a grant to the Ho-Chunk Nation to identify wolf habitat on reservation lands.

As a result of many past contacts with, and previous written comments from, the Midwestern Tribes and their inter-Tribal natural resource management agencies—the Great Lakes Indian Fish and Wildlife Commission (GLIFWC), the 1854 Authority, and the Chippewa Ottawa Treaty Authority—it is clear that their predominant sentiment is strong support for the continued protection of wolves at a level that ensures that viable wolf populations remain on reservations and throughout the treaty-ceded lands surrounding the reservations. While several Tribes stated that their members may be interested in killing small numbers of wolves for spiritual or other

purposes, this would be carried out in a manner that would not impact reservation or ceded territory wolf populations.

The Red Lake Band of Chippewa Indians (Minnesota) completed a wolf management plan in 2010 (Red Lake Band of Chippewa Indians 2010). A primary goal of the management plan is to maintain wolf numbers at a level that will ensure the long-term survival of wolves on Red Lake lands. Key components of the plan are habitat management, public education, and law enforcement. To address human-wolf interactions, the plan outlines how wolves may be taken on Red Lake lands. Wolves thought to be a threat to public safety may be harassed at any time, and if they must be killed, the incident must be reported to Tribal law enforcement. Agricultural livestock are not common on Red Lake lands, and wolf-related depredation on livestock or pets is unlikely to be a significant management issue. If such events do occur, Tribal members may protect their livestock or pets by lethal means, but "* * * all reasonable efforts should be made to deter wolves using non-lethal means" (Red Lake Band of Chippewa Indians 2010, p. 15). Hunting or trapping of wolves on Tribal lands will be prohibited. The Reservation currently has seven or eight packs with an estimated 40–48 wolves within its boundaries (Red Lake Band of Chippewa Indians 2010, p. 12).

In 2009, the Little Traverse Bay Bands of Odawa Indians (LTBB) finalized a management plan for the 1855 Reservation and portions of the 1936 ceded territory in the northern LP of Michigan (Little Traverse Bay Bands of Odawa Indians Natural Resource Department 2009). The plan provides the framework for managing wolves on the LTBB Reservation with the goal of maintaining a viable wolf presence on the LTBB Reservation or within the northern LP should a population become established by (1) prescribing scientifically sound biological wolf management, research, and monitoring strategies; (2) addressing wolf-related conflicts; (3) facilitating wolf-related benefits; and (4) developing and implementing wolf-related education and public information.

The Tribal Council of the Leech Lake Band of Minnesota Ojibwe (Council) approved a resolution that describes the sport and recreational harvest of wolves as an inappropriate use of the animal. That resolution supports limited harvest of wolves to be used for traditional or spiritual uses by enrolled Tribal members if the harvest is done in a respectful manner and would not negatively affect the wolf population. The Council is revising the Reservation Conservation Code to allow Tribal members to harvest some wolves after Federal delisting (Googgleye, Jr. in litt. 2004). The Tribe is currently developing a wolf management plan (Mortensen 2011, pers. comm.). In 2005, the Leech Lake Reservation was home to an estimated 75 wolves, the largest population of wolves on a Native American reservation in the 48 conterminous States (Mortensen 2006, pers. comm.; White in litt. 2003). Although no recent surveys have been conducted, the number of wolves on the reservation likely remains the same (Mortensen 2009, pers. comm.).

The Fond du Lac Band (Minnesota) believes that the "well being of the wolf is intimately connected to the well being of the Chippewa People" (Schrage in litt. 2003). In 1998, the Band passed a resolution opposing Federal delisting and any other measure that would permit trapping, hunting, or poisoning of the wolf (Schrage in litt. 1998b; in litt. 2003; 2009, pers. comm.). If this prohibition is rescinded, the Band's Resource Management Division will coordinate with State and Federal agencies to ensure that any wolf hunting or trapping would be "conducted in a biologically sustainable manner" (Schrage in litt. 2003).

The Red Cliff Band (Wisconsin) has strongly opposed State and Federal delisting of the gray wolf. Current Tribal law protects wolves from harvest, although harvest for ceremonial purposes would likely be permitted after Federal delisting (Symbal in litt. 2003).

The Menominee Indian Tribe of Wisconsin is committed to establishing a self-sustaining wolf population, continuing restoration efforts, ensuring the long-term survival of the wolf in Menominee, placing emphasis on the cultural significance of the wolf as a clan member, and resolving conflicts between wolves and humans. They are currently working on developing a Menominee Wolf Management Plan (Cox 2011, pers. comm.).

The Tribe has shown a great deal of interest in wolf recovery and protection. In 2002, the Tribe offered their Reservation lands as a site for translocating seven depredating wolves that had been trapped by WI DNR and Wildlife Services. Tribal natural resources staff participated in the soft release of the wolves on the Reservation and helped with the subsequent radio-tracking of the wolves. Although by early 2005 the last of these wolves died on the reservation, the Tribal conservation department continued to monitor another pair that had moved onto the Reservation, as well as other wolves near the reservation (Wydeven in litt. 2006a). When that pair produced pups in 2006, but the adult female was killed, Reservation biologists and staff worked diligently with the WI DNR and the Wildlife Science Center (Forest Lake, Minnesota) to raise the pups in captivity in the hope that they could later be released to the care of the adult male. However, the adult male died prior to pup release, and they were moved back to the Wildlife Science Center (Pioneer Press 2006), and were subsequently transferred to the International Wolf Center in Ely, Minnesota, where they remain in captivity.

The Menominee Tribe continues to support wolf conservation and monitoring activity in Wisconsin. In recent years the Menominee Tribe has assisted the WI DNR in radio-telemetry wolf flights, allowing more regular flights to occur across all of northern Wisconsin.

The Keweenaw Bay Indian Community (Michigan) will continue to list the wolf as a protected animal under the Tribal Code following any Federal delisting, with hunting and trapping prohibited (Mike Donofrio 1998, pers. comm.). Furthermore, the Keweenaw Bay Community plans to develop a management plan that will address wolves (Donofrio in litt. 2003; Warner 20010, pers. comm.). At least three other Tribes (Stock-bridge Munsee Community, Lac Courte Oreilles Band of Ojibwe, the Mille Lacs Band of Ojibwe, and Grand Portage Band of Lake Superior Chippewa) have indicated that they are currently developing Tribal wolf management plans.

Several Midwestern Tribes (for example, the Bad River Band of Lake Superior Chippewa Indians and the LTBB) have expressed concern that Federal delisting will result in increased mortality of wolves on reservation lands, in the areas immediately surrounding the reservations, and in lands ceded by treaty to the Federal Government by the Tribes (Kiogama and Chingwa in litt. 2000). The Tribe's goal is to reduce the threats to reservation wolf packs when they are temporarily off the reservation. Other Tribes have expressed interest in such an agreement. If this and similar agreements are implemented, they will provide additional protection to certain wolf packs in the western Great Lakes area.

The GLIFWC has stated its intent to work closely with the States to cooperatively manage wolves in the ceded territories in the core areas, and will not develop a separate wolf

management plan (Schlender in litt. 1998). Furthermore, the Voigt Intertribal Task Force of GLIFWC has expressed its support for strong protections for the wolf, stating "[delisting] hinges on whether wolves are sufficiently restored and will be sufficiently protected to ensure a healthy and abundant future for our brother and ourselves" (Schlender in litt. 2004).

According to the 1854 Authority, "attitudes toward wolf management in the 1854 Ceded Territory run the gamut from a desire to see total protection to unlimited harvest opportunity." However, the 1854 Authority would not "implement a harvest system that would have any long-term negative impacts to wolf populations" (Edwards in litt. 2003). In comments submitted for our 2004 delisting proposal for a larger Eastern DPS of the gray wolf, the 1854 Authority stated that the Authority is "confident that under the control of State and Tribal management, wolves will continue to exist at a self-sustaining level in the 1854 Ceded Territory. Sustainable populations of wolves, their prey and other resources within the 1854 Ceded Territory are goals to which the 1854 Authority remains committed. As such, we intend to work with the State of Minnesota and other Tribes to ensure successful state and Tribal management of healthy wolf populations in the 1854 Ceded Territory" (Myers in litt. 2004). The 1854 Authority is currently developing a wolf management plan for the 1854 Ceded Territory, based on the above principles (Edwards 2011, pers. comm.).

While there are few written Tribal protections currently in place for wolves, the highly protective and reverential attitudes that have been expressed by Tribal authorities and members have assured us that any post-delisting harvest of reservation wolves would be very limited and would not adversely impact the delisted wolf populations. Furthermore, any off-reservation harvest of wolves by Tribal members in the ceded territories would be limited to a portion of the harvestable surplus at some future time. Such a harvestable surplus would be determined and monitored jointly by State and Tribal biologists, and would be conducted in coordination with the Service and the Bureau of Indian Affairs, as is being successfully done for the ceded territory harvest of inland and Great Lakes fish, deer, bear, moose, and furbearers in Minnesota, Wisconsin, and Michigan. Therefore, we conclude that any future Native American take of delisted wolves will not significantly impact the viability of the wolf population, either locally or across the proposed WGL DPS.

The Service and the Department of the Interior recognize the unique status of the Federally recognized Tribes, their right to self-governance, and their inherent sovereign powers over their members and territory. If we ultimately determine that delisting the WGL DPS is supported by the best available science, the Department, the Service, the Bureau of Indian Affairs (BIA), and other Federal agencies, as appropriate, will take the needed steps to ensure that Tribal authority and sovereignty within reservation boundaries are respected as the States implement their wolf management plans and revise those plans in the future. Furthermore, there may be Tribal activities or interests associated with wolves encompassed within the Tribes' retained rights to hunt, fish, and gather in treaty-ceded territories. The Department is available to assist in the exercise of any such rights. If biological assistance is needed, the Service may provide it via our field offices. Upon delisting, the Service would remain involved in the post-delisting monitoring of the wolves in the WGL, but all Service management and protection authority under the Act would end. Legal assistance would be provided to the Tribes by the Department of the Interior, and the BIA will be involved, when needed. If this proposal is finalized, we strongly encourage the States and Tribes to work cooperatively toward post-delisting wolf management.

Consistent with our responsibilities to Tribes and our goal to have the most comprehensive data available for our post-delisting monitoring, if the proposal to delist the WGL DPS is made final, we will annually contact Tribes and their designated intertribal natural resource agencies within the DPS during the 5-year post-delisting monitoring period to obtain any information they wish to share regarding wolf populations, the health of those populations, or changes in their management and protection. Reservations within the WGL DPS that may have significant wolf data to provide during the post-delisting period include Bois Forte, Bad River, Fond du Lac, Grand Portage, Keweenaw Bay Indian Community, Lac Courte Oreilles, Lac du Flambeau, Leech Lake, Menominee, Oneida, Red Lake, Stockbridge-Munsee Community, and White Earth. Throughout the 5-year post-delisting monitoring period, the Service will annually contact the natural resource agencies of each of these reservations and that of the 1854 Treaty Authority and Great Lakes Indian Fish and Wildlife Commission. We encourage the States and Tribes within the WGL DPS to work together on management and monitoring issues post-delisting.

Federal Lands

The five national forests with resident wolves (Superior, Chippewa, Chequamegon-Nicolet, Hiawatha, and Ottawa National Forests) in Minnesota, Wisconsin, and Michigan are all operating in conformance with standards and guidelines in their management plans that follow the 1992 Recovery Plan for the Eastern Timber Wolf's recommendations for the eastern timber wolf (USDA FS 2004a, chapter 2, p. 31; USDA FS 2004b, chapter 2, p. 28; USDA FS 2004c, chapter 2, p. 19; USDA FS 2006a, chapter 2, p. 17; USDA FS 2006b, chapter 2, pp. 28–29). Delisting is not expected to lead to an immediate change in these standards and guidelines; in fact, the Regional Forester for U.S. Forest Service Region 9 is expected to maintain the classification of the wolf as a Regional Forester Sensitive Species for at least 5 years after Federal delisting (Moore in litt. 2003). Under these standards and guidelines, a relatively high prey base will be maintained, and road densities will be limited to current levels or decreased. For example, on the Chequamegon-Nicolet National Forest in Wisconsin, the standards and guidelines specifically include the protection of den sites and key rendezvous sites, and management of road densities in existing and potential wolf habitat (USDA 2004c, Chap. 2, p. 19).

The trapping of depredating wolves would likely be allowed on national forest lands under the guidelines and conditions specified in the respective State wolf management plans. However, there are relatively few livestock raised within the boundaries of national forests in the upper Midwest, so wolf depredation and lethal control of wolves is neither likely to be a frequent occurrence, nor constitute a significant mortality factor, for the wolves in the proposed WGL DPS. Similarly, in keeping with the practice for other State-managed game species, any public hunting or trapping season for wolves that might be opened in the future by the States would likely include hunting and trapping within the national forests (Lindquist in litt. 2005; Williamson in litt. 2005; Piehler in litt. 2005; Evans in litt. 2005). The continuation of current national forest management practices will be important in ensuring the long-term viability of wolf populations in Minnesota, Wisconsin, and Michigan.

Wolves regularly use four units of the National Park System in the proposed WGL DPS and may occasionally use three or four other units. Although the National Park Service (NPS) has participated in the development of some of the State wolf management plans in this area, NPS is not bound by States' plans. Instead, the NPS Organic Act and the NPS Management Policy on Wildlife generally require the agency to conserve natural and cultural resources and the wildlife present within the parks. National Park Service management policies require that native species be protected against harvest, removal, destruction, harassment, or harm through human action, although certain parks may allow some harvest in accordance with State management plans. Management emphasis in National Parks after delisting will continue to minimize the human impacts on wolf populations. Thus, because of their responsibility to preserve all native wildlife, units of the National Park System are often the most protective of wildlife. In the case of the wolf, the NPS Organic Act and NPS policies will continue to provide protection following the proposed Federal delisting.

Management and protection of wolves in Voyageurs National Park, along Minnesota's northern border is not likely to change after delisting. The park's management policies require that "native animals will be protected against harvest, removal, destruction, harassment, or harm through human action." No population targets for wolves will be established for the National Park (Holbeck in litt. 2005). To reduce human disturbance, temporary closures around wolf denning and rendezvous sites will be enacted whenever they are discovered in the park. Sport hunting is already prohibited on park lands, regardless of what may be allowed beyond park boundaries (West in litt. 2004). A radio-telemetry study conducted between 1987 and 1991 of wolves living in and adjacent to the park found that all mortality inside the park was due to natural causes (for example, killing by other wolves or starvation), whereas the majority (60–80 percent) of mortality outside the park was human-induced (for example, shooting and trapping) (Gogan *et al.* 2004, p. 22). If there is a need to control depredating wolves outside the park, which seems unlikely due to the current absence of agricultural activities adjacent to the park, the park would work with the State to conduct control activities where necessary (West in litt. 2004).

The wolf population in Isle Royale National Park is described above (see Michigan Recovery). The NPS has indicated that it will continue to closely monitor and study these wolves. This wolf population is very small and isolated from the other wolf populations in the proposed WGL DPS; as described above, it is not considered to be significant to the recovery or long-term viability of the wolf (USFWS 1992, p. 28).

Two other units of the National Park System, Pictured Rocks National Lakeshore and St. Croix National Scenic Riverway, are regularly used by wolves. Pictured Rocks National Lakeshore is a narrow strip of land along Michigan's Lake Superior shoreline. Lone wolves periodically use, but do not appear to be year-round residents of, the Lakeshore. If denning occurs after delisting, the Lakeshore would protect denning and rendezvous sites at least as strictly as the Michigan Plan recommends (Gustin in litt. 2003). Harvesting wolves on the Lakeshore may be allowed (if the Michigan DNR allows for harvest in the State), but trapping is not allowed. The St. Croix National Scenic Riverway, in Wisconsin and Minnesota, is also a mostly linear ownership. Approximately 54–58 wolves from 11 packs used the Riverway on the Wisconsin side in 2010 (Wydeven 2011, pers. comm.). The Riverway is likely to limit public access to denning and rendezvous sites and to follow other management and protective practices outlined in the respective State wolf management plans, although trapping is not allowed on NPS lands except possibly by Native Americans (Maercklein in litt. 2003).

At least one pack of 4–5 wolves used the shoreline areas of the Apostle Islands National Lake Shore, with a major deer yard area occurring on portions of the Park Service land. Wolf tracks have been detected on Sand Island, and a wolf was photographed by a trail camera on the island in September 2009. It is not known if wolves periodically swim to this and other islands, or if they only travel to islands on ice in winter.

Wolves occurring on NWRs in the proposed WGL DPS will be monitored, and refuge habitat management will maintain the current prey base for them for a minimum of 5 years after delisting. Trapping or hunting by government trappers for depredation control will not be authorized on NWRs. Because of the relatively small size of these NWRs, however, most or all of these packs and individual wolves also spend significant amounts of time off these NWRs.

Wolves also occupy the Fort McCoy military installation in Wisconsin. In 2003, one pack containing five adult wolves occupied a territory that included the majority of the installation; in 2004 and 2006, the installation had one pack with two adults; in 2005 there was a single pack with four wolves. In 2008–09, there were seven wolves using the installation (Wilder 2009, pers. comm.). In 2010 a pack of three wolves occurred in the northern portions of the Fort, and a pack of two occurred on the south side (Wydeven *et al.* 2010, p. 42). Management and protection of wolves on the installation would not change significantly after Federal or State delisting. Den and rendezvous sites would continue to be protected, hunting seasons for other species (coyote) would be closed during the gun-deer season, and current surveys would continue, if resources are available. Fort McCoy has no plans to allow a public harvest of wolves on the installation (Nobles in litt. 2004; Wydeven *et al.* 2005a, p. 25; 2006a, p. 25).

Minnesota National Guard's (MNG) Camp Ripley contains parts of two pack territories, which typically include 10 to 20 wolves. MNG wildlife managers try to have at least one wolf in each pack radio-collared and to fit an additional one or two wolves in each pack with satellite transmitters that may record long-distance movements. There have been no significant conflicts with military training or with the permit-only public deer-hunting program at the camp, and no new conflicts are expected following delisting. Long-term and intensive monitoring has detected only two wolf mortalities within the camp boundaries—both were of natural causes (Dirks 2009, pers. comm.).

The protection afforded to resident and transient wolves, their den and rendezvous sites, and their prey by five national forests, four National Parks, two military facilities, and numerous National Wildlife Refuges in Minnesota, Wisconsin, and Michigan would further ensure the conservation of wolves in the three States after delisting. In addition, wolves that disperse to other units of the National Refuge System or the National Park System within the proposed WGL DPS will also receive the protection afforded by these Federal agencies.

*Summary of Factor D*

In summary, if this proposed delisting of the WGL DPS of gray wolves is made final, there would be varying State and Tribal classifications and protections provided to wolves. The wolf management plans currently in place for Minnesota, Wisconsin, and Michigan

will be more than sufficient to retain viable wolf populations in each State that are above the Federal recovery criteria for wolf metapopulation subunits, and even for three completely isolated wolf populations. These State plans provide a very high level of assurance that wolf populations in these three States will not decline to nonviable levels in the foreseeable future. Furthermore, the 2006 Update to the Wisconsin Wolf Management Plan (WI DNR 2006a, p. 3–4) demonstrates the State's commitment by retaining the previous management goal of 350 wolves, and it did not weaken any significant component of the original 1999 Plan. Similarly, the 2008 revised Michigan wolf plan continues to maintain the State's commitments to maintain viable wolf populations after Federal delisting. While these State plans recognize there may be a need to control or even reduce wolf populations at some future time, none of the plans include a public harvest of wolves, and all would maintain sufficient numbers of wolves to ensure their continued survival.

If Federally delisted, wolves in Minnesota, Wisconsin, and Michigan would continue to receive protection from general human persecution by State laws and regulations. Michigan met the criteria established in their management plan for State delisting and in April 2009 removed gray wolves from the State's threatened and endangered species list and amended the Wildlife Conservation Order to grant "protected animal" status to the gray wolf in the State (Roell 2009, pers. comm.). That status "prohibit[s] take, establish[es] penalties and restitution for violations of the Order, and detail[s] conditions under which lethal depredation control measures could be implemented" (Humphries in litt. 2004).

Since 2004 wolves have been listed as a "protected wild animal" by the WI DNR, allowing no lethal take unless special authorization is requested from the WI DNR (Wydeven *et al.* 2009c). Following the proposed Federal delisting, Wisconsin will fully implement that "protected wild animal" status for the species, including protections that provide for fines of $1,000 to $2,000 for unlawful hunting.

Minnesota DNR will consider population management measures, including public hunting and trapping, but this will not occur sooner than 5 years after Federal delisting, and MN DNR will maintain a wolf population of at least 1,600 animals (MN DNR 2001, p. 2). In the meantime, wolves may be taken legally in Zone A only when they pose an immediate threat to pets, domestic animals, or livestock or to protect human safety (MN DNR 2001, pp. 3–4). Since the wolf management plan was completed in 2001, MN DNR has fully staffed its conservation officer corps in the State's wolf range (Stark 2009a, pers. comm.).

Except for the very small portions of Indiana and Ohio, if delisted, wolves in the proposed WGL DPS are likely to remain protected by various State designations for the immediate future. States within the boundaries of the DPS either currently have mechanisms in place to kill depredating wolves (North Dakota and South Dakota) or can be expected to develop mechanisms following the proposed Federal delisting of the DPS, in order to deal with wolf-livestock conflicts in areas where wolf protection would no longer be required by the Act. Because these States (Illinois, Indiana, Iowa, Ohio, North Dakota, and South Dakota) constitute only about one-third of the land area within the DPS, and contain virtually no suitable habitat of sufficient size to host viable wolf populations, it is clear that even complete protection for wolves in these areas would neither provide significant benefits to wolf recovery in the DPS, nor to the long-term viability of the recovered populations that currently reside in the DPS. Therefore, although current and potential future regulatory mechanisms may allow the killing of wolves in these six States, these threats, and the area in which they will be, will not impact the recovered wolf populations in the DPS now or in the foreseeable future.

Finally, based on our review of the completed Tribal management plans and communications with Tribes and Tribal organizations, Federally delisted wolves are very likely to be adequately protected on Tribal lands. Furthermore, the numerical recovery criteria (and for Minnesota, the numerical planning goal) in the Recovery Plan would be achieved and maintained (based on the population and range of off-reservation wolves) even without Tribal protection of wolves on reservation lands. In addition, on the basis of information received from other Federal land management agencies in Minnesota, Wisconsin, and Michigan, we expect National Forests, units of the National Park System, military bases, and National Wildlife Refuges will provide protections to wolves in the areas they manage if delisted that will match, and in some cases will exceed, the protections provided by State wolf management plans and State protective regulations.

Therefore, we conclude that the regulatory mechanisms that will be in place subsequent to Federal delisting are adequate to control threats to wolves in the proposed WGL DPS such that wolves in the proposed WGL DPS are not likely to become endangered in the foreseeable future in all or a significant portion of the range.

### E. Other Natural or Manmade Factors Affecting Its Continued Existence

*Taking of Wolves by Native Americans for Certain Purposes*

As noted elsewhere in this proposed rule, the wolf has great significance to many Native Americans in the western Great Lakes area, especially to Wolf Clan members, and has a central role in their creation stories. The wolf, Ma"ingan, is viewed as a brother to the Anishinaabe people, and their fates are believed to be closely linked. Ma"ingan is a key element in many of their beliefs, traditions, and ceremonies, and wolf pack systems are used as a model for Anishinaabe families and communities. We are not aware of any takings of wolves in the Midwest for use in these traditions or ceremonies while the wolf has been listed as a threatened or endangered species. While wolves have been listed as threatened in Minnesota, we have instructed Wildlife Services to provide, upon request, wolf pelts and other parts from wolves killed during depredation control actions to Tribes in order to partially serve these traditional needs.

Some Tribal representatives, as well as the GLIFWC, have indicated that if wolves are delisted, there is likely to be interest in the taking of small numbers of wolves for traditional ceremonies (King in litt. 2003; White in litt. 2003). This take could occur on reservation lands where it could be closely regulated by a Tribe to ensure that it does not affect the viability of the reservation wolf population. Such takings might also occur on off-reservation treaty lands on which certain Tribes retained hunting, fishing, and gathering rights when the land was ceded to the Federal Government in the 19th Century. Native American taking of wolves from ceded lands would be limited to a specified portion of a harvestable surplus of wolves that is established in coordination with the Tribes, consistent with past Federal court rulings on treaty rights. Such taking would not occur until such time as a harvestable surplus has been documented based on biological data, and regulations and monitoring have been established by the States and Tribes to ensure a harvest can be carried out in a manner that ensures the continued viability of the wolf

population in that State. Previous court rulings have ensured that Native American treaty harvest of fish or wildlife species have not risked endangering the resource.

If requested by the Tribes, multitribal natural resource agencies, or the States, the Service or other appropriate Federal agencies will work with these parties to help determine if a harvestable surplus exists, and if so, to assist in devising reasonable and appropriate methods and levels of harvest for delisted wolves for traditional cultural purposes.

We conclude that the small number of wolves that may be taken by Native Americans would not be a threat sufficient to cause the wolves in the proposed WGL DPS to be in danger of extinction in the foreseeable future.

*Public Attitudes Toward the Wolf*

Human behavior has had a tremendous effect on wolf populations around the world. Theory and social science research have identified attitudes, and the beliefs on which they are based, as important drivers of behavior. Therefore, understanding public attitudes toward wolves is a key component of wolf management. The success of the United States wolf-eradication programs of the late-nineteenth and early twentieth centuries are often accepted as evidence of negative public attitudes that were based on perceptions and beliefs brought by European settlers that portrayed the wolf as an evil, menacing threat (Browne-Nunez and Taylor 2002, p. 1; Fogleman 1988; Kellert 1986; Schanning 2009, pp. 252–253) and were perpetuated by exaggerated accounts of marauding wolves preying on livestock (Schanning 2009, p. 253).

As the wolf arrived on the brink of extinction, there was a shift in management and a parallel shift in attitudes (Kellert *et al.* 1996; Schanning 2009, pp. 253–254; Williams *et al.* 2002, p. 581). In the Great Lakes region, bounty systems were repealed (Wisconsin in 1957, Michigan in 1960, and Minnesota in 1965) and, in 1972, the first of many attitudinal studies regarding wolves was carried out in Minnesota (Johnson 1974). In the last three decades, investigations of attitudes toward wolves and wolf management have burgeoned.

Minnesota

The first empirical examination of attitudes toward wolves was conducted using a convenience sample of 1,692 attendees of the Minnesota State Fair (Johnson 1974). It was based on the premise that children's stories, which typically cast the wolf as a villainous creature, shape attitudes from an early age. Although it found children to be more negative toward the wolf, a vast majority of adults held positive beliefs and attitudes. Most respondents felt that wolves were not a danger to humans, should not be exterminated, had value for Minnesota, and are good for the deer and moose populations.

Llewellyn (1978) reported the results of a content analysis of 1,083 public comment letters received by the Service regarding the proposed reclassification of the timber wolf in Minnesota from endangered to threatened. Of the 700 letters from Minnesota residents (the other letters were from out-of-state), 23 percent favored retention of endangered status, 7 percent supported reclassification, and 70 percent were in favor of delisting and return to State management. Of note were differences between urban and rural residents, with a large majority (78 percent) of urban residents and a minority (16 percent) of rural residents in favor of continued Federal protection of wolves. Support for delisting was largely based on concern for livestock and fear of wolves.

Kellert (1986) conducted a statewide phone survey of Minnesota residents' knowledge, attitudes, and behaviors toward the wolves. The study sample comprised the general public (Minneapolis-St. Paul residents and mostly rural, northern county residents), deer hunters, trappers, and livestock producers. Most respondents held favorable attitudes toward wolves (except farmers), supported protection of wolves and their habitat as long it did not interfere with human needs, and supported control of problem wolves. Urban residents expressed more protectionist attitudes, while rural residents' attitudes were more utilitarian in nature. There was "somewhat-limited" factual knowledge among the general public, but a higher knowledge level among trappers and, to a lesser degree, hunters and individuals with a higher income. Fear of wolves was expressed by some respondents, although most did not feel that wolves are a threat to people. Rather large percentages of farmers (12 percent) and trappers (17 percent) reported capturing or killing a wolf, and a majority of farmer, hunter, trapper, and northern county respondents reported knowing someone who captured or killed a wolf. Additionally, almost one-third of farmers, hunters, and trappers and a quarter of northern county respondents indicated that, given the opportunity, they might shoot a wolf while deer hunting.

In 1999, a second statewide phone survey of Minnesota residents was conducted, similar to the 1985 study, using a stratified random sample of northern residents, southern residents, farmers, hunters, and trappers (Kellert 1999). During this study period, Minnesota wolves were being considered for Federal delisting. Compared to the 1985 survey, this study found an overall increase in positive perceptions of the wolf. The general public expressed more affection and ethical concern for wolves than did farmers, although there was not a significant difference between groups in level of dislike of wolves. Over 70 percent of respondents believed wolves symbolize the beauty in nature and a large portion of the sample perceived other values of wolves, including ecological, scientific, and moral. Suburban and urban residents, the college educated, and younger respondents were more likely to have positive attitudes. Farmers were more knowledgeable about the wolf and more likely to support delisting. Of note was a substantial increase in the number of northern Minnesota residents who reported either killing a wolf themselves or knowing someone who did.

Chavez *et al.* (2005) assessed attitudes of residents of northwestern Minnesota. The sample of 600 rural residents was stratified by location: inside wolf range and outside but adjacent to wolf range. The study did not find large differences between geographic groups or farmers and non-farmers, with all groups indicating slightly unfavorable attitudes toward wolves. The authors suggest this could be attributable to shared rural cultural values and utilitarian attitudes. They also consider the possible influence of immigrant roots in Europe where folklore and early conflicts with wolves fostered negative attitudes. Both geographic groups agreed that wolves cause unacceptable levels of damage to northwest Minnesota's livestock industry, although predators were perceived as less of an agricultural threat than other threats (*e.g.,* livestock diseases, crop pests).

Using a random sample of 909 respondents (18 percent response rate), Schanning (2005) reported "pragmatic/utilitarian" beliefs regarding wolves among Minnesota residents. Most respondents supported compensation to livestock owners and having problem wolves shot by the DNR. Counter to Kellert's earlier findings, there was a significant level of fear of wolves among Schanning's sample, including fear for personal safety (31 percent), the safety of children (64 percent), and pets (70 percent).

Michigan

In Michigan, Hook and Robinson (1982, pp. 388–391) found that only a small percentage of respondents scored high on their anti-predator scale and most respondents were in favor of wolf restoration. Hunters were more positive toward predators than nonhunters. Fear of the wolf was the most important factor related to an anti-predator attitude, followed by negativistic attitudes toward all animals, and age, with older people holding more negative attitudes.

Kellert (1990) conducted a statewide mail survey of Michigan residents' knowledge, attitudes, and behaviors toward wolves. There were 639 respondents from the Upper (UP) and Lower (LP) peninsulas and members of three special interest groups: hunters, trappers, and livestock producers. Livestock producers were the most likely of the special interest groups to hold negative attitudes toward the wolf. LP residents were more likely than UP residents to express fear and dislike of wolves. A majority of respondents in each group, except livestock producers, supported restoration (64 percent of UP residents, 57 percent of LP residents, 76 percent of hunters, 66 percent of trappers, and 37 percent of livestock producers). Support was primarily motivated by the existence, ecological, and cultural values of the wolf.

A 2002 statewide survey of 557 Michigan residents' attitudes toward wolf recovery found that support for recovery by UP residents had declined since Kellert's 1990 study (Mertig 2004). At the time this study was conducted, the UP's wolf population had risen to about 250 animals (Hammill 2007), but in the LP, where wolves were not known to be present, there was increased support for wolf recovery in the UP. Other differences from Kellert's (1990) findings included increased support for wolf control and for hunting and trapping for pelts.

Based on a sample of 1,017 Michigan residents (20 percent response rate), Schanning (2004) found that a majority of respondents in his survey agreed with pro-wolf statements including "wolves are a part of our vanishing wilderness and should be protected" (51 percent). Similar to his 2005 study of Minnesota residents and his 2003 study of Wisconsin residents (reported below), Schanning found a substantial level of fear of wolves among the Michigan sample. Respondents reported fear for their personal safety (40 percent), the safety of children (70 percent), pets (7 percent), and livestock (66 percent).

Using a stratified random sample of respondents from five regions in Michigan, Beyer (2006) measured tolerance of wolves using a scale for social carrying capacity. The scale was based on Michigan wolves' perceived range, numbers, and the type and number of interactions with people. The study found that most people were at the most tolerant end of the scale, with smaller percentages classified as intolerant (7 percent) or least tolerant (20 percent).

Wisconsin

Knight (1985, reported in Schanning 2009, p. 257) surveyed hunter attitudes in two Wisconsin counties in wolf range where a minority (20 percent) of hunters reported negative attitudes toward wolves and most (69 percent) believed that wolves should not be eliminated.

In 1988, when there were only 20 wolves in Wisconsin, Nelson and Franson (1988) compared farmer' and non-farmers' attitudes toward wolves and wolf recovery in six Wisconsin counties. A series of agree-disagree belief statements was used to gauge attitudes toward wolves. Non-farmers were more positive than farmers, and a majority agreed that the wolf "symbolizes the beauty and wonder in nature" and "it would be wonderful to hear the wolf howl in the wild" (64 percent and 62 percent respectively). Almost half of farmers agreed with the same statements. Both groups disagreed that they would be afraid of an attack if they saw a wolf while walking in the woods. Farmers and non-farmers were divided about wolf restoration, with half of farmers and about one-third of non-famers opposed. Both groups favored trapping and removal of problem wolves.

Wilson (1999) examined knowledge, attitudes, and behaviors toward wolves in a 1997 survey of two random samples: all Wisconsin license plate owners and those who purchased an Endangered Resources (ER) license plate. Fifty percent of all license plate owners and almost 90 percent of ER license plate owners supported efforts to increase the State wolf population. There were slight differences between hunters (47 percent) and non-hunters (54 percent) who support wolf recovery.

Naughton *et al.* (2003) assessed tolerance of wolves among 535 rural Wisconsin residents using a mail-back questionnaire (82 percent response rate). They examined the influence of compensation for livestock losses to wolves and preferences for wolf management actions among different segments of the sample, including livestock producers, bear hunters, general residents, wolf damage complainants, recipients of compensation, and demographic segments. The strongest predictor of tolerance was social group. A large majority of bear hunters (73 percent) were in favor of reducing or eliminating the wolf population, compared to 45 percent of the livestock producers and 29 percent of general residents. Individuals who had lost a domestic animal to a predator were less tolerant of wolves than those who had not. Preferences for management actions depended on the conflict situation. Approval for lethal control was highest for depredation on livestock and pets. Bear hunters also were highly in favor of lethal control when hunting hounds are killed, but other groups did not muster a majority for this option. Compensation was not associated with higher tolerance when comparing recipients to nonrecipients among those who reported losing a domestic animal to wolves.

Similar to his studies in Minnesota and Michigan, Schanning (2003) surveyed 644 Wisconsin residents' (13 percent response rate) attitudes toward wolves. He found a majority of respondents held pro-wolf attitudes based on their agreement with three belief statements: "the wolf is a symbol of the beauty and wonder in nature," "wolves are part of our vanishing wilderness and should be protected," and "wolves are essential to maintaining the balance in nature" (72 percent, 56 percent, and 62 percent in agreement, respectively). There was substantial support for wolf hunting (41 percent), and a majority (60 percent) indicated they would shoot a wolf if it threatened their pet.

In a followup to Naughton *et al.* (2001), Treves *et al.* (2009) reported attitudes of 1,364 respondents (62 percent response rate) toward compensation after wolf recovery. They compared the attitudes of individuals who contributed to Wisconsin's voluntary compensation fund with those of noncontributors and found that attitudes of each group differed in several ways. Contributors favored nonlethal over lethal problem wolf management actions and supported all types of payments more strongly with the exception of payment for hunting dogs injured or killed by wolves on public land, but a majority of respondents of both groups supported compensation "even when wolves are no longer threatened or endangered." Noncontributors were more likely to believe that wolf damages were part of raising livestock and should not be compensated.

Treves *et al.* (in review) report the first longitudinal results for change in individual attitudes over time using findings from surveys conducted in 2001 (Naughton *et al.* 2003), 2004 (Treves *et al.* 2009), and 2009. During the data collection period, wolf numbers nearly tripled and greatly exceeded the State population goal, the level of wolf depredation on pets increased and became the third most frequent conflict after attacks on beef calves and bear-hunting dogs, and wolf management authority was granted to State governments and subsequently revoked several times after Federal court challenges. The 2009 survey found attitudes toward wolves had become less favorable, and fear of wolves, perceived competition for deer, and reported inclination to illegally kill wolves increased. In the 2009 survey, 18 percent of hunters indicated they would shoot a wolf if they saw one while hunting. Nearly half of respondents agreed their tolerance for wolves in Wisconsin would increase if people could hunt them.

Shelley *et al.* (in review) compared attitudes of Ojibwe Indians and nontribal residents of Wisconsin's wolf range. Tribal membership was the best predictor of attitudes. Ojibwe respondents had more positive attitudes toward wolves, were more supportive of wolf protection policy, and were less supportive of a public wolf harvest and lethal control of problem wolves. A considerable percentage (Ojibwe 33 percent, nontribal 44 percent) of each group indicated they would be afraid if wolves lived near their homes. Fewer Ojibwe (8 percent) than nontribal respondents (16 percent) indicated that they would shoot a wolf if they saw one while hunting. Nontribal respondents (57 percent) were more likely than Ojibwe respondents (26 percent) to believe that wolves threaten deer hunting opportunities. Shelley *et al.* (in review) point out the potential significance of treaty rights, which grant the Tribe half of any harvest, including wolves, within the territories ceded by them in nineteenth century Federal treaties upheld by Federal courts in the 1980s.

Treves and Martin (2011) examined the attitudes of 2,320 respondents, hunters and nonhunters, living within or adjacent to wolf range in surveys conducted in Wisconsin in 2001 and 2004 (reported above) and the northern Rocky Mountain (NRM) States of Idaho, Montana, and Wyoming. A majority of respondents supported regulated, public wolf hunting, although support was dependent on potential justifications for a hunting season.

In Wisconsin, bear hunters in 2001, followed by other hunters, were most likely to support an immediate hunt, whereas nonhunters in favor of wolf hunting were more likely to be supportive when managers estimate the wolf population could sustain harvests or when the majority of the public believe damages have become intolerable. There was a shift in 2004 when a majority of hunters indicated they would support wolf hunting when the population was deemed to be at a level that could sustain harvests. More nonhunters agreed with a hunt when the public felt damages had become intolerable. Inclination to kill a wolf illegally in Wisconsin in 2001 and 2004 was high among hunters, particularly among likely carnivore-hunters. These two groups favored a significant reduction (up to half) of the Wisconsin wolf population.

In addition to the studies summarized above, citizen input on the wolf management plans of Minnesota, Wisconsin, and Michigan has provided additional insight on public support for wolf recovery. Namely, it shows strong support for wolf recovery if the adverse impacts on recreational activities and livestock production can be minimized (MI DNR 1997, pp. 13–14, 50–56; MN DNR 1998, p. 2; WI DNR 1999, pp. 51–55; WI DNR 2006c, pp. 9–11).

Summary of Public Attitudes

While there is a lack of empirical data on early attitudes toward wolves, historical accounts describe an antagonist view of wolves during the 19th and early 20th centuries. Attitudinal research conducted throughout the lower 48 States in the last three decades has shown that a shift toward more positive attitudes took place during the 20th century (Browne-Nuñez and Taylor 2002, Kellert *et al.* 1996, Williams *et al.* 2002). Although the basis for this shift is not understood, suggested causes include changes in the portrayal of wolves in the media (Kellert *et al.* 1996) and a broader shift in societal values of wildlife (Manfredo *et al.* 2003).

Although direct comparisons cannot be made of each study summarized here, given different research methods and contextual circumstances, we can summarize some common findings and general conclusions. Similar to research conducted outside the Great Lakes region (summarized in Williams *et al.* 2002), many of the studies reviewed here demonstrate urban-rural differences in attitudes, with urban residents displaying more positive attitudes; farmers and livestock producers are more negative toward wolves; those with higher education levels have more positive attitudes; and compensation does not translate into increased tolerance.

In several studies, hunters were mostly positive toward wolves (Hook and Robinson 1982, Kellert 1990, Knight 1985), with the exception of Wisconsin bear hunters who were the most negative among special interest groups (Naughton *et al.* 2003). Cross-sectional studies suggest increasing support for control of problem wolves and public harvest of wolves (Kellert 1985, Mertig 2004, Naughton *et al.* 2003), and one recent study shows this support has increased among individuals re-sampled over time (Treves *et al.,* in review). Some respondents indicated they had or would kill a wolf illegally (Kellert 1985; Treves *et al.,* in review).

While most respondents were positive toward wolves, it is evident that there have long been competing attitudes toward wolves. While attitudes in other regions have been shown to be relatively stable (Williams *et al.* 2002, Wilson and Bruskotter 2009), a troubling finding for managers in the Great Lakes region is the most recent research showing declining support for wolves (Hammill 2007; Mertig 2004; Treves *et al.,* in review) and an increasing inclination to kill wolves illegally (Treves *et al.,* in review). Possible explanations for this decline include increasing wolf numbers, negative interactions with humans, and negative media coverage (Hammill 2007). It is unclear how delisting will affect attitudes and behavior toward wolves. Also in question is how public wolf harvest might affect attitudes and behaviors. While we do not believe the affects of public attitudes on wolves will be a significant threat to the species in the foreseeable future, as the status and management of the wolf evolves, there will be a need for continued collaboration between managers and researchers to monitor public attitudes toward wolves and their management.

*Hybridization with Coyotes*

Genetic data relevant to possible interbreeding between North American wolves and coyotes was first reported in a study of mtDNA restriction fragment length polymorphisms by Lehman *et al.* (1991). They found mtDNA haplotypes in wolf populations in the Great Lakes region that they interpreted as being derived from coyotes (Lehman *et al.,* p. 108). As wolf haplotypes were not found in coyotes, the apparent introgression occurred through matings of wolf males with coyote females. They determined that a minimum of six instances of coyote-wolf hybridization

could account for the diversity of "coyote-type" haplotypes observed in wolves (p. 112). Their general interpretation was that introgression primarily occurred as coyotes expanded their ranges into the Great Lakes region within historical time, although they allow that two coyote-type haplotypes commonly observed in Great Lakes wolves may have been the result of ancient hybridization. Their data also indicated (Lehman *et al.,* Figure 4) that coyote-type haplotypes were less common in the western part of the Great Lakes region than in the east.

Wilson *et al.* (2000, Figure 6, p. 2165) provided a different interpretation of wolf-coyote relationships in the region. They found coyote-like mtDNA sequences in eastern Canadian wolves from Algonquin Provincial Park, Ontario, southern Manitoba, and northeastern Minnesota that were intermediate in sequence divergence between coyotes and gray wolves. As these haplotypes were apparently absent in coyotes, they were thought not to result from hybridization with coyotes, but to represent an eastern wolf species, *Canis lycaon.* They suggest that these *Canis lycaon* haplotypes may have been previously reported as "coyote-type" in the study of Lehman *et al.* (1991).

It is now generally agreed that historical and most contemporary Great Lakes wolves have unique mtDNA haplotypes that are distinct from those of other wolves, and more related to but still distinct from those of coyotes. Haplotypes specific to the early 20th century wolf population of the western Great Lakes region were identified by Leonard and Wayne (2008, pp. 2–3), from a study of 17 historical specimens from Michigan, Wisconsin, Ontario, and Quebec. Of the 17 specimens that gave conclusive results, 14 were either the same or most similar to the haplotypes described by Wilson *et al.* (2000) as *C. lycaon.* Only one had a coyote haplotype. Wheeldon and White (2009) reported haplotypes from three additional historical specimens from the western Great Lakes region. Two individuals from Minnesota (collected 1899 and 1900) had the same coyote-like haplotypes (C13) found in a late 19th century specimen from Maine, 50 years before recorded coyote sightings in Maine (Wilson *et al.* 2003), as well as in contemporary western Great Lakes wolves from Minnesota to Quebec (Leonard and Wayne 2008, pp. 2–3). The third specimen, collected in the winter of 1907–08 in Wisconsin, had the common Great Lakes wolf haplotype C1. Microsatellite DNA analysis of these three specimens grouped them with wolves rather than coyotes.

Koblmüller *et al.* (2009) addressed the issue of coyote hybridization in the Great Lakes region from analyses of mtDNA sequence and both Y-chromosome and autosomal microsatellite DNA. They found evidence of repeated incidences of ancient introgression of coyotes into Great Lakes wolves, although they also suggested that introgression by coyotes is recent and ongoing, especially north of the Great Lakes.

Wheeldon and White (2009, p. 2) and Fain *et al.* (2010) concluded that the coyote-related haplotype C13 is actually a *C. lycaon* marker based on its presence mainly in *C. lycaon-C. lupus* hybrids in the western Great Lakes region, the absence of C13 in non-hybridizing coyotes, and its occurrence in historical eastern wolves. Assessments based on mtDNA, Y-chromosome, and autosomal microsatellite DNA data consistently found that the wolf population in the western Great Lakes region does not currently interbreed with coyotes (Fain *et al.* 2010, p. 14; Wheeldon *et al.* 2010). Previous reports of coyote-wolf hybridization in the WGL region were based on the misidentification of coyote-like haplotypes, which are now understood to be unique markers for *C. lycaon,* as discussed above.

Lehman *et al.*'s (1991, p. 114) interpretation of coyote introgression into Great Lakes wolves included an explanation that it occurred at a time when wolf population densities were low in the region, so that wolves would be less likely to find mates of the same species and mating with coyotes was more likely to take place. Conversely, Lehman *et al.* (1991) suggested that coyote introgression does not appear to occur when wolf densities are higher. If so, the increase in population size that has occurred over the last 30 years renders the western Great Lakes wolf population less vulnerable to whatever threat may have been presented by coyote introgression. The wolf population of the region has likely been exposed to this factor for centuries and has rebounded from near extirpation, yet retains essential genetic, behavioral, and other biological features of wolves without being displaced by coyotes. This fact suggests that the threat of coyote hybridization to a recovered wolf population is small.

*Hybridization Between C. lupus and C. lycaon*

Although it is clear that *C. lycaon* and *C. lupus* have hybridized in the western Great Lakes region, same-species combinations of paternal and maternal markers in male wolves are more common than expected by random mating (Wheeldon *et al.* 2010). This suggests that there is some constraint on complete hybridization between the two species and that complete blending of the two components of the population is not inevitable. The limited number of historical specimens from the western Great Lakes region that have been genetically characterized all have mtDNA indicative of *C. lycaon* (Leonard and Wayne 2008, pp. 2–3; Wheeldon and White 2009, p. 1), but four of these from the early 20th century also had *C. lupus* Y-chromosome haplotypes, which indicates that hybridization had occurred by that time. The opportunity for hybridization between *C. lycaon,* which belongs to a North American lineage, and *C. lupus,* which evolved in Eurasia, has existed since *C. lupus* entered North America about 500,000 years ago (Kurtén and Anderson 1980), yet a predominantly *C. lycaon* population of wolves still persists in the western Great Lakes region.

Hybrid indices based on the co-occurrence of species specific mtDNA and nuclear markers have been used to assess the depth and extent of hybrid zones in tiger salamanders, cutthroat trout, red deer, and wolves (Abernathy 1994; Riley *et al.* 2003; Wheeldon and White 2009). Wheeldon and White (2009) used the mtDNA haplotype of an individual wolf in combination with the program STRUCTURE assignment of its microsatellite genotype to identify *C. lupus—C. lycaon* hybrids in historical WGL wolves. Applying this index, half of WGL females with *C. lupus* mtDNA also exhibited high assignment to *C. lupus* and half of WGL females with *C. lycaon* mtDNA were similarly assigned to *C. lycaon.* Considering both lineage markers in males, 44 percent of males with *C. lupus* mtDNA and Y-chromosome haplotypes exhibited high assignment to *C. lupus,* but only 28 percent of males exhibiting *C. lycaon* mtDNA and Y-chromosome haplotypes also exhibited high assignment to *C. lycaon.* The 8–12 microsatellite loci typically used in studies of *C. lupus—C. lycaon* introgression (Grewal *et al.* 2004; Wilson *et al.* 2000, 2009; Fain *et al.* 2010; Rutledge *et al.* 2010; Wheeldon *et al.* 2010) can effectively estimate the amount of mixing at the population level, but not the individual level (Allendorf *et al.* 2010). Based on the information presented in these studies, there is no evidence showing that hybridization between *C. lupus* and *C. lycaon* is a threat to *C. lupus.*

**Conclusion of the 5-Factor Analysis**

As required by the Act, we considered the five potential threat factors to assess whether the wolves in the proposed

WGL DPS are threatened or endangered throughout all or a significant portion of their range. When considering the status of the species, the first step in the analysis is to determine whether the species is in danger of extinction or likely to become endangered in the foreseeable future throughout all of its range.

Human-caused mortality is the most significant issue to the long-term conservation status of the wolves in the proposed WGL DPS. Therefore, managing this source of mortality (*i.e.,* human predation) remains the primary challenge to maintaining a recovered wolf population into the foreseeable future. We have concluded that Minnesota, Wisconsin, and Michigan will maintain their share and distribution of the WGL wolf population above recovery levels for the foreseeable future, and that the threats have been sufficiently reduced. All three States have wolf management laws, plans, and regulations that adequately regulate human-caused mortality. Each of the three States has committed to manage its wolf population at or above viable population levels, and this commitment is not expected to change.

Regulatory mechanisms in all three States are adequate to facilitate the maintenance of, and in no way threaten, the recovered status of the wolves in the WGL DPS. If Federally delisted, wolves in Minnesota, Wisconsin, and Michigan would continue to receive protection from general human persecution by State laws and regulations. Violation of regulations will be subject to prosecution.

As long as populations are maintained well above minimal recovery levels, wolf biology (namely the species' reproductive capacity) and the availability of large, secure blocks of suitable habitat will maintain strong populations capable of withstanding all other foreseeable threats. In terms of habitat, the amount and distribution of suitable habitat in public ownership provides, and will continue to provide, large core areas that contain high-quality habitat of sufficient size to anchor a recovered wolf population. Our analysis of land management shows these areas will maintain their suitability into the foreseeable future, if not indefinitely.

While disease and parasites can temporarily impact population stability, as long as populations are managed above recovery levels, these factors are not likely to threaten the wolf population at any point in the foreseeable future. Natural predation is also likely to remain an insignificant factor in population dynamics into the foreseeable future. Finally, we believe that other natural or manmade factors, such as potential hybridization with coyotes and public attitudes, are unlikely to threaten the wolves in the proposed WGL DPS in the foreseeable future in all portions of the range within the DPS.

We find that the threat of habitat destruction or degradation or a reduction in the range of the wolf; utilization by humans; disease, parasites, or predatory actions by other animals or humans; regulatory measures by State, Tribal, and Federal agencies; or other threats will not individually or in combination cause wolves in the proposed WGL DPS to likely become endangered within the foreseeable future throughout all of the species' range in the DPS. Ongoing effects of recovery efforts over the past decades, which resulted in a significant expansion of the occupied range of wolves in the proposed WGL DPS, in conjunction with future State, Tribal, and Federal agency wolf management across that occupied range, will be adequate to ensure the conservation of the proposed WGL DPS. These activities will maintain an adequate prey base, preserve denning and rendezvous sites, monitor disease, restrict human take, and keep wolf populations well above the numerical recovery criteria established in the Revised Recovery Plan (USFWS 1992, pp. 25–28). Thus, the gray wolves in the proposed WGL DPS do not merit continued listing as threatened or endangered throughout all of their range.

**Is the Species Threatened or Endangered in a Significant Portion of Its Range?**

Having determined that wolves in the proposed WGL DPS do not meet the definition of endangered or threatened throughout their entire range, we must next consider whether they are in danger of extinction or are likely to become so in a significant portion of their range. The Act does not define the term "significant portion of its range." Therefore, we must give meaning to this phrase based on our experience and expertise. We interpret a portion of a species' range as being significant if it is part of the current range of the species (species used here is as defined in the Act, to include species, subspecies, or DPS) and if it is important to the conservation of the species because it contributes meaningfully 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.

Applying the definition described above for determining whether a species is endangered or threatened in a significant portion of its range, we first address whether any portions of the range of wolves in the WGL DPS warranted further consideration. We evaluated the WGL DPS in the context of whether any potential remaining threats are concentrated in one or more areas, such that if there were concentrated impacts, those wolves might be threatened, and further, whether any such area might constitute a significant portion of the species ranges.

Wolves are highly adaptable habitat generalists, and their primary biological need is an adequate natural prey base of large ungulates. The primary current and likely future threats to wolves are excessive human-caused mortality and increased mortality from diseases and parasites. Based on the biology of the gray wolf, threats to its continued existence, and conservation biology principles, the Recovery Plan specifies that two populations (or what equates to a single metapopulation) are needed to ensure long-term viability (see *Recovery Criteria,* above). The Revised Recovery Plan states the importance of a large wolf population throughout Minnesota Wolf Management Zones 1 through 4 (geographically identical to Zone A in the 2001 Minnesota Wolf Management Plan, see Figure 2 in this rule) and the need for a second viable wolf population occupying 10,000 sq mi or 5,000 sq mi elsewhere in the eastern United States (depending on its isolation from the Minnesota wolf population) (USFWS 1992, pp. 24–29).

The Recovery Plan also discusses the importance of low-road-density areas, the importance of minimizing wolf–human conflicts, and the maintenance of an adequate natural prey base in the areas hosting these two necessary wolf populations. These portions of Minnesota (Management Zones 1 through 4) and the portions of the proposed DPS that support the second viable wolf population (Wisconsin Zones 1 and 2 and the entire UP of Michigan) provide an adequate wild prey base, suitably low levels of human-caused mortality, and sufficient representation, resiliency, and redundancy to buffer the impacts of disease and parasite-induced mortality (See the discussion under *Recovery Criteria,* above*)* regarding how achieving the goals of the Recovery Plan for the Eastern Timber Wolf assures a viable wolf population in terms of representation, resiliency, and redundancy).

Post-delisting wolf protection, management, and population and health monitoring by the States, Tribes, and Federal land management agencies will ensure the continuation of viable wolf populations above the Federal recovery criteria for the foreseeable future. This is particularly true in Minnesota Zone A, Wisconsin Zones 1 and 2, and across the UP of Michigan, because the State management plans provide for greater protections for the species in that area (see the discussion of the three plans in *State Wolf Management Planning,* above).

Post-delisting threats to wolves in Zone B in Minnesota, Zones 3 and 4 in Wisconsin, and in the Lower Peninsula of Michigan will be more substantial, and may preclude the establishment of wolf packs in most or all of these areas in Wisconsin and Michigan. The Recovery Plan f specifically recommends against managing wolves in large areas of unsuitable habitat, stating that Minnesota Zone 5 (identical to Minnesota Wolf Management Zone B, Figure 2) should be managed with a goal of zero wolves there, because "Zone 5 is not suitable for wolves. Wolves found there should be eliminated by any legal means" (USFWS 1992, p 20). Therefore, the Recovery Plan views Zone 5, which is roughly 60 percent of the State, as not an important part of the range of the wolf. This portion of the State is predominantly agricultural land, with high road densities, and high potential for wolves to depredate on livestock. Although individual wolves and some wolf packs occupy parts of Zone 5, these wolves are using habitat islands or are existing in other situations where conditions generally are not conducive to their long-term persistence.

The northern LP of Michigan appears to have the only unoccupied potentially suitable wolf habitat in the Midwest that is of sufficient size to maintain wolf packs (Gehring and Potter 2005, p. 1239; Potvin 2003, pp. 44–45), although its small size and fragmented nature may mean that northern LP wolf population viability would be dependent upon continuing immigration from the UP. The only part of Michigan's LP that may contain suitable habitat are those areas of fragmented habitat studied by Potvin (2003, pp. 44–45) and Gehring and Potter (2005, p. 1239). However, these areas amount to less than half of the minimal area identified by the Recovery Plan for the Eastern Timber Wolf as needed for the establishment of viable populations. These LP areas therefore might have difficulty maintaining wolf populations even with the help of occasional immigration of wolves from the UP (see *Suitable Habitat Within the Proposed Western Great Lakes DPS,* above, for additional discussion). While the UP wolves may be significant to any LP wolf population (occasional UP to LP movements may provide important genetic and demographic augmentation crucial to a small population founded by only a few individuals), the reverse will not be true—LP wolves would not be important to the wolf population in the UP, as that population is already large enough in size and range to be self-sustaining.

The lack of sufficient areas of suitable habitat in those parts of North Dakota, South Dakota, Iowa, Illinois, Indiana, and Ohio that are within the proposed WGL DPS are expected to preclude the establishment of viable populations in these areas, although dispersing wolves and packs may temporarily occur in some of these areas. As a result, wolf numbers in these areas will have no impact on the continued viability of wolves in the proposed WGL DPS, and are not necessary to maintain adequate representation, resiliency, and redundancy for wolves in the proposed DPS.

In conclusion, Minnesota Zone A, Wisconsin Zones 1 and 2, and the UP of Michigan provide an adequate wild prey base, suitably low levels of human-caused mortality, and sufficient numbers and distribution of wolves to ensure adequate representation, resiliency, and redundancy to buffer the impacts of disease and parasite-induced mortality. Post-delisting wolf protection, management, and population and health monitoring by the States, Tribes, and Federal land management agencies will ensure the continuation of viable wolf populations in those areas above the recovery criteria established in the Recovery Plan for the foreseeable future.

In coming to this determination, we considered the quality, quantity, and distribution of the habitat relative to the biological needs of the species, the need to maintain the remaining genetic diversity, the importance of geographic distribution in coping with catastrophes such as disease, the ability of the habitat to provide adequate wild prey, and the need to otherwise meet the conservation needs of the species. Reasonably foreseeable threats to wolves in all parts of the proposed WGL DPS are not likely to threaten wolf population viability in the WGL DPS in the foreseeable future. Therefore, we find that wolves in the WGL DPS are not in danger of extinction and are not likely to become endangered in the foreseeable future throughout all or a significant portion of their range.

**Proposed Determination**

After a thorough review of all available information and an evaluation of the five factors specified in section 4(a)(1) of the Act, as well as consideration of the definitions of "threatened" and "endangered" contained in the Act and the reasons for delisting as specified in 50 CFR 424.11(d), we propose that revising the boundary of the 1978 Minnesota gray wolf listing and removing the WGL DPS of gray wolf (*Canis lupus*) from the List of Endangered and Threatened Wildlife (50 CFR 17.11) is appropriate. Wolves have recovered in the proposed WGL DPS as a result of the reduction of threats as described in the analysis of the five categories of threats and no longer are in danger of extinction, nor are likely to become so in the foreseeable future, throughout all or a significant portion of their range.

We recognize recent taxonomic information indicating that the gray wolf subspecies *Canis lupus lycaon* should be elevated to the full species *C. lycaon.* Additionally, we acknowledge evidence that *C. lycaon* intercrosses with *C. lupus* in the western Great Lakes region, resulting in a mixed population composed of *C. lupus, C. lycaon,* and their hybrids. As discussed under *Procedural Aspects of Proposal Applying to the Gray Wolf* above, the procedural aspects of this proposed rule refer to the gray wolf (*C. lupus*), because that is the named entity currently on the List of Endangered and Threatened Wildlife. Our proposed action here is to establish the existence of a WGL distinct population segment of *C. lupus* that is neither endangered nor threatened, despite its proximity to a closely related species, *C. lycaon*—a species whose status we will evaluate for possible protection under the Act in the near future.

Because *C. lycaon* was recently recognized as a unique species (rather than a subspecies of *C. lupus*), a complete status review of this species has never been conducted. Therefore, we are initiating a status review for *C. lycaon* throughout its range in the United States and Canada.

We also are proposing to revise the range of the gray wolf (the species *C. lupus*) by removing all or parts of 29 states (see Effects of the Rule, below) because this area is outside of the currently known historical range of the gray wolf (see *Taxonomy and Historical Ranges of Wolves in the United States*). These areas should not have been included in the original listing of the gray wolf because gray wolves did not historically occur there; they were either

red wolf (*C. rufus*) range or eastern wolf (*C. lycaon*) range.

**Available Conservation Measures**

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, Tribal, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. This proposed rule, if made final, would remove these Federal conservation measures for gray wolves within the proposed WGL DPS.

**Effects of the Rule**

This proposal, if made final, would revise the pre-DPS policy Minnesota "species" listing and establish it as a WGL DPS of the gray wolf (*C. lupus*), expand the boundaries of that DPS, and remove the protections of the Act for that WGL DPS by removing the gray wolf wolves in that DPS from the List of Endangered and Threatened Wildlife.

This proposal, if made final, would remove the special regulations under section 4(d) of the Act for wolves in Minnesota. These regulations currently are found at 50 CFR 17.40(d).

Critical habitat was designated for the gray wolf in 1978 (43 FR 9607, March 9, 1978). That rule (codified at 50 CFR 17.95(a)) identifies Isle Royale National Park, Michigan, and Minnesota wolf management zones 1, 2, and 3, as delineated in 50 CFR 17.40(d)(1), as critical habitat. Wolf management zones 1, 2, and 3 comprise approximately 25,500 sq km (9,845 sq mi) in northeastern and north-central Minnesota. This proposal, if made final, would remove the designation of critical habitat for gray wolves in Minnesota and on Isle Royale, Michigan.

As described in the *Taxonomy and Historical Ranges of Wolves in the United States* section above, the species' historical range did not extend into many southern and eastern States. Therefore, our 1978 listing of the gray wolf throughout the 48 States and Mexico was partially in error. This proposed rule, if made final, would revise the geographic boundaries for the gray wolf as described in the 1978 listing by removing all or parts of 29 southern and eastern states (Maine, Massachusetts, Connecticut, New Hampshire, Rhode Island, Vermont, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Ohio (the part outside WGL DPS), West Virginia, Kentucky, Tennessee, Alabama, Mississippi, Louisiana, Texas (east of Interstate Highway 35), Oklahoma (east of Interstate Highway 35 and southeast of Interstate Highway 44 north of Oklahoma City), Arkansas, Missouri (southeast of Interstate Highway 44 and southeast of Interstate Highway 70 east of St. Louis), Indiana (the part outside WGL DPS), and Illinois (the part outside WGL DPS)) because this area is outside of the currently known historical range of the gray wolf.

We also note that this proposed rule initiates a 5-year status review and request information for wolves in the western United States, which may inform future rulemakings to replace the remainder of the revised lower 48-State listing with more targeted regional units (as discussed above under National Wolf Strategy). This proposed rule does not apply to the separate listing and protection of the red wolf (*C. rufus*). Furthermore, the remaining protections of the gray wolf under the Act do not extend to gray wolf-dog hybrids.

**Post-Delisting Monitoring**

Section 4(g)(1) of the Act, added in the 1988 reauthorization, requires us to implement a system, in cooperation with the States, to monitor for not less than 5 years the status of all species that have recovered and been removed from the Lists of Endangered and Threatened Wildlife and Plants (50 CFR 17.11 and 17.12). The purpose of this post-delisting monitoring (PDM) is to verify that a species delisted due to recovery remains secure from risk of extinction after it no longer has the protections of the Act. To do this, PDM generally focuses on evaluating (1) demographic characteristics of the species, (2) threats to the species, and (3) implementation of legal and/or management commitments that have been identified as important in reducing threats to the species or maintaining threats at sufficiently low levels. We are to make prompt use of the emergency listing authorities under section 4(b)(7) of the Act to prevent a significant risk to the well-being of any recovered species. Section 4(g) of the Act explicitly requires cooperation with the States in development and implementation of PDM programs, but we remain responsible for compliance with section 4(g) and, therefore, must remain actively engaged in all phases of PDM. We also will seek active participation of other entities that are expected to assume responsibilities for the species' conservation, after delisting.

We developed a PDM plan for the wolves in the proposed WGL DPS with the assistance of the Eastern Wolf Recovery Team. That document is available on our Web site (see **FOR FURTHER INFORMATION CONTACT**).

The PDM program will rely on a continuation of State monitoring activities, similar to those which have been conducted by Minnesota, Wisconsin, and Michigan DNR's in recent years, and Tribal monitoring. Minnesota, Wisconsin, and Michigan comprise the core recovery areas within the DPS, and, therefore, the numerical recovery criteria in the Recovery Plan apply only to the area encompassed by these States' boundaries. These activities will include both population and health monitoring of individual wolves. During the PDM period, the Service and the Recovery Team will conduct a review of the monitoring data and program. We will consider various relevant factors (including but not limited to mortality rates, population changes and rates of change, disease occurrence, range expansion or contraction) to determine if the population of wolves within the DPS warrants expanded monitoring, additional research, consideration for relisting as threatened or endangered, or emergency listing.

Minnesota, Wisconsin, and Michigan DNRs have monitored wolves for several decades with significant assistance from numerous partners, including the U.S. Forest Service, National Park Service, USDA–APHIS–Wildlife Services, Tribal natural resource agencies, and the Service. To maximize comparability of future PDM data with data obtained before delisting, all three State DNRs have committed to continue their previous wolf population monitoring methodology, or will make changes to that methodology only if those changes will not reduce the comparability of pre- and post-delisting data.

In addition to monitoring wolf population numbers and trends, the PDM will evaluate post-delisting threats, in particular human-caused mortality, disease, and implementation of legal and management commitments. If at any time during the monitoring period we detect a substantial downward change in the populations or an increase in threats to the degree that population viability may be threatened, we will work with the States and Tribes to evaluate and change (intensify, extend, and/or otherwise improve) the monitoring methods, if appropriate, and/or consider relisting the WGL DPS, if warranted.

This monitoring program will extend for 5 years beyond the effective delisting date of the DPS. At the end of the 5-year period, we and the Recovery Team will conduct another review and post the results on our Web site. In addition to the above considerations, the review will determine whether the PDM program should be terminated or extended.

**Required Determinations**

*Clarity of the Rule*

Executive Order 12866 requires agencies to write regulations that are easy to understand. We invite your comments on how to make this proposal easier to understand including answers to questions such as the following: (1) Is the discussion in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful to your understanding of the proposal? (2) Does the proposal contain technical language or jargon that interferes with its clarity? (3) Does the format of the proposal (groupings and order of sections, use of headings, paragraphing, *etc.*) aid or reduce its clarity? What else could we do to make the proposal easier to understand? Send a copy of any comments on how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You may also e-mail the comments to this address: *Exsec@ios.doi.gov.*

*National Environmental Policy Act*

We have determined that an environmental assessment or an environmental impact statement, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

*Paperwork Reduction Act*

Office of Management and Budget (OMB) regulations at 5 CFR part 1320 implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The OMB regulations at 5 CFR 1320.3(c) define a collection of information as the obtaining of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, 10 or more persons. Furthermore, 5 CFR 1320.3(c)(4) specifies that "ten or more persons" refers to the persons to whom a collection of information is addressed by the agency within any 12-month period. For purposes of this definition, employees of the Federal Government are not included. The Service may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This proposal does not include any collections of information that require approval by OMB under the Paperwork Reduction Act. As proposed under the Post-delisting Monitoring above, wolf populations in the Western Great Lakes DPS will be monitored by the States of Michigan, Minnesota, and Wisconsin in accordance with their wolf State management plans. There may also be additional voluntary monitoring activities conducted by a small number of Tribes in these three States. We do not anticipate a need to request data or other information from 10 or more persons during any 12-month period to satisfy monitoring information needs. If it becomes necessary to collect standardized information from 10 or more non-Federal individuals, groups, or organizations per year, we will first obtain information collection approval from OMB.

*Government-to-Government Relationship With Tribes*

In accordance with the President's memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951), E.O. 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have coordinated the proposed rule with the affected Tribes and, furthermore, throughout several years of development of earlier related rules and this proposed rule, we have endeavored to consult with Native American Tribes and Native American organizations in order to both (1) provide them with a complete understanding of the proposed changes, and (2) to understand their concerns with those changes. If requested, we will conduct additional consultations with Native American Tribes and multitribal organizations subsequent to any final rule in order to facilitate the transition to State and Tribal management of wolves within the proposed WGL DPS. We will fully consider all of the comments on the proposed rule that are submitted by Tribes and Tribal members during the public comment period and will attempt to address those concerns, new data, and new information where appropriate.

**References Cited**

A complete list of all references cited in this document is available upon request from the Ft. Snelling, Minnesota, Regional Office and is posted on our Web site (see **FOR FURTHER INFORMATION CONTACT**).

**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).

**Authors**

The primary authors of this proposed rule are the staff members of the Ft. Snelling, Minnesota, Regional Office (see **FOR FURTHER INFORMATION CONTACT**), with contributions from staff from Service Regions 2, 4, and 5. Staff from the Michigan DNR, Minnesota DNR, and Wisconsin DNR provided current information regarding wolves in their States. Staff from the Nelson Institute for Environmental Studies at the University of Wisconsin-Madison compiled the current data on public attitudes toward the wolf.

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Proposed Regulation Promulgation**

Accordingly, we hereby propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, 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.

**§ 17.11 [Amended]**

2. Amend § 17.11(h) by revising the entry for "Wolf, gray" under "MAMMALS" in the List of Endangered and Threatened Wildlife to read as follows:

**§ 17.11 Endangered and threatened wildlife.**

* * * * *

(h) * * *

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| MAMMALS | | | | | | | |
| * | * | * | * | * | * | | * |
| Wolf, gray | *Canis lupus* | Holarctic | U.S.A.: All of CA, CO, KS, NE, NV, OR, UT, and WA; those portions of AZ, NM, TX, ID, MT, and WY not included in an experimental population as set forth below; and portions of IA, MO, ND, OK, SD, and TX as follows: (1) Southern IA, (that portion south of the centerline of Highway 80); (2) Northwestern MO (that portion northwest of the centerline of Interstate Highway 44 and northwest of the centerline of Interstate Highway 70 east of St. Louis); | E | 1, 6, 13, 15, 35 | N/A | N/A |
| | | | (3) Western ND (that portion south and west of the Missouri River upstream to Lake Sakakawea and west of the centerline of Highway 83 from Lake Sakakawea to the Canadian border); | | | | |
| | | | (4) Western OK (that portion west of the centerline of Interstate Highway 35 and northwest of the centerline of Interstate Highway 44 north of Oklahoma City); | | | | |
| | | | (5) Western SD (that portion south and west of the Missouri River); and | | | | |
| | | | (6) Western TX (that portion west of the centerline of Interstate Highway 35). Mexico. | | | | |
| Do | do | do | U.S.A. (portions of AZ, NM, and TX—see § 17.84(k)). | XN | 631 | N/A | 17.84(k) |

| Species | | Historic range | Vertebrate population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| Do | do | do | U.S.A. (portions of ID, MT, and WY—see § 17.84(i)). | XN | 561, 562 | N/A | 17.84(i), 17.84(n). |
| * | * | * | * | * | * | | * |

**§ 17.40 [Amended]**

3. Amend § 17.40 by removing and reserving paragraph (d).

**§ 17.95 [Amended]**

4. Amend § 17.95(a) by removing the critical habitat entry for "Gray Wolf (*Canis lupus*)."

Dated: April 12, 2011.

**Rowan W. Gould,**

*Acting Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2011–9557 Filed 5–4–11; 8:45 am]

BILLING CODE 4310–55–P

# FEDERAL REGISTER

Vol. 76 Thursday,

No. 87 May 5, 2011


Part IV

## Department of Veterans Affairs

38 CFR Parts 17 and 71
Caregivers Program; Interim Final Rule

**DEPARTMENT OF VETERANS AFFAIRS**

**38 CFR Parts 17 and 71**

**RIN 2900–AN94**

## Caregivers Program

**AGENCY:** Department of Veterans Affairs.
**ACTION:** Interim final rule.

**SUMMARY:** This document promulgates Department of Veterans Affairs (VA) interim final regulations concerning a new caregiver benefits program provided by VA. This rule implements title I of the Caregivers and Veterans Omnibus Health Services Act of 2010, which was signed into law on May 5, 2010. The purpose of the new caregiver benefits program is to provide certain medical, travel, training, and financial benefits to caregivers of certain veterans and servicemembers who were seriously injured in the line of duty on or after September 11, 2001.

**DATES:** *Effective Date:* This rule is effective on May 5, 2011. Comments must be received on or before July 5, 2011.

**ADDRESSES:** Written comments may be submitted by email through *http://www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to "RIN 2900–AN94, Caregivers Program." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Deborah Amdur, Chief Consultant, Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, 202–461–6780. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On May 5, 2010, the President signed into law the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163. Among other things, title I of the law established 38 U.S.C. 1720G, which requires VA to "establish a program of comprehensive assistance for family caregivers of eligible veterans," as well as a program of "general caregiver support services" for caregivers of "veterans who are enrolled in the health care system established under [38 U.S.C. 1705(a)] (including caregivers who do not reside with such veterans)." 38 U.S.C. 1720G(a),(b). This rulemaking implements this new statutory authority.

Veterans and servicemembers may be eligible for the Family Caregiver program if they incurred or aggravated a serious injury in the line of duty on or after September 11, 2001. We anticipate that roughly 3,596 veterans and servicemembers will qualify to receive benefits under this rule during the first year, at an estimated cost of $69,044,469.40 for FY2011 and $777,060,923.18 over a 5 year period. VA distinguishes between three types of caregivers based on the requirements of the law: Primary Family Caregivers, Secondary Family Caregivers, and General Caregivers. A Primary Family Caregiver is an individual designated as a "primary provider of personal care services" for the eligible veteran under 38 U.S.C. 1720G(a)(7)(A), who the veteran specifies on the joint application and is approved by VA as the primary provider of personal care services for the veteran. A Secondary Family Caregiver is an individual approved as a "provider of personal care services" for the eligible veteran under 38 U.S.C. 1720G(a)(6)(B), and generally serves as a back-up to the Primary Family Caregiver. General Caregivers are "caregivers of covered veterans" under the program in 38 U.S.C. 1720G(b), and provide personal care services to covered veterans, but do not meet the criteria for designation or approval as a Primary or Secondary Family Caregiver.

In general, caregivers receive the following benefits and services:

- General Caregivers—Education and training on caring for an enrolled Veteran; use of telehealth technologies; counseling and other services under § 71.50; and respite care.
- Secondary Family Caregivers—All benefits and services available to General Caregivers; monitoring; veteran-specific instruction and training; beneficiary travel under 38 CFR part 70; ongoing technical support; and counseling.
- Primary Family Caregivers—All benefits and services available to both General Caregivers and Secondary Family Caregivers; monthly caregiver stipend; respite care available for at least 30 days per year, and may exceed 30 days per year if clinically appropriate and if requested by the Primary Family Caregiver; and health care coverage (if they are eligible).

We refer throughout these rules to the wide array of benefits provided to veterans and their caregivers under section 1720G using the term "caregiver benefits." Some of these benefits are delivered directly to veterans, such as monitoring the quality of the care provided by caregivers to ensure that the veteran is able to live in a residential setting without unnecessary deterioration of his or her disability, and safe from potential abuse or neglect. Other benefits are delivered directly to the veteran's caregiver, such as a stipend or enrollment in the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), which provides health coverage for certain Primary Family Caregivers. The fact that caregiver benefits are offered and delivered to both the veteran and his or her caregiver makes the benefits significantly different from virtually all other benefits programs offered through the Veterans Health Administration. For this reason, we have organized the regulations implementing section 1720G in a new part 71 of title 38, U.S. Code of Federal Regulations. This will make the benefits easy to find, and will emphasize the unique nature of the program.

VA welcomes comments on any aspect of this rule.

We now discuss the new regulations section by section.

### *71.10 Purpose and Scope*

Section 71.10 establishes the purpose and scope of the new part 71, CFR. The purpose of this part is to implement VA's caregiver benefits program. Receipt of "caregiver benefits" under 38 CFR part 71 is based on an independent eligibility determination for benefits—it is not a barrier to, or substitute for, other benefits offered by VA. If you are a veteran and a caregiver to another veteran, you will not lose eligibility for any of your veteran benefits because you are a caregiver.

### *71.15 Definitions*

Section 71.15 provides definitions for the purposes of part 71.

We define an "inability to perform an activity of daily living (ADL)" as inability to perform any of six activities that are widely recognized as ADLs by clinicians and are found in the *Katz Basic ADL Scale.* In addition, we include a seventh activity specific to veterans who require the use of prosthetics or orthopedic appliance. Inability to perform an activity of daily living is one of several alternative bases for a determination that an individual is in need of personal care services under § 71.20(c)(1), and is one of the

alternative bases for such need per section 1720G(a)(2)(C)(i).

We believe that the seven activities listed in the definition sufficiently identify the activities that would be impaired for an extended period of 6 months or more as a result of a serious injury, as that term is defined in this rulemaking; however, we welcome suggestions from the public as to additional activities that should be included in this list.

We define an eligible veteran as "a veteran, or a servicemember, who is found eligible for a caregiver under § 71.20." This term is established for ease of reference throughout the part 71 regulations. The term is also used in section 1720G(a).

We define "General Caregiver," "Primary Family Caregiver," and "Secondary Family Caregiver" by referencing the sections that set forth the eligibility requirements for, and describe how to establish eligibility for, benefits as such a caregiver.

We define "in the best interest" to mean, "for the purpose of determining whether it is in the best interest of the eligible veteran to participate in the Family Caregiver program under 38 U.S.C. 1720G(a), a clinical determination that participation in such program is likely to be beneficial to the eligible veteran. Such determination will include consideration, by a clinician, of whether participation in the program significantly enhances the eligible veteran's ability to live safely in a home setting, supports the eligible veteran's potential progress in rehabilitation, if such potential exists, and creates an environment that supports the health and well-being of the eligible veteran."

Under 38 U.S.C. 1720G(a)(1)(B), VA "shall only provide support under the [Family Caregiver program] to a family caregiver of an eligible veteran if the Secretary determines it is in the best interest of the eligible veteran to do so." Congress has left it to the Secretary to define "in the best interest" for this purpose. VA concludes that determinations of "in the best interest" must be clinical determinations, guided by VA health professionals' judgment on what care will best support the health and well-being of the veteran or servicemember—including that which offers the best opportunity for recovery and rehabilitation, whenever possible. In some cases a clinician may determine that other care and maintenance options would better promote the eligible veteran's functional capabilities and potential for independence.

We define the "[n]eed for supervision or protection based on symptoms or residuals of neurological or other impairment or injury" as requiring supervision or assistance based on any one of seven listed impairments. We based these impairments on the *UK Functional Independence Measure and Functional Assessment Measure, and the Neuropsychiatric Inventory.* Like the definition of activity of daily living (ADL), we believe that this definition targets the population that section 1720G(a) is clearly intended to benefit. The need for supervision or protection based on symptoms or residuals of neurological or other impairment or injury is the second alternative basis for a determination that an individual is in need of personal care services under § 71.20(c)(2), and is one of the alternative bases for such need per section 1720G(a)(2)(C)(ii). As with the definition of ADL, we welcome suggestions from the public as to additional impairments that should be included in this list.

This regulation provides elaboration upon the statutory definition of "personal care services" set out in 38 U.S.C. 1720G(d)(4). There, personal care services is said to mean "[a]ssistance with one or more independent activities of daily living [and] [a]ny other non-institutional extended care (as such term is used in section 1701(6)(E) of [title 38])." The term "independent activity of daily living" does not have a commonly understood usage or meaning. Consistent with the purpose of the statute, we interpret "independent activity of daily living" to mean personal functions required in everyday living to sustain health and well-being and keep oneself safe from hazards or dangers incident to one's daily environment.

Similarly, non-institutional extended care services are not defined in 38 U.S.C. 1701(6)(E) in a manner that delineates the types of non-institutional extended care that constitute "personal care services" under the statute—rather that section merely authorizes the Secretary to provide non-institutional extended care. (See 38 U.S.C. 1701(6)(E) explaining that the term "medical services" includes "noninstitutional extended care services, including alternatives to institutional extended care that the Secretary may furnish directly, by contract, or through provision of case management by another provider or payer.") VA provides non-institutional care services to enrolled veterans (and as provided in 38 CFR 17.36(a)) through VA's medical benefits package, which include but are not limited to "noninstitutional geriatric evaluation, noninstitutional adult day health care, and noninstitutional respite care." 38 CFR 17.38(a)(1)(xi)(B).

Based on the types of non-institutional care services provided under title 38 and our interpretation of the term "independent activities of daily living" within the context of the statute, we read these terms together to mean "care or assistance of another person necessary in order to support the eligible veteran's health and well-being, and perform personal functions required in everyday living ensuring the eligible veteran remains safe from hazards or dangers incident to his or her daily environment." We welcome public comments on our interpretation of this term.

We define a "primary care team" as "a group of medical professionals who care for a patient and who are selected based on the clinical needs of the patient. The team must include a primary care provider who coordinates the care, and may include clinical specialists (e.g., a neurologist, psychiatrist, etc.), resident physicians, nurses, physicians' assistants, nurse practitioners, occupational or rehabilitation therapists, social workers, etc., as indicated by the needs of the particular veteran." The term is used throughout the regulations to refer to the medical professionals who approve and/or monitor caregiver benefits. A team, rather than a single individual, is generally necessary due to the complex nature of a serious injury or injuries and their impact on the veteran and their caregivers that are prerequisites to eligibility and to the ongoing obligation on the part of VA to monitor and provide support for the veteran's home-based care.

Consistent with 38 U.S.C. 1720G(a), we define "serious injury" as "any injury, including traumatic brain injury, psychological trauma, or other mental disorder, incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, that renders the veteran or servicemember in need of personal care services." See discussion of section 71.20(c) below, which explains VA's rationale for establishing a causal relationship between the need for personal care services as it relates to the veteran or servicemember's serious injury.

We define "[u]ndergoing medical discharge" by requiring "that the servicemember has been found unfit for duty due to a medical condition by their Service's Physical Evaluation Board, and a date of medical discharge has been issued." This term is used to determine eligibility for a caregiver for active duty servicemembers. The

process of disability evaluation and medical discharge in some cases can be quite lengthy, and we do not believe that Congress intended to authorize prolonged caregiver benefits for active duty servicemembers, particularly because they have authorized Department of Defense to provide similar benefits to active duty servicemembers. Rather, we interpret the inclusion of servicemembers undergoing medical discharge in 38 U.S.C. 1720G(a)(2)(A) as an effort to ensure that, upon discharge, the individual will have a person identified and prepared to provide care. Therefore, this definition will ensure that the individual is far enough along in the medical discharge process that there will not be extended overlap between the individual's period of service and the time that he or she achieves veteran status. This definition will however, allow sufficient opportunity for a servicemember and caregiver to initiate an application for, and begin participation in, the VA program.

*71.20 Eligible Veterans and Servicemembers*

Section 71.20 sets forth the eligibility criteria for a veteran or servicemember seeking a Primary or Secondary Family Caregiver.

Section 71.20(a) and (b) restate the eligibility criteria from 38 U.S.C. 1720G(a)(2)(A) and (B) without substantive change. VA's interpretation of the terms "serious injury" and "undergoing medical discharge" are addressed earlier in this notice.

Paragraph (c) implements 38 U.S.C. 1720G(a)(2)(C)(i) through (iii). Therein, the law premises eligibility on the individual being in need of personal care services because the individual is unable "to perform one or more activities of daily living"; having a "need for supervision or protection based on symptoms or residuals of neurological or other impairment or injury"; or "such other matters as the Secretary considers appropriate." Although the statute does not clearly state that the need for personal care services must relate to the "serious injury" required under section 1720G(a)(2)(B), such a causal relationship is at a minimum strongly implied by the overall purpose and language of the law. We believe that it is reasonable to interpret the statute, which premises eligibility on a serious injury, as requiring that such serious injury is the basis for the individual's need for a caregiver. It would not be rational to decouple the concepts such that, for example, a veteran with a serious injury incurred during service could be eligible for a caregiver based on an injury incurred after service and that is unrelated to the veteran's service. We would explicitly require such a connection in paragraph (c). We invite public comment as to whether another interpretation is possible and consistent with Congressional intent.

We also have included a requirement that the individual need personal care services "for a minimum of 6 continuous months (based on a clinical determination)." We believe it is clear the intent of the statute—as far as direct-to-caregiver benefits—was not to invoke family caregiver designations for shorter-term periods of recovery, for example a recovery from a single surgery that is not connected with a long-term condition. We believe throughout the public discussion and deliberations the focus is on persons with longer term disabilities. We believe that a 6-month minimum requirement of these services, based on a clinical determination, is a reasonable way to ensure that caregiver benefits are provided to those individuals who are most likely the intended beneficiaries of the law. This 6-month period, we believe, is a reasonable period on which to distinguish these more temporary circumstances. We note that the Family and Medical Leave Act (FMLA) uses 26 workweeks (approximately 6 months) as the period to which an eligible employee who is the spouse, son, daughter, parent, or next of kin of a covered servicemember may be accorded unpaid leave to provide care to that covered servicemember. While such leave is unpaid, we believe the fact this period was used for the protection of a caregiver's employment relationship buttresses the choice of 6 months as a reasonable dividing line to distinguish episodic periods of care.

Paragraph (c)(3) establishes another basis upon which an individual can be determined to be "in need of personal care services"—by establishing a basis for eligibility of veterans and servicemembers whose serious injury is a psychological trauma or mental disorder, and who have received Global Assessment of Functioning (GAF) scores of 30 or less continuously for a 90-day period immediately preceding VA's receipt of the application for a Caregiver. The GAF assessment is a well-established mental health examination that uses a score of zero to 100 to determine an individual's ability to function psychologically and socially. The following description from the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM–IV) of GAF scores in the 21–30 range is the minimum impairment standard that VA will require to consider a mental health diagnosis a serious injury: "Behavior is considerably influenced by delusions or hallucinations OR serious impairment, in communication or judgment (e.g., sometimes incoherent, acts grossly inappropriately, suicidal preoccupation) OR inability to function in almost all areas (e.g., stays in bed all day, no job, home, or friends)." At this assessed level of impairment, the supervision or protection of a caregiver is essential to the individual. An individual who has been assessed as having a psychological trauma or mental disorder scored at 30 GAF or less generally requires a higher level of care that would provide constant supervision. We require that, during the 90-day period immediately preceding the date on which VA receives the Caregiver application, the individual was continuously scored at 30 GAF or less. For purposes of determining eligibility, we intend that this requirement will eliminate consideration of injuries that only consist of temporary psychological conditions, periodic exacerbations of such conditions, or conditions that have improved with treatment such that a caregiver is not required.

Under paragraph (c)(3), VA will consider a GAF score to be "continuous" if there are at least two scores during the 90-day period (one that shows a GAF score of 30 or less at the beginning of the 90-day period and one that shows a GAF score of 30 or less at the end of the 90-day period) and there are no intervening GAF scores of more than 30. We believe that this is sufficient evidence that the individual's GAF score has not changed to be more than 30 during that 90-day period.

Paragraph (c)(4) establishes another basis upon which a veteran can be determined to be "in need of personal care services"—if the veteran was awarded service connection for a serious injury incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, has been rated 100 percent disabled for that serious injury, and has been awarded special monthly compensation that includes an aid and attendance allowance. The Secretary considers appropriate the inclusion of this category of veterans.

The criteria set forth under paragraph (c)(3) and (c)(4) are authorized by 38 U.S.C. 1720G(a)(2)(C)(iii) as alternate bases for the need for personal care services required by section 1720G(a)(2)(C).

Paragraph (d) requires a clinical determination that it is in the best interest of the individual to participate in the program. This requirement is

based on 38 U.S.C. 1720G(a)(1)(B), which requires that the Secretary only provides support under the program if it is in the best interest of the individual to do so.

Paragraph (e) bars authorization of a Family Caregiver if the services that would be provided by the Family Caregiver would be simultaneously and regularly provided by or through another individual or entity. This is to ensure that caregivers are authorized for those who do not simultaneously and regularly use other means to obtain personal care services. Our intent is to ensure that the Family Caregiver is not depending on VA or another agency to provide the personal care services that the Family Caregiver is expected to provide.

Paragraphs (f) and (g) require that the individual, after VA designates a Family Caregiver, must agree to "receive care at home" and "receive ongoing care from a primary care team." Under 38 U.S.C. 1720G(a)(9)(A), VA must "monitor the well-being of each eligible veteran receiving personal care services" from a VA-designated caregiver. We are also required to document findings "pertinent to the appropriate delivery of personal care services to an eligible veteran under the program," and ensure appropriate follow up, which may include visiting the eligible veteran's home and taking corrective action when necessary, including additional training to a Family Caregiver. *See* 38 U.S.C. 1720G(a)(9)(B) and (C). The consent required by paragraphs (f) and (g) as a prerequisite to an award of caregiver benefits will enable VA to perform these statutorily required functions and will help VA ensure that the assignment of a specific caregiver and the provision of care in the veteran's home will continue to be in the best interest of the individual.

*71.25 Approval and Designation of Primary and Secondary Family Caregivers*

The rules governing approval and designation of particular individuals to serve as Family Caregivers, including the rules governing such individuals' eligibility to serve as Primary or Secondary Family Caregivers, are set forth in § 71.25. Paragraph (a)(1) requires anyone who would serve as a Primary or Secondary Family Caregiver to complete and sign a joint application, along with the eligible veteran. This implements the joint-application requirement in 38 U.S.C. 1720G(a)(4).

Upon receiving the application, § 71.25(a)(2) requires VA to determine whether the caregivers, as identified on the joint application, are appropriate to serve as caregivers and, if so, whether to designate applicants as Primary and Secondary Family Caregivers. These determinations require VA to perform all clinical evaluations and decide whether the application should be granted and, if so, whether each applicant should be designated as identified in the application, i.e., whether the identified Primary Family Caregiver should be so designated. Section 1720G(a)(7)(A) requires that VA, not the veteran, officially make the designation of Primary Family Caregiver, and, generally, section 1720G(a) requires VA to make certain evaluations prior to approving an application. In § 71.25(a)(3) we recognize that veterans and servicemembers may not have a "continuous" GAF score available at the time of their application. Therefore, in these instances, an application may be put on hold for no more than 90 days, from the date the application was received. This will enable VA to determine whether the GAF score of 30 or less is simply a transient condition likely to respond quickly to treatment obviating the need for a caregiver.

We note that section 1720G(a)(7)(A) appears to require that there be one Primary Family Caregiver as a prerequisite to receiving caregiver benefits under the law. It states that VA "shall designate one family member of such eligible veteran as the primary provider of personal care services for such eligible veteran." However, we do not believe that such a narrow interpretation of the law is consistent with the overall intent of the statute. If an eligible veteran does not desire a Primary Family Caregiver, and, if VA's clinical assessment leads to the determination that one or more Secondary Family Caregivers can, collectively, provide sufficient personal care services to enable the veteran to remain at home, there is no reason to deny the application simply because no individual Family Caregiver wants or assumes the responsibilities and benefits that would come with designation as the Primary Family Caregiver. Rather, we interpret the statutory language concerning "one family member * * * as the [Primary Family Caregiver]" to indicate that there cannot be more than one Primary Family Caregiver.

Paragraph (b) sets forth the requirements for basic eligibility to serve as a Primary or Secondary Family Caregiver. Our authority to assess applicants and determine whether we believe that they are capable of serving as Primary Family Caregivers derives from 38 U.S.C. 1720G(a)(7)(B)(iv) (the Primary Family Caregiver must be "considered by [VA] as competent to be the [Primary Family Caregiver]"). We are also required, under section 1720G(a)(1)(B), to provide caregiver benefits "only * * * if [VA] determines it is in the best interest of the eligible veteran to do so." We believe that the criteria specified under paragraph (b) are reasonable restrictions that are in the best interest of every veteran or servicemember who could be eligible for a caregiver under this part. If the public has concerns about these criteria, or believes that there should be fewer restrictions or greater oversight, we welcome public comments on this issue.

Paragraph (b)(1) requires that all Primary and Secondary Family Caregivers be at least 18 years of age. We do not believe that individuals under the age of majority can be relied upon to provide personal care services as defined by part 71. It is in the best interest of the eligible veteran to ensure that caregiver services are provided by individuals who are mature enough to understand the serious nature of this responsibility.

Paragraph (b)(2) requires that the Family Caregiver either be a member of the eligible veteran's family, i.e., his or her spouse, son, daughter, parent, step-family member, or extended family member; or a person who lives full-time with the eligible veteran or will do so if designated as a Family Caregiver. These restrictions are directly from the definition of family member set forth in 38 U.S.C. 1720G(d)(3).

Paragraph (b)(3) states that there "must be no determination by VA of abuse or neglect of the eligible veteran by the applicant." We think it is not in the best interest of the eligible veteran to place an eligible veteran with a caregiver who has abused or neglected that eligible veteran.

Paragraph (c) describes how VA assesses and trains applicants prior to granting an application and designating the applicants as Primary or Secondary Family Caregivers. Under 38 U.S.C. 1720G(a)(5)(B), we are required to assess applicants and under section 1720G(a)(6)(A) we are required to provide training and instruction to such applicants. Under section 1720G(a)(6)(B), VA cannot approve an applicant until such training has been completed successfully.

Assessment for caregiver training is required under paragraph (c)(1), and authority is delegated to the eligible veteran's primary care team in collaboration with the facility Caregiver Support Coordinator, who will be in the best position to determine whether specific applicants are able to meet the

needs of a specific eligible veteran. Paragraphs (c)(1)(A) and (B) prescribe basic requirements for any assessment, which concern the applicant's ability to communicate and whether the applicant will be capable of following without supervision the eligible veteran's treatment plan. These two requirements are essential to completion of caregiver training, the ability to appropriately care for the eligible veteran, and there is no reason to provide such training to individuals who cannot meet these two basic requirements.

Paragraph (c)(2) requires actual completion of caregiver training, which is discussed in detail in paragraph (d), and demonstration of "the ability to carry out the specific personal care services, core competencies, and other additional care requirements prescribed by the eligible veteran's primary care team." We believe that demonstration of the necessary skills is an essential part of "the successful completion * * * of instruction, preparation, and training" required by 38 U.S.C. 1720G(a)(6)(B). Moreover, without such demonstration, we cannot be assured that it is in the "best interest of the eligible veteran" to provide caregiver services through the particular applicant. 38 U.S.C. 1720G(a)(1)(B).

Paragraph (d) concerns the education and training of applicants who wish to be Family Caregivers. Under section 1720G(a)(6)(C), "subject to regulations [VA] shall prescribe, [VA shall] provide for necessary travel, lodging, and per diem expenses incurred by a family member of an eligible veteran in undergoing instruction, preparation, and training" to be a Family Caregiver. The statute does not link this benefit to VA's beneficiary travel authority under 38 U.S.C. 111(e); however, the requirement to promulgate regulations authorizes VA to make such a link in this rulemaking. Moreover, we note that after the caregiver education and training is complete, section 1720G(a)(3)(A)(i)(IV) requires VA to provide Primary and Secondary Family Caregivers with "lodging and subsistence under [38 U.S.C.] 111(e)." Rather than establish a different program for travel benefits before and after training, we authorize beneficiary travel benefits (as implemented in 38 CFR part 70) in § 71.25(d) to support the education and training of family members. This means that the provision of beneficiary travel is subject to any limitations or exclusions under part 70 as well. There is no reason to believe that section 1720G extends beneficiary travel benefits to Family Caregivers but does not also require the equal application of the limitations that apply to all individuals eligible for benefits under part 70.

Under section 1720G(a)(6)(D), respite care is to be provided to the eligible veteran during the initial provision of education and training to a Family Caregiver, if the Family Caregiver's participation in training "would interfere with the provision of personal care services to the eligible veteran." We implement this requirement in paragraph (d).

Paragraph (d) also sets forth the essential components of caregiver training. Of course, it is impossible to establish by regulation all that will be required for a particular eligible veteran. However, we have developed a program of caregiver training that covers the essential components of home-based care. These essential components are called "core competencies" in the regulation. We understand that, in a particular case, an eligible veteran might not need much assistance in one particular competency, such as skin care or pain control; however, we believe that all of these identified competencies are present to at least some degree in virtually all situations in which we will find a veteran or servicemember eligible for a Family Caregiver. If a particular eligible veteran presents complex challenges in any or all of these core competencies, we will provide more specific training in addition to the minimum training provided to all caregiver applicants.

Under 38 U.S.C. 1720G(a)(9)(C)(i), VA is authorized to visit an eligible veteran at home "to review directly the quality of personal care services provided to the eligible veteran." Paragraph (e) details the at-home assessment that must be conducted within 10 business days after the completion of caregiver education and training in order to determine whether the Family Caregiver has completed training and is competent to provide personal care services to the eligible veteran. This assessment is to be performed in the eligible veteran's home. Paragraph (e) does not obviate VA's right, or duty, to monitor the eligible veteran on an ongoing basis; however, it does establish that an assessment will be performed no later than 10 days after completion of Caregiver education and training.

Paragraph (f) authorizes the facility Caregiver Support Coordinator or designee to approve or disapprove applications, based on the clinical assessment of the primary care team, and designate the applicants as Primary and/or Secondary Caregivers. We note that such approval is predicated on the veteran or servicemember's and caregivers' continuing eligibility under part 71, and we cross-reference § 71.45, which concerns revocation.

*71.30 General Caregivers*

Pursuant to 38 U.S.C. 1720G(b)(1), VA is required to establish a program, distinct from the Family Caregiver program, of support services for caregivers of veterans who are enrolled in the VA health care system and who are in need of personal care services because they are either unable to perform an ADL or have a "need for supervision or protection based on symptoms or residuals of neurological care or other impairment or injury." These caregivers are referred to in our regulations as General Caregivers, to distinguish them from Primary or Secondary Family Caregivers. Unlike Family Caregivers, a General Caregiver need not be a family member of the veteran within the meaning of the law, and the veteran to whom service is provided need not have had a "serious injury" or have served on or after September 11, 2001. The benefits provided under section 1720G to General Caregivers are significantly less than those provided to Family Caregivers and are described in § 71.40(a). Section 71.30(a) and (b) describe these General Caregivers using the statutory requirements.

Paragraph (c) of § 71.30 states that no formal application is required to obtain General Caregiver benefits. In most cases, General Caregivers are individuals who live with or near a veteran and help that veteran with less-critical personal care, such as cooking meals, but they may, in some cases, benefit from the caregiver education and training that we offer under § 71.40(a), particularly if the veteran whom they assist is profoundly disabled. We want to make it easy for these types of "good Samaritans" to obtain education and training. The cost of providing these benefits is negligible in comparison to the benefits that veterans derive from having caring people voluntarily assisting them at home.

*71.40 Caregiver Benefits*

Under section 38 U.S.C. 1720G(b)(3)(A)(i), VA must provide General Caregivers with specified "support services" including "(I) educational sessions made available both in person and on an Internet Web site; (II) use of telehealth and other available technologies; and (III) teaching techniques, strategies, and skills for caring for a disabled veteran[.]" We implement all of these services under paragraph (a)(1), using virtually the same language as required by the statute.

Section 1720G(b)(3)(A)(ii) requires that VA provide General Caregivers with "[c]ounseling and other services" under 38 U.S.C. 1782. We define the scope of these benefits in this rulemaking under § 71.50.

Under 38 U.S.C. 1720G(b)(3)(A)(iii), VA must provide veterans serviced by General Caregivers with "[r]espite care under [38 U.S.C. 1720B] that is medically and age appropriate for the veteran (including 24-hour per day in-home care)." VA currently provides respite care under section 1720B, but we have not needed separate respite care regulations to do so. From this current practice, we know that VA is capable of providing such respite care.

Paragraph 71.40(b) implements the benefits to be provided to Secondary Family Caregivers under 38 U.S.C. 1720G(a)(3)(A). Secondary Family Caregivers are generally eligible for all of the benefits authorized for General Caregivers, based on our interpretation and application of section 1720G(a)(3)(A) and (B), in addition to the Secondary Family Caregiver benefits discussed further, below. Similarly, Primary Family Caregivers are authorized by section 1720G(a)(3)(A)(ii)(I) to receive all of the benefits that VA provides to Secondary Family Caregivers—in addition to a higher level of benefits authorized only for Primary Family Caregivers. Thus, we discuss the benefits provided to Secondary Family Caregivers under § 71.40(b) in terms of providing those benefits to both types of Family Caregivers, despite the fact that the paragraph's title only refers to Secondary Family Caregivers. The paragraph title is for ease of readability: A Secondary Family Caregiver can tell, based on the paragraph title, that all of his or her benefits will be described in § 71.40(b).

Under section 1720G(a)(9), VA must "monitor the well-being of each eligible veteran receiving personal care services," maintain a record regarding the delivery of personal care services to the eligible veteran, and establish "appropriate follow-up" regarding information in the record. Follow-up procedures may include home visits by VA to review the quality of personal care services being provided to the eligible veteran, and "corrective action" including additional training or revocation of the Caregiver's approval. Although we interpret these monitoring requirements as a condition for continued participation as a Family Caregiver, we believe that it is accurate to classify these requirements as "benefits" because they provide the Family Caregiver with support. VA's monitoring procedures will include evaluation of the eligible veteran's and caregiver's physical and emotional states, observing for signs of abuse or neglect, adequacy of care and supervision being provided by the Primary and Secondary Family Caregivers, the eligible veteran's and Family Caregivers' overall adjustment to care at home, identifying any additional training or equipment needs, and assessing the Family Caregivers' level of stress. Monitoring will occur no less often than every 90 days, unless otherwise clinically indicated.

Section 1720G(a)(3)(A)(i)(I) requires that VA provide to Primary and Secondary Family Caregivers "such instruction, preparation, and training" as appropriate to provide personal care services to the eligible veteran. In paragraph 17.40(b)(3), VA will provide these "continuing" services to Primary and Secondary Family Caregivers. We note that preliminary instruction, preparation, and training are required before VA designates family members as Primary or Secondary Family Caregivers. Those services offered by VA under this section refer to those services that follow after the Primary or Secondary Family Caregiver has begun providing personal care services to the eligible veteran. Depending on the eligible veteran's treatment plan, the caregiver may require additional training to improve the services already being provided to the eligible veteran, learn how to use new technology that will improve the provision of care, or meet changing clinical needs of the eligible veteran.

Section 1720G(a)(3)(A)(i)(II) requires VA to provide "ongoing technical support consisting of information and assistance to address, in a timely manner, the routine, emergency, and specialized caregiving needs of the [Secondary F]amily [C]aregiver in providing personal care services to the eligible veteran." We interpret this sentence to require that VA maintain regular contact with the Primary and Secondary Family Caregiver and be available as a resource for questions about providing personal care services to the eligible veteran for routine, emergency, and specialized matters that pertain to the unique needs of the eligible veteran. Under paragraph (b)(4), VA will provide "[o]ngoing technical support, consisting of information and assistance to address, in a timely manner, the routine, emergency, and specialized needs of the Caregiver in providing personal care services to the eligible veteran."

Under section 1720G(a)(3)(A)(i)(III), VA must provide Primary and Secondary Family Caregivers with "counseling." Similarly, under section 1720G(a)(3)(A)(ii)(II), VA must provide Primary Family Caregivers with "such mental health services as the Secretary determines appropriate." We understand that the stresses of caregiving can lead to depression, anger, interpersonal conflict, anxiety, substance use, sleep disturbances, social isolation, and other personal and social issues. We also believe that these concerns are not unique to Primary Family Caregivers and intend to provide Secondary Family Caregivers with the same mental health services. We therefore interpret "counseling" for the purposes of the benefits offered to Primary and Secondary Family Caregivers to include individual and group therapy, counseling and peer support groups. We do not interpret the provision to include medication, inpatient psychiatric care, or other medical procedures related to mental health treatment. We also note that these services are broader than the "[c]ounseling and other services" provided to General Caregivers under § 71.40(a)(3) because the services under that authority, derived from 38 U.S.C. 1782, require that the services provided to the caregiver be connected to the treatment plan of the veteran. No such limitation exists under the section 1720G(a)(3)(A)(i)(III) or 1720G(a)(3)(A)(ii)(II) authorities. The counseling provided to Family Caregivers is intended to treat those Family Caregivers, independent of whether that treatment is likely to support the clinical objectives of the eligible veteran's treatment plan.

Under section 1720G(a)(3)(A)(i)(IV), VA must provide Primary and Secondary Family Caregivers with "lodging and subsistence under [38 U.S.C.] 111(e)." In addition, section 104 of Public Law 111–163 amended 38 U.S.C. 111(e) to authorize VA to provide to family caregivers the "expenses of travel (including lodging and subsistence)" during the period of time in which the veteran is traveling to and from a VA facility for the purpose of medical examination, treatment, or care, and the duration of the medical examination, treatment, or care episode for the veteran. VA implements 38 U.S.C. 111(e) through regulation under 38 CFR part 70. In § 71.40(b)(6), we state that Family Caregivers "are to be considered eligible for beneficiary travel under 38 CFR part 70." This means that the provision of beneficiary travel is subject to any limitations or exclusions under part 70 as well. There is no reason to believe that section 1720G extends beneficiary travel benefits to

Family Caregivers but does not also require the equal application of the limitations that apply to all individuals eligible for benefits under part 70.

The benefits available to Primary Family Caregivers are described in § 71.40(c).

Under section 1720G(a)(3)(A)(ii)(III), VA must provide Primary Family Caregivers with "respite care of not less than 30 days annually, including 24-hour-per day care of the veteran commensurate with the care provided by the family caregiver to permit extended respite." We believe that the 30-day provision was intended to emphasize that Primary Family Caregiver respite cannot be limited by VA to less than 30 days per year. Paragraph (c)(2) authorizes respite care that "may exceed 30 days per year if clinically appropriate and if requested by the Primary Family Caregiver."

Under section 1720G(a)(3)(A)(ii)(IV), VA must provide certain Primary Family Caregivers with medical care under 38 U.S.C. 1781. VA administers the section 1781 authority through the CHAMPVA program and its implementing regulations. As we did with beneficiary travel, we interpret this as a provision establishing eligibility, and such eligibility is subject to the same limitations to which all CHAMPVA beneficiaries are subjected. However, section 1720G does not authorize CHAMPVA coverage to Primary Family Caregivers who are covered by other health insurance. Section 102 of Public Law 111–163 amended subsection (a) of section 1781 of title 38 by including Primary Family Caregivers as a category of individuals eligible for medical care under 38 U.S.C. 1781. 38 U.S.C. 1781(a)(4), as amended, defines the new beneficiaries as "an individual designated as a primary provider of personal care services under section 1720G(a)(7)(A) of [title 38] * * * who is not entitled to care or services under a health-plan contract (as defined in section 1725(f) of [title 38])." We believe that the benefit provided by 38 U.S.C. 1720G(a)(3)(A)(ii)(IV), as added by section 101, should be read together with the amendment to 38 U.S.C. 1781(a) in section 102, and that a Primary Family Caregiver would only be eligible for medical care under 38 U.S.C. 1781 if he or she was not entitled to care or services under a health-plan contract (as defined in section 1725(f) of title 38).

As a matter of policy, we want to discourage Primary Family Caregivers from opting out of other health insurance to which they may be entitled. The facility Caregiver Support Coordinator or other designated case manager will review coverage options with the Primary Family Caregiver. VA is only authorized to provide CHAMPVA for the family member's duration as a Primary Family Caregiver. Therefore, if the individual's Primary Family Caregiver status ends for any reason, including the health of that Family Caregiver, improved condition of the eligible veteran, death of the eligible veteran, or for cause, the CHAMPVA coverage would terminate as well. We do not intend to interrupt enrollment in other health insurance that could persist despite the termination of one's status as a Family Caregiver. Doing so would raise serious issues of continuity of care, and could negatively impact eligible veterans who continue to live with a family member whose CHAMPVA coverage terminates as a result of that family member no longer serving as a Primary Family Caregiver.

Under section 1720G(a)(3)(A)(ii)(V), VA must provide a monthly stipend to the eligible veteran's designated Primary Family Caregiver. Under section 1720G(a)(3)(C)(i), VA must base the stipend amount on "the amount and degree of personal care services provided." VA must also, "to the extent practicable," ensure that the stipend amount "is not less than the monthly amount a commercial home health care entity would pay an individual in the geographic area of the eligible veteran to provide equivalent personal care services to the eligible veteran." 38 U.S.C. 1720G(a)(3)(C)(ii). If that geographic area does not have a commercial home health entity, then VA must "tak[e] into consideration the costs of commercial providers of personal care services in providing personal care services in geographic areas other than the geographic area of the eligible veteran with similar costs of living." 38 U.S.C. 1720G(a)(3)(C)(iii). The stipend amount will be based on the United States Department of Labor's Bureau of Labor Statistics (BLS) weekly wage rate for a Home Health Aide, multiplied by 4.35. The multiplier of 4.35 is based on the number of weeks per month for which care is provided and, therefore, the monthly stipend is payable. There are 365 days in a year, divided by 12 months, which equals 30.42. Thus, there are an average of 30.42 days per month. We then divided that number by 7, the number of days in a week, to reach 4.35, the average number of weeks per month. If 40 hours of care are provided per week, then the monthly stipend would be 40 hours multiplied by 4.35 to determine a flat, average cost—rather than make each monthly payment based on the days in that specific month. The BLS website (*http://www.bls.gov*) provides the geographic average pay rates for a Home Health Aide. The direct stipend payment is calculated based on the BLS wage rate for a Home Health Aide using the 75th percentile of the hourly wage rate in the geographic area of residence of the eligible veteran. We determined that the 75th percentile most accurately reflects the national hourly wage rate for the competencies to be performed. There is a large standard deviation on wage rates for home health aides depending on their experience and education as well as the economic factors in the geographic area (mainly supply and demand). Given the wide range in wage rates, the seventy-fifth percentile most accurately meets the intent of the statute that Caregivers not be paid less than home health aides in a geographic area. Currently, BLS provides 2009 wage rates therefore VA will factor in a cost of living adjustment based on the Consumer Price Index to calculate the current year's hourly wage rate. The foregoing explains the formula in paragraph (c)(4)(v), which is that the stipend amount "will be calculated by multiplying the Bureau of Labor Statistics hourly wage for home health aides in the geographic area by the Consumer Price Index and then multiplying that total by the number of weekly hours of Caregiver assistance required under paragraph (c)(4)(iv) of this section. This product will then be multiplied by 4.35." We will now address how we will determine the numbers that will be applied to this formula.

First, in paragraph (c)(4), we explain that "[t]o determine the stipend amount, VA first will determine the eligible veteran's level of dependency based on the degree to which the eligible veteran is unable to perform one or more ADLs, or the degree to which the veteran is in need of supervision or protection based on symptoms or residuals of neurological or other impairment or injury." The ADLs and supervision/protection needs will be the 14 ADLs and needs (which we will call categories for the purposes of this discussion) that are listed in the definitions of those terms in § 71.15 (i.e., the seven ADLs and the seven "needs" or impairments).

In paragraph (c)(4)(iii) we explain that each of 14 categories will be assigned a clinical rating of zero to four, with zero meaning that no caregiver assistance is required by the eligible veteran in that category and a four meaning that the eligible veteran requires total assistance in that category, which is parenthetically defined as being able to

complete less than 25 percent of the specific task or function. These percentages, and the zero-to-four scale used in the regulation, are based on three widely accepted clinical tools for measuring ADLs and functional dependence, as applicable: The Katz Basic Activities of Daily Living Scale; the UK Functional Independence Measure and Functional Assessment Measure; and the Neuropsychiatric Inventory.

Pursuant to paragraph (c)(4)(iv), the sum of the zero-to-four scores assigned to each of the 14 categories is then used to assign a presumed number of hours required of the Caregiver. This sum total is then applied to a presumptive level of need: Eligible veterans who score 21 or higher, which can be achieved by having the need for assistance in at least six of the 14 categories, are presumed to need a full-time Caregiver (i.e., one who provides 40 hours of care per week). Under paragraph (c)(4)(iv)(B), a eligible veteran who scores 13 to 20 total in all categories will be presumed to require 25 hours per week of Caregiver assistance. Under paragraph (c)(4)(iv)(C), an eligible veteran who scores 1 to 12 will be presumed to require 10 hours per week of Caregiver assistance.

We believe it is not realistically possible for a veteran or servicemember who meets the other requirements of these regulations to score a zero based on the above formula. However, if a veteran or servicemember were theoretically able to score a zero, we do not believe that that veteran or servicemember's Caregiver would be entitled to a stipend because that veteran would not require any hours of care per week. Hence, the rule would not provide a stipend based on a zero sum score.

We also note that these scoring criteria are based on the definitions of ADL and need of supervision or protection based on symptoms or residuals of neurological or other impairment or injury, but under § 71.20(c)(4), Caregiver eligibility extends to a veteran who is service connected for a serious injury that was incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, and has been rated 100 percent disabled for that serious injury, and has been awarded special monthly compensation that includes an aid and attendance allowance. Such a veteran will also have impairment in the categories used for this formula, and therefore it is reasonable to calculate the stipend for such a veteran using this formula. Likewise veterans and servicemembers who establish eligibility under § 71.20(c)(3) will also have an impairment in the categories used for this formula.

In paragraph (c)(4)(v), we explain the stipend-calculation formula described above. Paragraph (c)(4)(vi) explains the circumstances under which stipend payments will be prorated/adjusted.

The stipend is an acknowledgement of the sacrifices that Primary Family Caregivers are making to care for seriously injured eligible veterans. The law states that nothing in 38 U.S.C. 1720G, as added by section 101 of Public Law 111–163, shall be construed to create any entitlement of any assistance or support provided, nor to create an employment relationship between VA and an individual in receipt of assistance or support, which includes Primary Family Caregivers. 38 U.S.C. 1720G(c)(2). The stipend payments to Primary Family Caregivers under 38 U.S.C. 1720G(a)(3)(A)(ii)(V) constitute "payments [of benefits] made to, or on account of, a beneficiary" that are exempt from taxation under 38 U.S.C. 5301(a)(1). VA does not intend that the stipend replace career earnings. 38 U.S.C. 1720G(c)(2)(A) ("[n]othing in this section shall be construed to create * * * an employment relationship between the Secretary and an individual in receipt of assistance or support under this section"). This principle is set forth in paragraph (c)(4)(vii).

Paragraph (d) provides effective-date and payment-date rules that are consistent with VA practice and policy regarding the effective and payment dates of other VA benefits.

*71.45 Revocation*

Section 71.45 concerns revocation of the Family Caregiver designation. It is important that we allow revocation by the eligible veteran, by the Family Caregiver him- or herself, and by VA; however, the bases for such revocation will differ based on who initiates the revocation proceeding.

Under paragraph (a), we allow a Family Caregiver to revoke his or her caregiver status, and to provide a "present or future date" of such revocation. Many revocations will be requested immediately, but in some cases a Family Caregiver may wish to inform VA in advance that he or she will no longer be able to serve as a Family Caregiver at a specific, future date. The individual need not state a basis for revocation, as participation in the caregiver program is purely voluntary; however, we do require written revocation because the benefits provided to Family Caregivers are not insubstantial, and we want to ensure that there is formality to this process. We also will assist the Family Caregiver, if requested and applicable, in transitioning to alternative health care coverage and mental health services in order to help avoid to the maximum extent possible problems with continuity of medical care provided to that caregiver.

Under 38 U.S.C. 1720G(a)(7)(C), the eligible veteran may revoke the status of a Primary Family Caregiver. We implement this authority in § 71.45(b) and apply it to Secondary Family Caregivers as well. We establish straightforward procedures for such revocation, and we allow for a maximum 30-day period during which VA will review the request for revocation and determine whether there is a possibility for remediation. We allow up to 30 days because in some cases it may be necessary to allow for a "cooling off," during which time the eligible veteran may reconsider his or her request.

We also allow for up to 30 days continuing caregiver benefits, in order to assist the revoked individual in transitioning to other health care. Unlike the situation in paragraph (a), where the Family Caregiver is personally revoking his or her own status, in this situation, the Family Caregiver may not have had time to prepare for a transition from caregiver to non-caregiver status. There may be serious financial issues if the Family Caregiver has come to rely on the stipend, and there may be serious continuity of care issues if the Family Caregiver has been obtaining health care as a result of his or her caregiver status.

But this 30-day extension, which is not specifically authorized by statute, is not without limitation. First, if VA determines that the revoked individual committed fraud or abused or neglected the eligible veteran, we will not continue the benefits after the date of revocation. Second, we will terminate caregiver benefits immediately if the revoked individual was the Primary Family Caregiver, and another Primary Family Caregiver is assigned within 30 days after the date of revocation because the law allows for there to be only one individual receiving benefits as the Primary Family Caregiver. Similarly, caregiver benefits will terminate if another individual becomes a Family Caregiver during the 30-day period, because our regulations will only allow for three Family Caregivers at any one time. Finally, if the revoked individual stops living with the eligible veteran or dissolves his or her relationship with the eligible veteran, we do not believe that it is appropriate to continue to

provide support to that individual. We recognize that neither the 30-day post-revocation period during which benefits may continue, nor the limitations on that period, are clearly contemplated by statute. However, we believe that these rules are consistent with the legislation's purpose. We would like to consider public comment on this issue.

Finally, under paragraph (c), VA is authorized to revoke immediately the designation of a Family Caregiver "if the eligible veteran or individual designated as a Family Caregiver no longer meets the requirements of this part, or if VA makes the clinical determination that having the Family Caregiver is no longer in the best interest of the eligible veteran." However, if revocation is due to improvement in the eligible veteran's condition, death, or permanent institutionalization, the Family Caregiver will continue to receive caregiver benefits for 90 days, unless any of the conditions described in paragraph (b)(4)(i) through (iv) of this section apply. As above, this continuing period of eligibility for benefits is not contemplated by 38 U.S.C. 1720G, but we believe that it is an appropriate and compassionate way to interpret and enforce the law.

*71.50 Provision of Certain Counseling, Training, and Mental Health Services to Certain Family Members of Veterans*

Under 38 U.S.C. 1782(a), VA is required to provide specified benefits to eligible individuals in connection with the treatment of veterans with certain service-connected disabilities, and under § 1782(b), VA may provide the same benefits to eligible individuals in connection with the treatment of veterans with certain nonservice-connected disabilities. In the Veterans' Mental Health and Other Care Improvements Act of 2008, Public Law 110–387, § 301(a), Congress expanded the benefits that VA is authorized to provide to family members by adding "marriage and family counseling" to a list of benefits that already included consultation, professional counseling, training, and mental health services. Those benefits are listed in 38 CFR 17.38(a)(1)(vii) as part of the medical benefits package, as a result of a recent amendment to that section. 75 FR 54028 (Sep. 3, 2010).

The 2010 regulatory amendment to § 17.38 did not explain or clarify the scope of the benefits offered under 38 U.S.C. 1782. Many benefits listed in § 17.38 cross-reference sections that explain the benefit in more detail when the meaning or scope of the listed benefit is not entirely clear on its face, when the benefit is specifically limited by law, or when other regulations govern the actual provision of the benefit. *See, e.g.,* 38 CFR 17.38(a)(1)(v) (bereavement counseling), (a)(1)(viii) (certain durable medical equipment), (a)(1)(xii) (beneficiary travel). We believe that such a clarifying regulation would be helpful to explain the scope of the benefits provided under section 1782 as well, notwithstanding that these benefits have been authorized and provided by VA for several years without regulation.

Moreover, the Caregivers and Veterans Omnibus Health Services Act of 2010 amended section 1782 to provide eligibility for certain caregivers to the benefits and services authorized under section 1782. *See* Public Law 111–163, § 103(a) (amending section 1782(c)). General Caregivers of covered veterans under part 71 are also eligible for benefits under section 1782 pursuant to 38 U.S.C. 1720G(b)(3)(A)(ii). Thus, we believe it is important to include in part 71 the regulation that implements 38 U.S.C. 1782, collocated with the "Caregivers" rules, notwithstanding that section 1782 benefits are not limited to caregivers identified under part 71.

We note as well that caregivers identified under part 71 would receive section 1782 benefits under the same limitations that apply to individuals who receive section 1782 benefits under other provisions of law. There is no indication in section 1720G(b)(3)(A)(ii) that Congress intended, by making caregivers eligible for section 1782 benefits, to affect the manner in which such benefits are provided, or to lift any restrictions on the provision of such benefits.

In § 71.50(a), we do not differentiate between service-connected and non-service-connected disabilities. As noted above, VA is required to provide these benefits to service-connected veterans but is merely authorized to provide them to nonservice-connected veterans. VA has consistently exercised its authority to provide section 1782 benefits without regard to service connection, and we would not change our administration of the benefit now.

Paragraph (a) lists the benefits authorized by section 1782 verbatim, and states that they will be provided "to a family member when necessary in connection with the treatment of a disability for which the veteran is receiving treatment through VA." This restriction is specifically required by 38 U.S.C. 1782(a) and (b), both of which authorize the provision of these listed benefits to the family member of a veteran receiving treatment from VA "as are necessary in connection with that treatment." Because the meaning of this restriction may not be clear in all contexts, we explain in paragraph (a) that "in connection with the treatment" of the veteran's disability means that "in the clinical judgment of a VA medical professional who is providing treatment to the veteran, the provision of the benefit to the family member would further the objectives of the veteran's medical treatment plan." For example, a VA clinician is authorized to prescribe family participation is psychoeducational courses, if such courses are required for the treatment of a veteran's disability, because the courses are in connection with such treatment. In practice, our medical providers clearly articulate this limitation at the outset of treatment provided under section 1782, so that the individual being treated is aware of the limitations before beginning his or her course of care.

The goal of this rule is to provide care to a qualified family member that connects to the treatment plan of the veteran, so that the services provided to the family member will be a component of VA's overall treatment of the veteran's disability. In view of our longstanding primary purpose to provide veteran-focused care and the statutory limitation that VA provide services that are necessary in connection with the treatment of the veteran, we do not interpret section 1782 to allow us to provide medical care for family members unless such care will improve the veteran's own condition from a clinical perspective. Thus, under this rule, VA would not provide treatment to family members for the purposes of overall wellness, but would instead do so to help families participate in the treatment of a veteran. For example, VA would not provide counseling and referral for a depressed family member because his or her depression makes the veteran feel sad out of empathy. However, VA may provide counseling and referral to a veteran's caregiver if the caregiver is unable to help the veteran engage in or sustain engagement in VA treatment. Similarly, if a qualified veteran relies upon a family member to drive him or her to a VA facility on a regular basis, and a mental health condition renders the family member unable to drive a car, then the veteran is left without access to needed treatment. In this instance, VA will provide the appropriate psychotherapy or counseling for the family member's condition, or help the family member find appropriate care in the private sector, because such treatment is necessary in connection

with the course of treatment for the veteran's disability.

We also propose several clarifying paragraphs to help reduce potential confusion about the nature of the benefits authorized by section 1782. VA has interpreted the statutory list of benefits to contemplate psychotherapy, counseling, training, or education. VA will not provide prescriptions or medications to family members. Similarly, VA will not provide inpatient services under this section because such intensive care is, in our view, inconsistent with the types of benefits listed in the statute and with our veteran-focused mandate for medical care. This limitation is stated in paragraph (a)(1).

Paragraph (a)(2) states that "[t]his section does not authorize the provision of clinical evaluation or treatment that is not necessary in connection with the veteran's treatment or that involves treatment other than consultation, professional counseling, marriage and family counseling, training, and mental health services." We restate this limitation because it is important to emphasize the narrow nature of this benefit.

We explain in paragraph (a)(3) that "[m]arriage and family counseling includes services helping the veteran address mental health issues, manage physical health problems, and strengthen environmental supports as specified in the veteran's treatment plan" and "also includes interventions to reduce the negative impact for the veteran of mental illnesses or other medical conditions in family members."

Paragraph (b) defines "family member" for the purpose of this rule. The definition is derived from 38 U.S.C. 1782(c). The statute discusses members of the veteran's "immediate family," which we interpret as "person related to the veteran by birth or marriage who lives with the veteran or has regular personal contact with the veteran." We believe the term "immediate" connotes regular contact, usually living in the same household, and we would include this requirement in the definition. We consider this definition to be consistent with the overall intent of the law, which is to provide limited benefits to people who might be required to participate in the care of a veteran's condition or with whom the veteran might experience interactions that regularly exacerbate or contribute to his or her symptomatology.

*Effect of Rulemaking*

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures on this subject are authorized. All VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

*Administrative Procedure Act*

In accordance with 5 U.S.C. 553(b), the Secretary of Veterans Affairs finds good cause to issue this interim final rule prior to notice and comment procedures. This interim final rule implements statutory authorization for a comprehensive program of assistance and support services for caregivers of eligible servicemembers and veterans. In passing the Caregivers and Veterans Omnibus Health Services Act of 2010 (the Act), Congress indicated a clear intent to have this program implemented as swiftly as possible, requiring implementation no later than 270 days after the statutory enactment, namely by January 30, 2011. The statute required extensive consultation with particular stakeholders prior to implementation, and since the enactment, the Secretary of VA has continued to engage with such stakeholders as directed. Under these circumstances, the Secretary finds that seeking public notice and comment in addition to the statutorily-directed stakeholder consultations prior to issuance is impracticable and that further delay would thwart Congressional intent to deliver these benefits to caregivers in need expeditiously.

The statute required the Secretary to develop and implement a unique and highly complex program offering the following benefits to eligible caregivers:

- A monthly stipend;
- Health care coverage;
- Travel expenses, including lodging and per diem while accompanying veterans undergoing care;
- Respite care (not less than 30 days annually to allow the caregiver time away from caring for the veteran);
- Training; and
- Mental health services and counseling.

Before implementation could occur, the Act expressly required the Secretary consult with specified stakeholders. Accordingly, the Secretary immediately began a process of consultation with:

- Veterans;
- Their family members;
- The Secretary of Defense;
- Veterans services organizations;
- National organizations specializing in the provision of assistance to individuals with disabilities;
- National organizations that specialize in the provision of assistance to family members of veterans who provide personal care services; and
- Other organizations with an interest in the provision of care to veterans and assistance to Family Caregivers.

The Secretary has submitted to Congress a publicly available implementation plan that describes these mandatory consultations in detail, including recommendations from participants. Where such recommendations were not accepted, the Secretary's justifications were described as well. The Secretary now finds, having completed these required preliminary steps and provided Congress with an implementation plan, that it is imperative that the VA commence provision of the authorized assistance as quickly as possible.

The Secretary further finds that it is contrary to the public interest to delay issuance of this rule for the purpose of soliciting prior public comment because there is an immediate and pressing need for the assistance and support services that will be provided under the rule, without which harm to America's wounded, injured veterans and their caregivers would result. The conflicts in Iraq and Afghanistan have led to a sharp increase in the number of servicemembers and veterans returning with serious injuries that require substantial care. Recognizing this problem, Congress required the Secretary to take quick action to assist these veterans and their caregivers. Hundreds of seriously injured servicemembers and veterans have caregivers or potential caregivers who may be eligible for the assistance and support services that will be provided under this rule. Many caregivers, in order to assist their loved ones in a time of dire need, may have left or foregone employment due to the time commitment required to provide care for a seriously injured individual. These caregivers may have lost health insurance as a result of lost employment opportunities and may be in urgent need of mental health counseling due to the great emotional strain of caring for a severely injured servicemember or veteran. Further, caregivers may be in need of the training that will be provided under this rule in order to ensure that they are able to provide care in a manner that protects the safety and well being of their seriously injured servicemember or veteran. The assistance and services to be provided under this rule are needed as soon as

possible to respond to this increase in servicemembers and veterans with serious injuries in order to avoid financial hardship for caregivers and to ensure the provision of appropriate care for eligible seriously injured servicemembers and veterans.

For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be impracticable and contrary to the public interest, and is accordingly issuing this rule as an interim final rule. The Secretary will consider and address comments that are received within 60 days after the date that this interim final rule is published in the **Federal Register**, including comments regarding eligibility criteria, and address them in a subsequent **Federal Register** notice announcing a final rule incorporating any changes made in response to the public comments.

In order to ensure timely implementation of the program established by this rule, and for the reasons stated above, the Secretary also finds, in accordance with 5 U.S.C. 553(d), that there is good cause for this interim rule to be effective immediately upon publication. For the same reasons detailed above—i.e., clear Congressional intent to implement the program swiftly and on a tight statutory schedule after extensive Secretarial consultation with stakeholders, as well as an immediate and pressing need for the assistance provided under this rule—it is in the public interest to commence this program as soon as possible, and this will be facilitated by an immediate effective date.

*Unfunded Mandates*

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule will have no such effect on State, local, or tribal governments, or on the private sector.

*Paperwork Reduction Act*

The interim final rule at § 71.25(a) contains a collection of information, which constitutes a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521) and requires approval by the Office of Management and Budget (OMB). Accordingly, under section 3507(d) of the Act, VA has submitted a copy of this rulemaking to OMB for review. OMB assigns a control number for each collection of information it approves. Except for emergency approvals under 44 U.S.C. 3507(j), VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. We have requested that OMB approve the collection of information on an emergency basis. If OMB does not approve the collection of information as requested, we will immediately remove § 71.25(a) or take such other action as is directed by OMB.

We are also seeking an approval of the information collection on a non-emergency basis. Accordingly, we are also requesting comments on the collection of information provisions contained in § 71.25(a) on a non-emergency basis. Comments must be submitted by *July 5, 2011.*

Comments on the collection of information should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies mailed or hand-delivered to: Director, Office of Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or through www.regulations.gov. Comments should indicate that they are submitted in response to "RIN 2900–AN94, Caregivers Program."

*Title:* Caregivers Program.

*Summary of collection of information:* The interim final rule at § 71.25(a) contains application provisions for individuals who wish to be considered for designation by VA as Primary or Secondary Family Caregivers for certain veterans. These provisions require the submission of a joint application completed by a veteran or servicemember and no more than three other individuals who intend to serve as Family Caregivers for an eligible veteran, with no more than one individual serving as veteran's Primary Family Caregiver.

*Description of the need for information and proposed use of information:* This information is needed to determine eligibility for benefits under the Caregiver Program and to ensure that eligible veterans receive suitable caregiver services.

*Description of likely respondents:* Veterans' family members.

*Estimated number of respondents per year:* 5,000.

*Estimated frequency of responses per year:* 1.

*Estimated total annual reporting and recordkeeping burden:* 1,250 hours.

*Estimated annual burden per collection:* 15 minutes.

OMB is required to make a decision concerning the collection of information contained in this interim final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the interim final rule. VA considers comments by the public on collections of information in—

- Evaluating whether the collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including responses 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.

*Regulatory Flexibility Act*

The Secretary of VA has determined that this regulatory action will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–12. This regulatory action affects individuals and would not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this regulatory action is exempt from the initial and final flexibility analysis requirements of sections 603 and 604.

*Congressional Review Act*

This regulatory action is a major rule under the Congressional Review Act, 5 U.S.C. 801–08, because it is likely to result in an annual effect on the economy of $100 million or more. Although this regulatory action is a major rule within the meaning of the Congressional Review Act, 5 U.S.C. 804(2), it is not subject to the 60-day delay in effective date applicable to major rules under 5 U.S.C. 801(a)(3) because the Secretary finds that good cause exists under 5 U.S.C. 808(2) to make this regulatory action effective

immediately, consistent with the publication of this interim final rule. Congress established this program and intended it to be in effect by January 30, 2011, but the implementing regulations have taken longer to develop. In establishing this program, Congress and VA recognize the immediate and urgent need that many veterans, servicemembers, and their family members have for caregiver assistance and benefits. Accordingly, the Secretary finds that additional advance notice and public procedure thereon are impractical, unnecessary, and contrary to the public interest. In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis (RIA).

*Executive Order 12866 and Executive Order 13563*

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 12866 defines a "significant regulatory action," which requires review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This rule has been designated a "economically" significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and followed OMB Circular A–4 to the extent feasible in this Regulatory Impact Analysis. The circular first calls for a discussion of the need for the regulatory action.

*Statement of Need*

This rulemaking is necessary to implement title I of the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163, which was signed into law on May 5, 2010. The purpose of the caregiver benefits program is to provide certain medical, travel, training, and financial benefits to eligible caregivers of veterans and certain servicemembers who incurred or aggravated a serious injury in the line of duty on or after September 11, 2001.

*Summary of Estimated Impact*

The estimated costs associated with this regulation are $69,044,469.40 for FY2011 and $777,060,923.18 over a 5 year period. These include costs associated with the implementation and development of the caregiver support program.

Cost Projections for Caregiver Program - (FY2011 - FY2015)

| Description of Costs | FY 2011 | FY 2012 | FY 2013 | FY 2014 | FY 2015 | 5 Year Total |
|---|---|---|---|---|---|---|
| Caregiver Program Staffing | $8,083,644.80 | $19,400,747.43 | $20,176,777.32 | $20,983,848.42 | $21,823,202.37 | $90,468,220.34 |
| Caregiver Program Stipend | $27,617,530.00 | $77,658,984.00 | $83,992,329.20 | $90,834,536.00 | $98,215,650.00 | $378,319,029.20 |
| Respite Care | $13,815,832.00 | $35,156,000.00 | $37,966,400.00 | $41,107,360.00 | $44,436,480.00 | $172,482,072.00 |
| Mental Health Services | $305,660.00 | $992,970.00 | $1,073,088.00 | $1,158,606.00 | $1,254,894.00 | $4,785,218.00 |
| General Caregiver Educ. & Trng. | $6,057,760.00 | $190,185.60 | $205,852.80 | $222,682.50 | $240,683.40 | $6,917,164.30 |
| Lodging/Mileage/Meal Per Diem (Veteran Inpatient/ Outpatient Visits) | $466,975.52 | $1,211,092.78 | $1,308,547.76 | $1,413,433.83 | $1,528,241.79 | $5,928,291.68 |
| Mileage for Caregiver Training | $373,085.00 | $35,856.00 | $37,350.00 | $38,844.00 | $40,338.00 | $525,473.00 |
| Healthcare Coverage (CHAMPVA) | $2,752,390.92 | $6,765,401.32 | $6,943,472.78 | $7,505,688.62 | $8,205,989.03 | $32,172,942.66 |
| Caregiver Oversight (Contract) | $0.00 | $1,448,846.08 | $1,567,203.20 | $1,694,887.36 | $1,833,527.52 | $6,544,464.16 |
| Caregiver Oversight (VA) | $4,014,070.96 | $10,420,334.14 | $11,271,763.58 | $12,189,701.34 | $13,184,910.50 | $51,080,780.52 |
| Caregiver Support Line | $1,500,000.00 | $2,500,000.00 | $2,599,999.58 | $2,703,999.11 | $2,812,159.03 | $12,116,157.72 |
| Study and Survey | $245,959.20 | $238,359.20 | $225,859.20 | $0.00 | $0.00 | $710,177.60 |
| Outreach & Additional Supt.Programs | $3,811,561.00 | $2,673,358.00 | $2,772,356.00 | $2,830,224.00 | $2,923,433.00 | $15,010,932.00 |
| TOTAL | $69,044,469.40 | $158,692,134.55 | $170,140,999.42 | $182,683,811.18 | $196,499,508.63 | $777,060,923.18 |

Estimated costs and projections are based on the best, reasonably obtainable, and economic information available. Some portions of the analysis rely upon assumptions that may change, due to the unpredictability of catastrophic and severe injuries resulting from military service and combat during war. This analysis sets forth the basic assumptions, methods, and data underlying the analysis and discusses the uncertainties associated with the estimates. Assumptions and methodologies for each portion of the analysis are explained in more detail in the Estimate of Potential Program Costs below. As VA develops claims data and becomes more cognizant of the cost of caregiver benefits, VA will make appropriate adjustments in the amount of funds requested for future fiscal years. VA invites public comments on all of these projections.

*Potential Benefits*

Hundreds of seriously injured servicemembers and veterans have caregivers or potential caregivers who may be eligible for the assistance and support services that will be provided under this rulemaking. The purpose of providing Family Caregiver assistance under this law is to benefit eligible veterans whose personal care service needs could be substantially satisfied with the provision of such services by a family member (as defined in the law); and to provide eligible veterans with additional options so that they can choose the setting for the receipt of personal care services that best suits their needs.

*Alternatives*

On May 5, 2010, the President signed into law the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163. Title I of the law established 38 U.S.C. 1720G, which requires VA to "establish a program of comprehensive assistance for family caregivers of eligible veterans," as well as a program of "general caregiver support services" for caregivers of "veterans who are enrolled in the health care system established under [38 U.S.C. 1705(a)] (including caregivers who do not reside with such veterans)." 38 U.S.C. 1720G(a)–(b).

The law authorizes assistance for caregivers of Post 9/11 veterans and servicemembers. It recognizes that Post 9/11 veterans and servicemembers return home with serious injuries that often were fatal in the past. These veterans present complex recovery and adjustment processes requiring ongoing medical supervision.

VA initially considered a narrow definition of eligibility, but ultimately decided to broaden the program's eligibility in order to encompass more seriously injured post-9/11 veterans. The law requires VA to report on the program's potential for future expansion to all era veterans, so under this law Congress will consider that aspect of the program at a later time.

*Estimate of Potential Program Costs*

To project the best possible economic impact of this regulation VA conducted an analysis on veterans and servicemembers who incurred or aggravated a serious injury in the line of duty on or after September 11, 2001. The analysis also focused on the number of veterans and servicemembers who have an impairment in one or more of seven activities of daily living (ADLs) or require supervision or protection based on symptoms or residuals of neurological or other impairment or injury, and those whose injury is strictly diagnosed as a mental health condition with a GAF score of no greater than 30. The results of this analysis identified an estimated 3,596 veterans and servicemembers who would meet the eligibility criteria established in § 71.20 of this regulation, thus being eligible for Family Caregiver benefits. The estimated 3,596 number of potentially eligible veterans and servicemembers was applied to the applicable methodologies and calculations in this regulatory impact analysis to project the best possible economic impact of this regulation.

*Caregiver Program Staffing*

Staffing costs were calculated for the following number of full-time employees (FTE) and salaries. Based on the publication date of this rulemaking (May 2011), the total staffing cost for FY11 ($8,083,644.80) is based on the 5 remaining months of FTE costs (May–Sep). A 4 percent total General Schedule Increase and Locality Payment rate was applied to the FTE costs for FY13 through FY15.

| Caregiver Program Staffing Cost | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Title | # of FTE | Grade | Salary (+ benefits) | FY11 | FY12 | FY13 | FY14 | FY15 | 5-Year Totals |
| VACO National Program Director | 1 | GS-15/5 | $186,530.44 | $77,721.02 | $186,530.44 | $193,991.66 | $201,751.33 | $209,821.38 | $869,815.83 |
| VACO Caregiver Program | 1 | GS-14/5 | $158,574.62 | $66,072.76 | $158,574.62 | $164,917.60 | $171,514.30 | $178,374.88 | $739,454.16 |
| VACO Health Systems Specialist | 1 | GS-13-14/5 | $158,574.62 | $66,072.76 | $158,574.62 | $164,917.60 | $171,514.30 | $178,374.88 | $739,454.16 |
| VACO Training Program Manager | 2 | GS-13-14/5 | $317,149.23 | $132,145.51 | $317,149.23 | $329,835.20 | $343,028.61 | $356,749.75 | $1,478,908.30 |
| VACO Peer Support/Mentor Program Manager | 1 | GS-13-14/5 | $158,574.62 | $66,072.76 | $158,574.62 | $164,917.60 | $171,514.30 | $178,374.88 | $739,454.16 |
| VACO Program Specialist | 1 | GS-12/5 | $112,848.66 | $47,020.28 | $112,848.66 | $117,362.61 | $122,057.12 | $126,939.40 | $526,228.07 |
| VACO Program Specialist | 1 | GS-11/5 | $94,148.94 | $39,228.73 | $94,148.94 | $97,914.90 | $101,831.49 | $105,904.75 | $439,028.81 |
| VISN Regional Training Program Coordinator | 4 | GS-13-14/5 | $634,298.46 | $264,291.03 | $634,298.46 | $659,670.40 | $686,057.22 | $713,499.51 | $2,957,816.62 |
| VA Chief Business Office Claims Processor | 2 | GS-9/5 | $155,627.56 | $64,844.82 | $155,627.56 | $161,852.66 | $168,326.77 | $175,059.84 | $725,711.65 |
| VA Chief Business Office Claims Program Manager | 1 | GS-12/5 | $112,848.66 | $47,020.28 | $112,848.66 | $117,362.61 | $122,057.12 | $126,939.40 | $526,228.07 |
| VA Caregiver Business Operations Program Manager | 1 | GS-14/5 | $158,574.62 | $66,072.76 | $158,574.62 | $164,917.60 | $171,514.30 | $178,374.88 | $739,454.16 |
| VAMC Caregiver Support Coordinators | 152 | GS-12/5 | $17,152,997.00 | $7,147,082.09 | $17,152,997.00 | $17,839,116.88 | $18,552,681.56 | $19,294,788.82 | $79,986,666.35 |
| | | | 5-Year Totals | $8,083,644.80 | $19,400,747.43 | $20,176,777.32 | $20,983,848.42 | $21,823,202.37 | $90,468,220.34 |

*Caregiver Program Stipend*

The caregiver stipend is based on the Department of Labor (DOL) national estimate for hourly wages of a Home Health Aide, which was $11.67 for FY09. To compute the FY11 rate, a 7.5 percent annual inflation rate was applied to obtain the FY11 rate of $12.55 per hour. To determine the number of stipend hours that each caregiver would be able to provide VA used Veterans Benefits Administration (VBA) data, which categorizes veterans by the severity of their disability or their injury. Based on this data, VA projects a caseload of 3,596 veterans and servicemembers, consisting of: 2,116 veterans and servicemembers with serious injuries and service-connected (SC) anatomical loss, or loss of use, and 220 veterans with 100 percent SC traumatic brain injury (TBI); 146 veterans with a 100 percent SC mental health (MH) condition with a GAF score of 30 or less; 394 service members with a serious injury; and 720 potentially new service members identified by the Department of Defense (DoD).

For FY 11, VA assumes that 50 percent of the R1, R2, L, M, N, O veterans (2,116/2 = 1,058), 50 percent of the 394 and 720 servicemembers (394 + 720 = 1,114/2 = 557), all of the SC MH with a GAF score of 30 or less (146), and 50 percent of the SC 100% TBI (220/2 = 110), totaling 1,871 or approximately 52 percent of the 3,596 caseload would fall into the high percentage of hours (26–40 hrs) that caregivers will provide.

VA assumes that 25 percent of the R1, R2, L, M, N, O veterans (2,116/4 = 529), 50 percent of the SC 100% TBI (220/2 = 110) and 50 percent of the servicemembers (557), totaling 1,196 or approximately 33 percent of the 3,596 caseload would fall into the medium percentage of hours (10–25 hrs) that caregivers will provide.

VA assumes that 25 percent of the R1, R2, L, M, N, O veterans (2,116/4 = 529), totaling 529 or approximately 15 percent of the 3,596 caseload would fall into the low percentage of hours (less than <10 hrs) that caregivers will provide.

Based on the publication of this rulemaking (May 2011), the Total Stipend Cost for FY11 ($27,617,530.00) is based on 5 months only (–20 weeks). A 4 percent inflation rate was applied to the stipend cost per hour and a 4 percent population growth rate was applied to the projected caregiver caseload for all out years.

| Estimated Caregiver Program Stipend Cost | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Percentage of Hours that Caregivers will Provide | | | Cost Per hour | Weeks | High (26-40 hrs) | Medium (10-25 hrs) | Low (<10 hrs) | Total Stipend Cost |
| | | High (26-40 hrs) | Medium (10-25 hrs) | Low (<10 hrs) | | | | | | |
| | | *52%* | *33%* | *15%* | | | Cost | Cost | Cost | |
| FY11 | 3,596 | 1,871 | 1,196 | 529 | $12.55 | 20 | $18,784,840.00 | $7,504,900.00 | $1,327,790.00 | $27,617,530.00 |
| FY12 | 3,740 | 1,946 | 1,244 | 550 | $13.05 | 52 | $52,822,224.00 | $21,104,460.00 | $3,732,300.00 | $77,658,984.00 |
| FY13 | 3,890 | 2,024 | 1,294 | 572 | $13.57 | 52 | $57,128,614.40 | $22,827,454.00 | $4,036,260.80 | $83,992,329.20 |
| FY14 | 4,046 | 2,105 | 1,346 | 595 | $14.11 | 52 | $61,779,224.00 | $24,689,678.00 | $4,365,634.00 | $90,834,536.00 |
| FY15 | 4,208 | 2,189 | 1,400 | 619 | $14.67 | 52 | $66,794,270.40 | $26,699,400.00 | $4,721,979.60 | $98,215,650.00 |
| 5-Year Totals | | | | | | | $257,309,172.80 | $102,825,892.00 | $18,183,964.40 | $378,319,029.20 |

*Respite Care*

VA assumed that respite care will be primarily in-home care for 24 hours per day. The FY11 rate of $226 was calculated using an actual FY09 rate of $209 and adding a 4 percent inflation rate. The rates were provided by VA's Geriatrics and Extended Care Strategic Healthcare Group. VA assumed 40 days of respite care. This includes the minimum of 30 days of respite care for the Primary Family Caregiver, plus 5 days for training for each (2) Secondary Family Caregiver. The 40 days of respite is consistent for all out year cost and encompasses respite care during training for all "new" Family Caregivers. VA assumes that all Family Caregivers will receive training simultaneously or provide coverage for each other during periods of training. Therefore, VA anticipates 3,596 Family Caregivers will request respite care during training in FY11. However, based on the publication date of this rulemaking (May 2011), Family Caregivers will only have 5 months to utilize respite benefits (May–Sep). Thus, FY11 respite care was calculated to be 17 days. A 4 percent inflation rate was applied to the respite cost per day.

| Estimated Respite Cost | | | | | | |
|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | In-Home Respite Cost per day (24 hrs) | Days of Respite | Total Days of Respite Per Year | Cost for Respite & Training per Caregiver | Total Cost for Respite |
| FY11 | 3,596 | $226.00 | 17 | 61,132 | $3,842.00 | $13,815,832.00 |
| FY12 | 3,740 | $235.00 | 40 | 149,600 | $9,400.00 | $35,156,000.00 |
| FY13 | 3,890 | $244.00 | 40 | 155,600 | $9,760.00 | $37,966,400.00 |
| FY14 | 4,046 | $254.00 | 40 | 161,840 | $10,160.00 | $41,107,360.00 |
| FY15 | 4,208 | $264.00 | 40 | 168,320 | $10,560.00 | $44,436,480.00 |
| 5-Year Totals | | | | | | $172,482,072.00 |

*Mental Health Services*

VA assumes that as many as 50 percent of the total caregivers might have mental health issues and of those, only half would seek mental health services based on trends in a review of medical literature (3,596/4 = 899). Recent National Alliance for Caregiving (NAC) literature indicates that 67 percent of caregivers of veterans report they are highly stressed, and may experience anxiety, sleep deprivation, or depression. Data from the National Institutes for Health indicate that mental health utilization rates average 12 percent for the general population. VA anticipates that a larger number of new caregivers will seek these services. VA acknowledges that the 50 percent assumption may be conservative, but VA has the resources to absorb increased requests for mental health services. Based on information obtained from VA's Mental Health Services, VA assumed six (6) visits per year at an initial cost of $170 per visit. Based on the publication of this rulemaking and when mental health services are expected to become available (May 2011), caregivers will only have a 5 month period to seek mental health service benefits (May–Sep). VA assumes that 5 months is not a sufficient amount of time for caregivers to fully utilize the annual average of six (6) visits. Caregivers must be trained and certified before they are eligible for these benefits. Therefore, the average number of visits for FY11 is estimated at two (2) visits ($6/12 \times 4 = 2$). A 4 percent inflation rate was applied to the mental health service cost per visit and a 4 percent population growth rate was applied to the projected caregiver caseload for all out years.

| Estimated Mental Health Services Cost | | | | | |
|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Avg # Visits per Year | Cost Per Visit | Total Cost per year per Caregiver | Total Cost for all Caregivers |
| FY11 | 899 | 2 | $170.00 | $340.00 | $305,660.00 |
| FY12 | 935 | 6 | $177.00 | $1,062.00 | $992,970.00 |
| FY13 | 972 | 6 | $184.00 | $1,104.00 | $1,073,088.00 |
| FY14 | 1,011 | 6 | $191.00 | $1,146.00 | $1,158,606.00 |
| FY15 | 1,051 | 6 | $199.00 | $1,194.00 | $1,254,894.00 |
| 5-Year Totals | | | | | $4,785,218.00 |

*Education and Training*

Cost projections were based on development and implementation of training for Family Caregivers using a core curriculum provided by a designated contractor. Training for General Caregivers will use a modified version of this core curriculum and will be managed by VA staff. The training modules will also be available through Workbook/DVD and web-based versions. VA assumes a maximum of two Secondary Family Caregivers per veteran. Comprehensive Family Caregiver training will only be provided once for each Family Caregiver, to include primary and secondary caregivers. This comprehensive Family Caregiver training will be reviewed annually. Updated core curriculum training and guidance will be available on the Caregiver Support Program's website and from a Caregiver Support Coordinator, at each VA Medical Center.

In FY11, VA projects 3,596 Primary Family Caregivers and 7,192 (3,596 × 2) Secondary Family Caregivers will be trained. VA projects that 10 percent (3,000) of veterans from all eras receiving VA Aid and Attendance, including seriously injured active servicemembers pending a medical discharge may be eligible for General Caregiver training and benefits. Therefore, the total cost for training all caregivers (13,788) for FY11 is estimated to be $6,057,760.00.

Caseload projections for FY12 and all out years are based on training "new" Family Caregivers. Comprehensive training in its entirety will only be provided once for each Family Caregiver. VA applied a 4 annual percent (4%) population growth rate, which is based on historical growth trends in compensation benefits, to determine the estimated number of "new" Family Caregivers (432 for FY12) that will require training annually.

In FY12, VA projects that 144 Primary Family Caregivers will be trained along with 288 (144 × 2) Secondary Family Caregivers and 3,120 General Caregivers. Therefore, the total cost for training all caregivers (3,552) for FY12 is estimated to be $190,185.60.

| Total Estimated Caregiver Education & Training Cost | | | | |
|---|---|---|---|---|
| FY | Comprehensive Caregiver Training for Primary Family Caregivers | Comprehensive Caregiver Training for (2) Secondary Family Caregivers | General Caregiver Training Conducted by VA Staff | Total Cost |
| FY11 | $5,752,000.00 | $215,760.00 | $90,000.00 | $6,057,760.00 |
| FY12 | $83,856.00 | $8,985.60 | $97,344.00 | $190,185.60 |
| FY13 | $90,850.00 | $9,702.55 | $105,300.25 | $205,852.80 |
| FY14 | $98,280.00 | $10,496.25 | $113,906.25 | $222,682.50 |
| FY15 | $106,110.00 | $11,372.40 | $123,201.00 | $240,683.40 |
| 5-Year Totals | $6,131,096.00 | $256,316.80 | $529,751.50 | $6,917,164.30 |

| Comprehensive Caregiver Training for Primary Family Caregivers | | | | | |
|---|---|---|---|---|---|
| FY | Caregivers attending Traditional Classroom Training | Caregivers who choose At-home Training (Workbook / DVD) | Caregivers who choose Web-Based Training | Total Primary Family Caregivers Trained | Total Cost to Train Primary Family Caregivers |
| FY11 | 1,199 | 1,199 | 1,198 | 3,596 | $5,752,000.00 |
| FY12 | 48 | 48 | 48 | 144 | $83,856.00 |
| FY13 | 50 | 50 | 50 | 150 | $90,850.00 |
| FY14 | 52 | 52 | 52 | 156 | $98,280.00 |
| FY15 | 54 | 54 | 54 | 162 | $106,110.00 |
| 5-Year Totals | | | | | $6,131,096.00 |

| Comprehensive Caregiver Training for (2) Secondary Family Caregivers (Workbook/DVD/Web-Based only) | | | | |
|---|---|---|---|---|
| FY | Projected Number of Secondary Family Caregivers | Cost to train via At-Home Training per Secondary Family Caregiver | Cost to train via web-based training | Total Cost to Train (2) Secondary Family Caregivers |
| FY11 | 7,192 | $30.00 | $0.00 | $215,760.00 |
| FY12 | 288 | $31.20 | $0.00 | $8,985.60 |
| FY13 | 299 | $32.45 | $0.00 | $9,702.55 |
| FY14 | 311 | $33.75 | $0.00 | $10,496.25 |
| FY15 | 324 | $35.10 | $0.00 | $11,372.40 |
| 5-Year Totals | | | | $256,316.80 |

| General Caregiver Training conducted by VA Staff (Workbook/DVD/Web-Based only) | | | | |
|---|---|---|---|---|
| FY | Projected Number of General Caregivers | Cost to train via At-Home Training per General Caregiver | Cost to train via web-based training | Total Cost per to Train General Caregivers |
| FY11 | 3,000 | $30.00 | $0.00 | $90,000.00 |
| FY12 | 3,120 | $31.20 | $0.00 | $97,344.00 |
| FY13 | 3,245 | $32.45 | $0.00 | $105,300.25 |
| FY14 | 3,375 | $33.75 | $0.00 | $113,906.25 |
| FY15 | 3,510 | $35.10 | $0.00 | $123,201.00 |
| 5-Year Totals | | | | $529,751.50 |

*Lodging/Mileage/Meal Per Diem (Veteran Inpatient/Outpatient)*

Mileage, lodging, and meal per diem will be provided to Family Caregivers when VA determines that an overnight stay is required. VA assumed that lodging would be provided within VA or VA-affiliated resources (i.e., at a Fisher House, VA Hoptel, or other setting at VA expense). VA determined that meal per diem for caregivers who require lodging would be no more than half of the highest rate ($35.00 to $70.00). The lodging per diem would be half of the average federal lodging and per diem rates for ten (10) facilities with Spinal Cord Injury (SCI) and VA's four (4) polytrauma centers ($223.00). Therefore, for FY11, VA assumes that meal per diem would be $35.00 per day and lodging per diem would be $111.50.00 per day. To determine the average length of stay (ALOS) for veterans requiring inpatient care, VA obtained data from VA's Office of the Assistant Deputy Under Secretary for Health, Policy and Planning. This data indicated that slightly more than 196,000 of 982,000 (20%) Priority Group 1 (PG1) veteran users were admitted in FY09 for an average length of stay (ALOS) of 7.3 days. VA assumes that the 7.3 days would increase to 9.3 days based on severity of this population and extensive rehabilitation needs. VA also assumed an ALOS of 1 day for Family Caregivers of veterans requiring outpatient services. In FY11, it is estimated that 1,438 (719 × 2) Family Caregivers will require lodging during the veteran's inpatient or outpatient visit. The total cost in FY11 for lodging, meal per diem and mileage is $466,975.52. Based on the publication date of this rulemaking, these costs are based on 5 months only (May–Sep). A 4 percent inflation rate was applied to the meal and lodging per diems. A 4 percent population growth rate was applied to the projected caregiver caseload for all out years.

| Total Estimated Lodging/Mileage/Meal Per Diem Cost | | |
|---|---|---|
| FY | Caregivers Eligible for Lodging/Mileage/ Meal Per Diem (Inpatient + Outpatient) | Total |
| 2011 | 1,438 | $466,975.52 |
| 2012 | 1,496 | $1,211,092.78 |
| 2013 | 1,556 | $1,308,547.76 |
| 2014 | 1,618 | $1,413,433.83 |
| 2015 | 1,684 | $1,528,241.79 |
| 5-Year Totals | | $5,928,291.68 |

| Estimated Lodging/Mileage/Meal Per Diem Cost (Inpatient) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Caseload x 20% | Lodging Rate | Average Length of Stay (ALOS) | Lodging Rate x ALOS | Total Lodging Cost | Meal Per Diem Rate | Total Meal Per Diem Costs | Mileage Rate | Miles per Visit | Total Mileage Cost | Total Costs for Caregivers Requiring Lodging |
| 2011 | 3,596 | 719 | $111.50 | 9.3 | $1,036.95 | $745,567.05 | $35.00 | $234,034.50 | 0.415 | 60 | $17,903.10 | $415,626.94 |
| 2012 | 3,740 | 748 | $115.96 | 9.3 | $1,078.43 | $806,664.14 | $36.40 | $253,212.96 | 0.415 | 60 | $18,625.20 | $1,078,502.30 |
| 2013 | 3,890 | 778 | $120.60 | 9.3 | $1,121.58 | $872,589.24 | $37.86 | $273,932.24 | 0.415 | 60 | $19,372.20 | $1,165,893.68 |
| 2014 | 4,046 | 809 | $125.42 | 9.3 | $1,166.41 | $943,622.45 | $39.37 | $296,208.07 | 0.415 | 60 | $20,144.10 | $1,259,974.62 |
| 2015 | 4,208 | 842 | $130.44 | 9.3 | $1,213.09 | $1,021,423.46 | $40.94 | $320,584.76 | 0.415 | 60 | $20,965.80 | $1,362,974.03 |
| 5-Year Totals | | | | | | | | | | | | $5,242,924.71 |

| Estimated Lodging/Mileage/Meal Per Diem Cost (Outpatient) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Caseload x 20% | Lodging Rate | Average Length of Stay (ALOS) | Lodging Rate x ALOS | Total Lodging Cost | Meal Per Diem Rate | Total Meal Per Diem Costs | Mileage Rate | Miles per Visit | Total Mileage Cost | Total Costs for Caregivers Requiring Lodging |
| 2011 | 3,596 | 719 | $111.50 | 1 | $111.50 | $80,168.50 | $35.00 | $25,165.00 | 0.415 | 60 | $17,903.10 | $51,348.58 |
| 2012 | 3,740 | 748 | $115.96 | 1 | $115.96 | $86,738.08 | $36.40 | $27,227.20 | 0.415 | 60 | $18,625.20 | $132,590.48 |
| 2013 | 3,890 | 778 | $120.60 | 1 | $120.60 | $93,826.80 | $37.86 | $29,455.08 | 0.415 | 60 | $19,372.20 | $142,654.08 |
| 2014 | 4,046 | 809 | $125.42 | 1 | $125.42 | $101,464.78 | $39.37 | $31,850.33 | 0.415 | 60 | $20,144.10 | $153,459.21 |
| 2015 | 4,208 | 842 | $130.44 | 1 | $130.44 | $109,830.48 | $40.94 | $34,471.48 | 0.415 | 60 | $20,965.80 | $165,267.76 |
| 5-Year Totals | | | | | | | | | | | | $645,320.11 |

*Mileage for Caregiver Training*

VA assumes that Family Caregiver training will be conducted in the proximity of the veteran's and caregiver's geographical residence. Thus, only mileage reimbursement will be provided. Costs were calculated assuming that an average of two caregivers per veteran would be undergoing training for 5 days each, for a total of 10 days. VA assumed that caregivers would drive no more than 60 miles total to attend training and would be reimbursed at a mileage rate of 41.5 cents per mile. The mileage rate of (41.5 cents per mile) is based on the beneficiary travel rate established for veterans, codified at 38 U.S.C. 111. Based on the publication date of this rulemaking (May 2011), the total travel mileage cost for FY11 is $373,085.00 and is based on 5 months only (May–Sep). Total Caseload projections for FY12 and all out years only include initial training for "new" primary and Secondary Family Caregivers (144). The 144 reflects a 4 percent (4%) population growth rate from the FY11 caseload.

| Total Estimated Travel/Mileage Cost for Caregivers Driving to Training (No Lodging) | | | | | | | |
|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Days of Travel | Total Days | Miles per Day | Total Miles | Mileage Rate | Total Travel Mileage Cost |
| 2011 | 3,596 | 10 | 35,960 | 60 | 2,157,600 | 0.415 | $373,085.00 |
| 2012 | 144 | 10 | 1,440 | 60 | 86,400 | 0.415 | $35,856.00 |
| 2013 | 150 | 10 | 1,500 | 60 | 90,000 | 0.415 | $37,350.00 |
| 2014 | 156 | 10 | 1,560 | 60 | 93,600 | 0.415 | $38,844.00 |
| 2015 | 162 | 10 | 1,620 | 60 | 97,200 | 0.415 | $40,338.00 |
| 5-Year Totals | | | | | | | $525,473.00 |

*Health Care (CHAMPVA)*

A 2010 NAC report indicates that around 70 percent of caregivers of veterans are spouses and thus likely eligible for TRICARE benefits based on the assumption that veterans eligible for this program will have received a medical retirement from the service based on 30 percent disability or greater. Therefore VA assumes that only 30 percent of Primary Family Caregivers (30% of 3,596 = 1079) will be eligible for CHAMPVA health care coverage.

Estimated costs for 1,079 Primary Caregivers in FY11 were calculated assuming seven (2) new FTE and five (5) contract or term employees for the initial start-up of the project. These staff will be utilized to verify enrollment and administer benefits for the new beneficiaries for the CHAMPVA program. In FY11, the seven (7) FTE costs represent a Denver-based GS–7/5 salary of $47,184 with a 33 percent benefit and overhead cost factor applied ($62,755). The total costs for CHAMPVA, FTE and Operating Costs in FY11 is $2,752,390.92. This amount reflects only 5 months of FTE and Medical cost (May–Sep), due to the publication date of this rulemaking (May 2011). The FTE figure was reduced to two (2) FTE for FY13–14. In FY15 there is an increase in one (1) FTE based the ratio of 1 FTE per 500 beneficiaries reflected in the caseload. A 4 percent total General Schedule Increase and Locality Payment was applied to the FTE costs beginning in FY13 through FY15. Additional costs associated with the start-up of the new program are identified in the chart below. These costs include the purchase of computers, cubicles, furniture, telephones, materials, and training to support the new Caregiver Program. The approximate cost of setup for each new FTE is $21,000.00 and ongoing training is estimated at $5,400.00 per person. The average annual cost per beneficiary for FY11 was estimated to be $5,389.00, which reflects the estimated medical cost per beneficiary when CHAMPVA is the primary payer. A 4 percent annual inflation rate was applied to the annual cost per caregiver for the out years. Based on the publication date of this rulemaking (May 2011), VA does not anticipate that the total projected caregiver caseload will apply and receive health care coverage within the 5 remaining months in FY11 (May–Sep). Caregivers must be trained and certified before they are eligible for these benefits. Therefore, the expected total medical cost per year in FY11 ($2,422,355.50) is based on 5 months only.

| Estimated Healthcare Coverage (CHAMPVA) & Operating Costs | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload | Projected # of FTE | Annual Cost per FTE w/ benefits (GS-7/5) | Total FTE Cost per Year | Start-Up & Additional Cost | Annual Medical Cost Per Caregiver | Total Medical Cost Per Year | Total Costs |
| FY11 | 1,079 | 7 | $62,755.00 | $183,035.42 | $147,000.00 | $5,389.00 | *$2,422,355.50* | $2,752,390.92 |
| FY12 | 1,122 | 7 | $62,755.00 | $439,285.00 | $37,800.00 | $5,604.56 | $6,288,316.32 | $6,765,401.32 |
| FY13 | 1,167 | 2 | $65,265.20 | $130,530.40 | $10,800.00 | $5,828.74 | $6,802,142.38 | $6,943,472.78 |
| FY14 | 1,214 | 2 | $67,875.81 | $135,751.62 | $10,800.00 | $6,061.89 | $7,359,137.00 | $7,505,688.62 |
| FY15 | 1,263 | 3 | $70,590.84 | $211,772.52 | $31,800.00 | $6,304.37 | $7,962,416.51 | $8,205,989.03 |
| 5-Year Totals | | | | | | | | $32,172,942.66 |

*Caregiver Oversight (Contract)*

Oversight for veterans and caregivers who live in remote areas will be contracted with a national home health agency. VA estimated that 40 percent of caregivers (3,596 × 40% = 1,438) would receive oversight or monitoring by VA contractors due to the veteran's or caregiver's geographical location. Costs were estimated using a home health agency contractor for one (1) visit per quarter by a registered nurse (RN) for two (2) hours per visit, using a national hourly rate of $116.40 for skilled nursing visits based on CMS Lupa rates. Based on the publication of this rulemaking (May 2011) and based on

VA's decision to ensure that the first home visit is conducted by VA clinical staff, there are no projected contract costs for FY11. A 4 percent inflation rate was applied to the cost per caregiver per/hr and a 4 percent population growth rate was applied to the projected caregiver caseload to produce costs for out years identified in the chart below.

| Estimated Caregiver Oversight (Contract) Cost | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| FY | Projected Caregiver Caseload (40%) | Hrs Per Qtr. | Total Hrs Per Qtr | Total Hrs Per Year | Cost Per Caregiver Per/Hr | Cost Per Caregiver Per Qtr | Cost Per Caregiver Per Year | Total Cost |
| FY11 | 1,438 | 0 | 0 | 0 | $116.40 | $0.00 | $0.00 | $0.00 |
| FY12 | 1,496 | 2 | 2,992 | 11,968 | $121.06 | $242.12 | $968.48 | $1,448,846.08 |
| FY13 | 1,556 | 2 | 3,112 | 12,448 | $125.90 | $251.80 | $1,007.20 | $1,567,203.20 |
| FY14 | 1,618 | 2 | 3,236 | 12,944 | $130.94 | $261.88 | $1,047.52 | $1,694,887.36 |
| FY15 | 1,683 | 2 | 3,366 | 13,464 | $136.18 | $272.36 | $1,089.44 | $1,833,527.52 |
| 5-Year Totals | 7,791 | | | | | | | $6,544,464.16 |

*Caregiver Oversight (VA)*

Based on the projected caregiver caseload (3,596), VA assumes that approximately 1,438 (40%) will utilize Telehealth in conjunction with contract oversight services compared to 2,158 (60%) that will utilize Home Based Primary Care (HBPC) or other similar services. Based on the publication of this rulemaking (May 2011), the total Telehealth and HBPC cost for FY11 is based on 5 months only. The Telehealth average cost per caregiver per month ($208.33) was provided by Telehealth Services. A 4 percent inflation rate was applied to the Telehealth average cost per caregiver per year and a 4 percent population growth to the projected caregiver caseload for all out years. Total HBPC Cost for each FY includes a 20 percent increase due to normal variation in staffing levels and geographic availability. HBPC cost per caregiver/per visit is estimated to be $583.00 (based on a four (4) hour visit including travel up to a sixty (60) mile radius and other associated costs). A 4 percent inflation rate applied for all out years.

| Total Estimated Caregiver Oversight (VA) Cost - Telehealth and HBPC | | | |
|---|---|---|---|
| FY | Telehealth | HBPC | Total Cost |
| FY11 | *$1,498,309.36* | $2,515,761.60 | $4,014,070.96 |
| FY12 | $3,889,540.16 | $6,530,793.98 | $10,420,334.14 |
| FY13 | $4,207,361.76 | $7,064,401.82 | $11,271,763.58 |
| FY14 | $4,550,010.16 | $7,639,691.18 | $12,189,701.34 |
| FY15 | $4,922,101.80 | $8,262,808.70 | $13,184,910.50 |
| 5-Year Totals | $19,067,323.24 | $32,013,457.28 | $51,080,780.52 |

| Estimated Telehealth Costs | | | | |
|---|---|---|---|---|
| FY | Projected Caregiver Caseload (40%) | Avg Cost Per Caregiver Per Month | Avg Cost Per Caregiver Per Year ($2,500) | Total Telehealth Cost |
| FY11 | 1,438 | $208.33 | $2,499.96 | *$1,498,309.36* |
| FY12 | 1,496 | $216.66 | $2,599.96 | $3,889,540.16 |
| FY13 | 1,556 | $225.33 | $2,703.96 | $4,207,361.76 |
| FY14 | 1,618 | $234.34 | $2,812.12 | $4,550,010.16 |
| FY15 | 1,683 | $243.72 | $2,924.60 | $4,922,101.80 |
| 5-Year Totals | | | | $19,067,323.24 |

| Estimated HBPC Costs | | | | |
|---|---|---|---|---|
| FY | Projected Caregiver Caseload (60%) | Cost Per Caregiver/ Per Visit | # of Visits per Year | Total HBPC Cost |
| FY11 | 2,158 | $583.00 | 4 | $2,515,761.60 |
| FY12 | 2,244 | $606.32 | 4 | $6,530,793.98 |
| FY13 | 2,334 | $630.57 | 4 | $7,064,401.82 |
| FY14 | 2,427 | $655.79 | 4 | $7,639,691.18 |
| FY15 | 2,524 | $682.02 | 4 | $8,262,808.70 |
| 5-Year Totals | | | | $32,013,457.28 |

*Caregiver Support Line*

The toll-free National Caregiver Support Line is staffed by licensed clinical social workers and will be available to answer questions from Caregivers, veterans, and members of the public as well as directing calls to their local Caregiver Support Coordinator. The costs for annual salary plus benefits include a 10 percent adjustment for night/weekend differentials, since the support line is staffed from Monday through Friday 8 a.m. to 11 p.m. and Saturday 10:30 a.m. to 6 p.m. Eastern Standard Time. The estimated costs for the facilities contract include: Human Resources costs, housekeeping, furniture, IT equipment, supplies, and other miscellaneous support expenses. The total costs projections will be based upon a Memorandum of Understanding between the VA Facility and the Caregiver Support Program. VA assumes $520,156.33 for initial start-up costs in FY11, with maintenance costs of $148,375.20 in FY12, adjusted for inflation at 4 percent for all out years.

| Caregiver Support Line | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| FTEE | 1 | 2 | 16 | 4 | 1 | 1 | 1 | | | |
| Title | Support Line Manager | Support Line Supervisors | Support Line Social Workers | Support Line Health Techs | Support Line Admin Officer | Support Line Program Asst. | Program Coordinator | | | |
| Grade | GS-14/5 | GS-12/5 | GS-11/5 | GS-6-7/5 | GS-9-11/5 | GS-6/5 | GS-13/5 | | | |
| Annual Salary + benefits | $153,413 | $109,176 | $91,085 | $61,550 | $91,085 | $55,384 | $129,825 | Total FTE Cost | Facilities Contract Costs | Total Costs |
| FY11 | $63,922.25 | $90,980.17 | $607,236.00 | $102,582.67 | $37,952.25 | $23,076.67 | $54,093.67 | $979,843.67 | $520,156.33 | $1,500,000.00 |
| FY12 | $153,413.40 | $218,352.40 | $1,457,366.40 | $246,198.40 | $91,085.40 | $55,384.00 | $129,824.80 | $2,351,624.80 | $148,375.20 | $2,500,000.00 |
| FY13 | $159,550.00 | $227,086.00 | $1,515,661.06 | $256,046.34 | $94,728.82 | $57,599.36 | $135,017.79 | $2,445,689.37 | $154,310.21 | $2,599,999.58 |
| FY14 | $165,932.00 | $236,169.00 | $1,576,287.50 | $266,288.19 | $98,517.97 | $59,903.33 | $140,418.50 | $2,543,516.49 | $160,482.62 | $2,703,999.11 |
| FY15 | $172,569.00 | $245,616.00 | $1,639,339.00 | $276,939.72 | $102,458.69 | $62,299.46 | $146,035.24 | $2,645,257.11 | $166,901.92 | $2,812,159.03 |
| 5-Year Cost | $715,386.65 | $1,018,203.57 | $6,795,889.96 | $1,148,055.32 | $424,743.13 | $258,262.82 | $605,390.00 | $10,965,931.44 | $1,150,226.28 | $12,116,157.72 |

*Study and Survey*

Estimated costs were based on MOU with a VA facility and the required resources to conduct a caregiver study/survey, which will evaluate the program and identify unmet caregiver needs.

| Study and Survey Cost | |
|---|---|
| FY | Total Cost |
| FY11 | $245,959.20 |
| FY12 | $238,359.20 |
| FY13 | $225,859.20 |
| FY14 | $0.00 |
| FY15 | $0.00 |
| 5 Year Total | $710,177.60 |

| Staffing | | YEAR 1 | YEAR 2 | YEAR 3 |
|---|---|---|---|---|
| Director (25% FTE) | | $30,138.00 | $30,138.00 | $30,138.00 |
| Health Services Researcher & Clinician (Content Expert) (5%FTE) | | $6,640.00 | $6,640.00 | $6,640.00 |
| Epidemiologist (25% FTE) | | $37,705.00 | $37,705.00 | $37,705.00 |
| Statistician (15% FTE) | | $19,050.00 | $19,050.00 | $19,050.00 |
| Statistician (MA level) (25% FTE Years 1 & 3 & 50% Year 2) | | $12,500.00 | $25,000.00 | $12,500.00 |
| Health Economist(15% FTE) | | $19,242.20 | $19,242.20 | $19,242.20 |
| Health Services Data Systems Expert (10%) | | $13,280.00 | $13,280.00 | $13,280.00 |
| Coordinator TBN (100% FTE) | | $57,404.00 | $57,404.00 | $57,404.00 |
| Total Cost | | $195,959.20 | $208,459.20 | $195,959.20 |
| OTHER COSTS | SUBCONTRACT | YEAR 1 | YEAR 2 | YEAR 3 |
| Systematic Review of the Literature (pre-survey) | VA Evidence Synthesis Center (to be completed Year 1) | $50,000.00 | | |
| Survey Administration (see attached) | Subcontract with Survey Research Center (to be completed Year 2) | | $29,900.00 | $29,900.00 |
| | Totals: | $245,959.20 | $238,359.20 | $225,859.20 |

*Outreach and Additional Support Programs*

Estimated costs for the additional support programs below are $3,811,561.00 for FY11 and $15,010,932.00 over a 5 year period. Cost estimates for outreach and support programs are based on price estimates provided by leading national non-profit and for-profit firms.

| Estimated Total Outreach and Additional Support Program Costs | | | | | | |
|---|---|---|---|---|---|---|
| *Description of Outreach Services and Support Programs* | FY11 | FY12 | FY13 | FY14 | FY15 | 5-Year Totals |
| Resources for Enhancing All Caregivers Health | $676,799.00 | $300,871.00 | $312,906.00 | $325,422.00 | $338,439.00 | $1,954,437.00 |
| Caregiver Notebooks, Training Manuals | $410,658.00 | $37,084.00 | $38,568.00 | $40,110.00 | $41,715.00 | $568,135.00 |
| Wellness/Prevention Education and Training | $135,959.00 | $141,398.00 | $147,053.00 | $119,910.00 | $124,706.00 | $669,026.00 |
| Transitional Assistance Program for Caregivers | $455,041.00 | $473,243.00 | $319,116.00 | $331,881.00 | $345,156.00 | $1,924,437.00 |
| Estimated Educational Outreach | $623,810.00 | $648,762.00 | $674,713.00 | $701,701.00 | $729,769.00 | $3,378,755.00 |
| Website and Training Cost | $924,294.00 | $500,000.00 | $500,000.00 | $500,000.00 | $500,000.00 | $2,924,294.00 |
| Caregiver Development | $585,000.00 | $572,000.00 | $780,000.00 | $811,200.00 | $843,648.00 | $3,591,848.00 |
| 5-Year Totals | $3,811,561.00 | $2,673,358.00 | $2,772,356.00 | $2,830,224.00 | $2,923,433.00 | $15,010,932.00 |

*Identification of Duplicative, Overlapping, or Conflicting Federal Rules*

There are no duplicative, overlapping, or conflicting Federal rules identified with this regulatory action.

*Accounting Statement and Table*

As required by OMB Circular A–4, in the table below, VA has prepared an accounting statement showing the classification of transfers, benefits and costs associated with the provisions of this rulemaking. Some portions of the analysis rely upon assumptions that may change, due to the unpredictability of catastrophic and severe injuries resulting from military service and combat during war. The analysis for this rulemaking sets forth the basic assumptions, methods, and data underlying the analysis and discusses the uncertainties associated with the estimates. As VA develops claims data and becomes more cognizant of the cost of caregiver benefits, VA will make appropriate adjustments in the amount of funds requested for future fiscal years.

| Category | | Transfers | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Federal Annualized Monetized Transfers | Year Dollar | | | | | | | | | |
| | 2011 | FY2011 | FY2012 | FY2013 | FY2014 | FY2015 | Present Value | | Annualized | |
| | | | | | | | 3% | 7% | 3% | 7% |
| | | $66.0 | $149.0 | $159.0 | $171.0 | $184.0 | $660.7 | $583.3 | $140.1 | $132.9 |
| **Category** | | **Benefits** | | | | | | | | |
| Qualitative benefits | | To benefit eligible veterans whose personal care service needs could be substantially satisfied with the provision of such services by a family member (as defined in the law); and to provide eligible veterans with additional options so that they can choose the setting for the receipt of personal care services that best suits their needs. | | | | | | | | |
| **Category** | | **Costs (Example PRA, any costs to beneficary)** | | | | | | | | |
| Costs | | The interim final rule at § 71.25(a) contains application provisions for individuals who wish to be considered for designation by VA as Primary or Secondary Family Caregivers for certain veterans. Description of likely respondents: veterans' family members. Estimated number of respondents per year: 5,000, estimated frequency of responses per year: 1, estimated total annual reporting and recordkeeping burden: 1,250 hours and estimated annual burden per collection: 15 minutes. | | | | | | | | |

*Catalog of Federal Domestic Assistance*

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, 64.015, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care.

*Signing Authority*

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on April 28, 2011, for publication.

**List of Subjects**

*38 CFR Part 17*

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

*38 CFR Part 71*

Administrative practice and procedure, Caregivers program, Claims, Health care, Health facilities, Health professions, Mental health programs, Travel and transportation expenses, Veterans.

Dated: May 2, 2011.

**Robert C. McFetridge,**

*Director, Regulations Policy and Management, Department of Veterans Affairs.*

For the reasons stated in the preamble, VA amends 38 CFR Chapter I as follows:

## PART 17—MEDICAL

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

**Authority:** 38 U.S.C. 510, and as noted in specific sections.

### § 17.38 [Amended]

■ 2. Section 17.38(a)(1)(vii) is amended by removing "treatment." and adding, in its place, "treatment as authorized under 38 CFR 71.50."

■ 3. Part 71 is added to read as follows:

## PART 71—CAREGIVERS BENEFITS AND CERTAIN MEDICAL BENEFITS OFFERED TO FAMILY MEMBERS OF VETERANS

Sec.
71.10 Purpose and scope.
71.15 Definitions.
71.20 Eligible veterans and servicemembers.
71.25 Approval and Designation of Primary and Secondary Family Caregivers.
71.30 General Caregivers.
71.40 Caregiver benefits.
71.45 Revocation.
71.50 Provision of certain counseling, training, and mental health services to certain family members of veterans.

(Authority: 38 U.S.C. 501, 1720G, and as noted in specific sections)

### § 71.10 Purpose and scope.

(a) *Purpose.* This part implements VA's caregiver benefits program, which, among other things, provides certain benefits to eligible veterans who have incurred or aggravated serious injuries during military service, and to their caregivers.

(b) *Scope.* This part regulates the provision of caregiver benefits authorized by 38 U.S.C. 1720G. Persons eligible for caregiver benefits may be eligible for other VA benefits based on other laws or other parts of title 38, CFR.

(Authority: 38 U.S.C. 501, 1720G)

### § 71.15 Definitions.

For the purposes of this part:

*Eligible veteran* means a veteran, or a servicemember, who is found eligible for a Family Caregiver under § 71.20.

*Family Caregiver* means both a Primary and Secondary Family Caregiver.

*General Caregiver* means an individual who meets the requirements of § 71.30.

*Inability to perform an activity of daily living (ADL)* means any one of the following:

(1) Inability to dress or undress oneself;

(2) Inability to bathe;

(3) Inability to groom oneself in order to keep oneself clean and presentable;

(4) Frequent need of adjustment of any special prosthetic or orthopedic appliance that, by reason of the particular disability, cannot be done without assistance (this does not include the adjustment of appliances that nondisabled persons would be unable to adjust without aid, such as supports, belts, lacing at the back, etc.);

(5) Inability to toilet or attend to toileting without assistance;

(6) Inability to feed oneself due to loss of coordination of upper extremities, extreme weakness, inability to swallow, or the need for a non-oral means of nutrition; or

(7) Difficulty with mobility (walking, going up stairs, transferring from bed to chair, etc.).

*In the best interest* means, for the purpose of determining whether it is in the best interest of the eligible veteran to participate in the Family Caregiver program under 38 U.S.C. 1720G(a), a clinical determination that participation in such program is likely to be beneficial to the eligible veteran. Such determination will include consideration, by a clinician, of whether participation in the program significantly enhances the eligible veteran's ability to live safely in a home setting, supports the eligible veteran's potential progress in rehabilitation, if such potential exists, and creates an environment that supports the health and well-being of the eligible veteran.

*Need for supervision or protection based on symptoms or residuals of neurological or other impairment or injury* means requiring supervision or assistance for any of the following reasons:

(1) Seizures (blackouts or lapses in mental awareness, etc.);

(2) Difficulty with planning and organizing (such as the ability to adhere to medication regimen);

(3) Safety risks (wandering outside the home, danger of falling, using electrical appliances, etc.);

(4) Difficulty with sleep regulation;

(5) Delusions or hallucinations;

(6) Difficulty with recent memory; and

(7) Self regulation (being able to moderate moods, agitation or aggression, etc.).

*Personal care services* means care or assistance of another person necessary in order to support the eligible veteran's health and well-being, and perform personal functions required in everyday living ensuring the eligible veteran remains safe from hazards or dangers incident to his or her daily environment.

*Primary care team* means a group of medical professionals who care for a patient and who are selected based on the clinical needs of the patient. The team must include a primary care provider who coordinates the care, and may include clinical specialists (e.g., a neurologist, psychiatrist, etc.), resident physicians, nurses, physicians' assistants, nurse practitioners, occupational or rehabilitation therapists, social workers, etc., as indicated by the needs of the particular veteran.

*Primary Family Caregiver* means an individual who meets the requirements of § 71.25.

*Secondary Family Caregiver* means an individual who meets the requirements of § 71.25.

*Serious injury* means any injury, including traumatic brain injury, psychological trauma, or other mental disorder, incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, that renders the veteran or servicemember in need of personal care services.

*Undergoing medical discharge* means that the servicemember has been found unfit for duty due to a medical condition by their Service's Physical Evaluation Board, and a date of medical discharge has been issued.

*VA* refers to the Department of Veterans Affairs.

(Authority: 38 U.S.C. 501, 1720G)

**§ 71.20 Eligible veterans and servicemembers.**

A veteran or servicemember is eligible for a Primary or Secondary Family Caregiver under this part if she or he meets all of the following requirements:

(a) The individual is either:

(1) A veteran; or

(2) A member of the Armed Forces undergoing a medical discharge from the Armed Forces.

(b) The individual has a serious injury, including traumatic brain injury, psychological trauma, or other mental disorder, incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001.

(c) Such serious injury renders the individual in need of personal care services for a minimum of 6 continuous months (based on a clinical determination), based on any one of the following clinical criteria:

(1) An inability to perform an activity of daily living.

(2) A need for supervision or protection based on symptoms or residuals of neurological or other impairment or injury, including traumatic brain injury.

(3) Psychological trauma or a mental disorder that has been scored, by a licensed mental health professional, with Global Assessment of Functioning (GAF) test scores of 30 or less, continuously during the 90-day period immediately preceding the date on which VA initially received the caregiver application. VA will consider a GAF score to be "continuous" if there are at least two scores during the 90-day period (one that shows a GAF score of 30 or less at the beginning of the 90-day period and one that shows a GAF score of 30 or less at the end of the 90-day period) and there are no intervening GAF scores of more than 30.

(4) The veteran is service connected for a serious injury that was incurred or aggravated in the line of duty in the active military, naval, or air service on or after September 11, 2001, and has been rated 100 percent disabled for that serious injury, and has been awarded special monthly compensation that includes an aid and attendance allowance.

(d) A clinical determination has been made that it is in the best interest of the individual to participate in the program.

(e) Personal care services that would be provided by the Family Caregiver will not be simultaneously and regularly provided by or through another individual or entity.

(f) The individual agrees to receive care at home after VA designates a Family Caregiver.

(g) The individual agrees to receive ongoing care from a primary care team after VA designates a Family Caregiver.

(Authority: 38 U.S.C. 501, 1720G(a)(2))

**§ 71.25 Approval and Designation of Primary and Secondary Family Caregivers.**

(a) *Application requirement.* (1) Individuals who wish to be considered for designation by VA as Primary or Secondary Family Caregivers must complete and sign a joint application, along with the veteran or

servicemember. Individuals interested in serving as Family Caregivers must be identified as such on the joint application, and no more than three individuals may serve as Family Caregivers at one time for an eligible veteran, with no more than one serving as the Primary Family Caregiver.

(2) Upon receiving such application, VA will perform the clinical evaluations required by this section; determine whether the application should be granted; and, if so, whether each applicant should be designated as identified in the application.

(3) An application may be put on hold for no more than 90 days, from the date the application was received, for a veteran or servicemember seeking to qualify through a GAF test score of 30 or less but who does not have a "continuous" GAF score available.

(b) *Eligibility to serve as Primary or Secondary Family Caregiver.* In order to serve as a Primary or Secondary Family Caregiver, the applicant must meet all of the following requirements:

(1) Be at least 18 years of age.

(2) Be either:

(i) The eligible veteran's spouse, son, daughter, parent, step-family member, or extended family member; or

(ii) Someone who lives with the eligible veteran full-time or will do so if designated as a Family Caregiver.

(3) There must be no determination by VA of abuse or neglect of the eligible veteran by the applicant.

(4) Meet the requirements of paragraph (c) of this section, and any other applicable requirements of this part.

(c) *Assessment, education, and training of applicants.* Before VA approves an applicant to serve as a Primary or Secondary Family Caregiver, the applicant must:

(1) Be initially assessed by a VA primary care team as being able to complete caregiver education and training. Such assessment will consider any relevant information specific to the needs of the eligible veteran, as well as:

(i) Whether the applicant can communicate and understand details of the treatment plan and any specific instructions related to the care of the eligible veteran (accommodation for language or hearing impairment will be made as appropriate); and

(ii) Whether the applicant will be capable of following without supervision a treatment plan listing the specific care needs of the eligible veteran.

(2) Complete caregiver training and demonstrate the ability to carry out the specific personal care services, core competencies, and other additional care requirements prescribed by the eligible veteran's primary care team.

(d) *Caregiver education and training.* For the purposes of this section, caregiver training is a program of education and training designed by and provided through VA that consists of issues that are generally applicable to Family Caregivers, as well as issues specific to the needs of the eligible veteran. During this program of education and training, family members are eligible for beneficiary travel under 38 CFR part 70. Respite care will be provided during the period of initial caregiver instruction, preparation, and training if the participation would interfere with the provision of personal care services to the eligible veteran. Caregiver training will cover, at a minimum, education and training concerning the following core competencies:

(1) Medication management;

(2) Vital signs and pain control;

(3) Infection control;

(4) Nutrition;

(5) Functional activities;

(6) Activities of daily living;

(7) Communication and cognition skills;

(8) Behavior management skills;

(9) Skin care; and

(10) Caregiver self-care.

(e) *Initial home-care assessment.* No later than 10 business days after completion of Caregiver education and training, or should an eligible veteran be hospitalized during this process, no later than 10 days from the date the eligible veteran returns home, a VA clinician or a clinical team will visit the eligible veteran's home and assess the Caregiver's completion of training and competence to provide personal care services at the eligible veteran's home, to measure the eligible veteran's well being.

(f) *Approval and designation.* If the eligible veteran and at least one applicant meet the requirements of this part, VA will approve the application and designate Primary and/or Secondary Family Caregivers, as appropriate. This approval and designation will be a clinical determination authorized by the eligible veteran's primary care team. Approval and designation is conditioned on the eligible veteran and designated Family Caregivers remaining eligible for caregiver benefits under this part.

(Authority: 38 U.S.C. 501, 1720G)

**§ 71.30 General Caregivers.**

(a) A General Caregiver is a person who:

(1) Is not a Primary or Secondary Family Caregiver; and

(2) Provides personal care services to a covered veteran under this section, even if the individual does not reside with the veteran.

(b) A covered veteran, for purposes of this section, is a veteran who is enrolled in the VA health care system and needs personal care services because the veteran either:

(1) Is unable to perform an activity of daily living; or

(2) Needs supervision or protection based on symptoms or residuals of neurological care or other impairment or injury.

(c) No application or clinical evaluation is required to obtain benefits as a General Caregiver. Veterans or General Caregivers may request any of the benefits listed in § 71.40(a) as needed, from the appropriate VA clinicians and staff at their local VA facilities.

(d) A veteran is not required to meet the eligibility requirements in § 71.20 to be considered a covered veteran.

(Authority: 38 U.S.C. 501, 1720G(b)(1), (2))

**§ 71.40 Caregiver benefits.**

(a) *General Caregiver benefits.* VA will provide to General Caregivers all of the benefits listed in paragraphs (a)(1) through (4) of this section.

(1) Continued instruction, preparation, training, and technical support. Caregivers will have access to each of the following services, which may be provided through:

(i) Online and in-person educational sessions.

(ii) Use of telehealth and other available technologies.

(iii) Teaching techniques, strategies, and skills for caring for the eligible or covered veteran.

(2) Information concerning the supportive services available to caregivers under paragraph (a) of this section and other public, private, and nonprofit agencies that offer support to caregivers.

(3) Counseling and other services, as described under § 71.50.

(4) Respite care to eligible and covered veterans in support of the caregiver that is medically and age appropriate for the eligible or covered veteran (including 24-hour per day in-home respite care).

(b) *Secondary Family Caregiver benefits.* VA will provide to Secondary Family Caregivers all of the benefits listed in paragraphs (b)(1) through (6) of this section.

(1) General Caregiver benefits described in paragraph (a) of this section, except that respite care under paragraph (a)(4) is limited to veterans

enrolled in the VA health care system. Respite care may be provided during a Family Caregiver's training, as described under § 71.25(d).

(2) The primary care team will maintain the eligible veteran's treatment plan and collaborate with clinical staff making home visits to monitor the eligible veteran's well-being, adequacy of care and supervision being provided. This monitoring will occur no less often than every 90 days, unless otherwise clinically indicated, and will include an evaluation of the overall health and well-being of the eligible veteran.

(3) Continuing instruction, preparation, and training to maintain or improve the personal care services provided to the eligible veteran.

(4) Ongoing technical support, consisting of information and assistance to address, in a timely manner, the routine, emergency, and specialized needs of the Caregiver in providing personal care services to the eligible veteran.

(5) Counseling, which for the purposes of paragraph (b) of this section includes individual and group therapy, individual counseling, and peer support groups. Counseling does not include the provision of medication, inpatient psychiatric care, or other medical procedures related to mental health treatment.

(6) Primary and Secondary Family Caregivers are to be considered eligible for beneficiary travel under 38 CFR part 70.

(c) *Primary Family Caregiver Benefits.* VA will provide to Primary Family Caregivers all of the benefits listed in paragraphs (c)(1) through (4) of this section.

(1) Secondary Family Caregiver benefits, as listed under paragraph (b) of this section.

(2) Respite care includes 24-hour-per day care of the eligible veteran commensurate with the care provided by the Family Caregiver to permit extended respite. Respite care will be available for at least 30 days per year and may exceed 30 days per year if clinically appropriate and if requested by the Primary Family Caregiver.

(3) Primary Family Caregivers are to be considered eligible for enrollment in the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), unless they are entitled to care or services under a health-plan contract (as defined in 38 U.S.C. 1725(f)).

(4) Primary Family Caregivers will receive a monthly stipend for each prior month's participation as a Primary Family Caregiver. To determine the stipend amount, VA first will determine the eligible veteran's level of dependency based on the degree to which the eligible veteran is unable to perform one or more activities of daily living (ADLs), or the degree to which the eligible veteran is in need of supervision or protection based on symptoms or residuals of neurological or other impairment or injury, as follows:

(i) VA will clinically rate the eligible veteran's inability to perform each of the seven ADLs listed in the definition of that term in § 71.15.

(ii) VA will clinically rate the eligible veteran's need for supervision or protection based on symptoms or residuals of neurological or other impairment or injury using the seven impairments listed in the definition of that term in § 71.15.

(iii) Clinical ratings under paragraphs (c)(4)(i) and (ii) of this section will be scored as follows: VA will assign a zero if the eligible veteran completes the task/activity without assistance; one if the eligible veteran requires minimal assistance (can complete 75 percent or more of the task without supervision or assistance); two if the eligible veteran requires moderate assistance (can complete 50 percent to 74 percent of the task without assistance); three if the eligible veteran requires maximal assistance (can complete 25 percent to 49 percent of the task without assistance); or four if the eligible veteran requires total assistance (can complete less than 25 percent of the task or is unable to do the task without assistance).

(iv) If the sum of all of the ratings assigned is:

(A) 21 or higher, then the eligible veteran is presumed to require 40 hours per week of Caregiver assistance.

(B) 13 to 20, then the eligible veteran is presumed to require 25 hours per week of Caregiver assistance.

(C) 1 to 12, then the eligible veteran is presumed to require 10 hours per week of Caregiver assistance.

(v) The monthly stipend payment will be calculated by multiplying the Bureau of Labor Statistics hourly wage for home health aides in the geographic area by the Consumer Price Index and then multiplying that total by the number of weekly hours of Caregiver assistance required under paragraph (c)(4)(iv) of this section. This product will then be multiplied by 4.35.

(vi) Stipend payments for the first month will be adjusted based on the number of days remaining in the month. Stipend payments will also be prorated where a Primary Family Caregiver's status is revoked and/or a new Primary Family Caregiver is designated prior to the end of a month. *See* § 71.45, Revocation.

(vii) Nothing in this section shall be construed to create an employment relationship between the Secretary and an individual in receipt of assistance or support under this part.

(d) *Effective date and payment date of benefits*—(1) *Effective date.* Caregiver benefits are effective as of the date that the signed joint application is received by VA or the date on which the eligible veteran begins receiving care at home, whichever is later. However, benefits will not be provided until the individual is designated as a Family Caregiver. Individuals who apply to be Family Caregivers must complete all necessary education, instruction, and training so that VA can complete the designation process no later than 30 days after the date that the joint application was submitted or, if the application has been placed on hold for a GAF assessment, 30 days after the hold has been lifted, or a new joint application will be required to serve as the date of application for payment purposes.

(2) *Payment date.* The stipend is paid monthly for personal care services that the Primary Family Caregiver provided in the prior month. Benefits due prior to such designation, based on the date of application, will be paid retroactive to the date that the joint application is received by VA or the date on which the eligible veteran begins receiving care at home, whichever is later.

(Authority: 38 U.S.C. 111(e), 501, 1720B, 1720G, 1782)

**§ 71.45 Revocation.**

(a) *Revocation by the Family Caregiver.* The Family Caregiver may request a revocation of caregiver status in writing and provide the present or future date of revocation. All caregiver benefits will continue to be provided to the Family Caregiver until the date of revocation. VA will, if requested and applicable, assist the Family Caregiver in transitioning to alternative health care coverage and with mental health services.

(b) *Revocation by the veteran, servicemember, or surrogate.* The veteran, servicemember, or the eligible veteran's surrogate may initiate revocation of a Primary or Secondary Family Caregiver.

(1) The revocation request must be in writing and must express an intent to remove the Family Caregiver.

(2) VA will notify the Family Caregiver verbally and in writing of the request for removal.

(3) VA will review the request for revocation and determine whether there

is a possibility for remediation. This review will take no longer than 30 days. During such review, the veteran, servicemember, or surrogate may rescind the request for revocation. If VA suspects that the safety of the eligible veteran is at risk, then VA may suspend the caregiver's responsibilities, and remove the eligible veteran from the home if requested by the eligible veteran, prior to making a formal revocation.

(4) Caregiver benefits will continue for 30 days after the date of revocation, and VA will, if requested by the Family Caregiver, assist the individual with transitioning to alternative health care coverage and with mental health services, unless one of the following is true, in which case benefit will terminate immediately:

(i) VA determines that the Family Caregiver committed fraud or abuse or neglect of the eligible veteran.

(ii) If the revoked individual was the Primary Family Caregiver, and another Primary Family Caregiver is assigned within 30 days after the date of revocation.

(iii) If another individual is assigned to be a Family Caregiver within 30 days after the date of revocation, such that there are three Family Caregivers assigned to the eligible veteran.

(iv) The revoked individual had been living with the eligible veteran and moves out, or the revoked individual abandons or terminates his or her relationship with the eligible veteran.

(c) *Revocation by VA.* VA may immediately revoke the designation of a Family Caregiver if the eligible veteran or individual designated as a Family Caregiver no longer meets the requirements of this part, or if VA makes the clinical determination that having the Family Caregiver is no longer in the best interest of the eligible veteran. VA will, if requested by the Family Caregiver, assist him or her in transitioning to alternative health care coverage and with mental health services. If revocation is due to improvement in the eligible veteran's condition, death, or permanent institutionalization, the Family Caregiver will continue to receive caregiver benefits for 90 days, unless any of the conditions described in paragraph (b)(4)(i) through (iv) of this section apply, in which case benefits will terminate immediately. In addition, bereavement counseling may be available under 38 U.S.C. 1783. If VA suspects that the safety of the eligible veteran is at risk, then VA may suspend the caregiver's responsibilities, and remove the eligible veteran from the home if requested by the eligible veteran or take other appropriate action to ensure the welfare of the eligible veteran, prior to making a formal revocation.

(Authority: 38 U.S.C. 501, 1720G)

**§ 71.50 Provision of certain counseling, training, and mental health services to certain family members of veterans.**

(a) *Benefits provided under this section.* VA will provide consultation, professional counseling, marriage and family counseling, training, and mental health services to a family member when necessary in connection with the treatment of a disability for which the veteran is receiving treatment through VA. For the purposes of this section, provision of a benefit is "in connection with the treatment" of a veteran's disability if, in the clinical judgment of a VA medical professional who is providing treatment to the veteran, the provision of the benefit to the family member would further the objectives of the veteran's medical treatment plan. The listed benefits provided under this section are to be provided within the following guidelines:

(1) All benefits will consist of psychotherapy, counseling, training, or education; VA will not provide prescriptions or medications to family members. VA also will not provide inpatient services under this section.

(2) This section does not authorize the provision of clinical evaluation or treatment that is not necessary in connection with the veteran's treatment or that involves treatment other than consultation, professional counseling, marriage and family counseling, training, and mental health services.

(3) Marriage and family counseling includes services to help the veteran address mental health issues, manage physical health problems, and strengthen environmental supports as specified in the veteran's treatment plan. It also includes interventions to reduce the negative impact for the veteran of mental illnesses or other medical conditions in family members.

(b) *Definition of family member.* For the purpose of this section, which provides certain benefits and services to eligible family members, a family member is:

(1) A person related to the veteran by birth or marriage who lives with the veteran or has regular personal contact with the veteran;

(2) The veteran's legal guardian or surrogate;

(3) A Primary or Secondary Family Caregiver or a General Caregiver; or

(4) The individual in whose household the veteran has certified an intention to live.

(c) *Family members or caregivers who need treatment not related to the treatment of the veteran.* Where a VA clinician believes that medical care or services are needed for a family member but cannot provide benefits under this section because such need is not necessary in connection with the treatment of the veteran, VA may refer such family member to an appropriate provider in the community, so that the family member may obtain care through other health coverage including care to which a Primary or Secondary Family Caregiver may be eligible under this part.

(Authority: 38 U.S.C. 1720G, 1782)

[FR Doc. 2011–10962 Filed 5–3–11; 4:15 pm]

BILLING CODE 8320–01–P

# Reader Aids

**Federal Register**

Vol. 76, No. 87

Thursday, May 5, 2011

## CUSTOMER SERVICE AND INFORMATION

| | |
|---|---|
| **Federal Register/Code of Federal Regulations** | |
| General Information, indexes and other finding aids | **202–741–6000** |
| **Laws** | **741–6000** |
| **Presidential Documents** | |
| Executive orders and proclamations | **741–6000** |
| **The United States Government Manual** | **741–6000** |
| **Other Services** | |
| Electronic and on-line services (voice) | **741–6020** |
| Privacy Act Compilation | **741–6064** |
| Public Laws Update Service (numbers, dates, etc.) | **741–6043** |
| TTY for the deaf-and-hard-of-hearing | **741–6086** |

## ELECTRONIC RESEARCH

### World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

### E-mail

**FEDREGTOC-L** (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

**PENS** (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

**FEDREGTOC-L** and **PENS** are mailing lists only. We cannot respond to specific inquiries.

**Reference questions.** Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

**Reminders.** Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

**CFR Checklist.** Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

## FEDERAL REGISTER PAGES AND DATE, MAY

24339–24786 ..... 2
24787–25210 ..... 3
25211–25514 ..... 4
25515–26176 ..... 5

## CFR PARTS AFFECTED DURING MAY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

**3 CFR**

**Proclamations:**
8658 ..... 24785
8659 ..... 25515
8660 ..... 25517
8661 ..... 25519
8662 ..... 25521
8663 ..... 25523
8664 ..... 25525
8665 ..... 25527
8666 ..... 25529
8667 ..... 25531

**Executive Orders:**
13571 ..... 24339
13572 ..... 24787

**Administrative Orders:**
01 ..... 24791

**5 CFR**

**Proposed Rules:**
550 ..... 24406
2640 ..... 24816

**7 CFR**

28 ..... 25533
4288 ..... 24343

**Proposed Rules:**
205 ..... 25612
271 ..... 24820, 25414
272 ..... 24820, 25414
273 ..... 25414
275 ..... 24820
1208 ..... 25618
1210 ..... 25619

**9 CFR**

93 ..... 24793
94 ..... 24793
95 ..... 24793
321 ..... 24714
332 ..... 24714
381 ..... 24714

**10 CFR**

429 ..... 24762
430 ..... 24762, 25211

**Proposed Rules:**
26 ..... 24831
61 ..... 24831
431 ..... 25622

**14 CFR**

25 ..... 25229
39 ..... 24343, 24345, 24349, 24351, 24354, 24356, 24358, 24360, 24793, 24796, 24798, 25534, 25535
71 ..... 25537
97 ..... 25231, 25232

**Proposed Rules:**
25 ..... 25648
39 ..... 24407, 24832, 25259, 25264
71 ..... 24409
460 ..... 24836

**17 CFR**

**Proposed Rules:**
Ch. I ..... 25274
229 ..... 25273
240 ..... 25273

**19 CFR**

210 ..... 24363

**20 CFR**

404 ..... 24802
405 ..... 24802
416 ..... 24802
422 ..... 24802

**21 CFR**

1 ..... 25531, 25542
73 ..... 25234

**24 CFR**

200 ..... 24363
207 ..... 24363

**26 CFR**

301 ..... 24813

**29 CFR**

1910 ..... 24576
1915 ..... 24576

**30 CFR**

**Proposed Rules:**
70 ..... 25277
71 ..... 25277
72 ..... 25277
75 ..... 25277
90 ..... 25277
104 ..... 25277

**31 CFR**

**Proposed Rules:**
1069 ..... 24410

**33 CFR**

117 ..... 24372
165 ..... 24813, 25545, 25548

**Proposed Rules:**
165 ..... 24837, 24840, 24843, 25278

**34 CFR**

**Proposed Rules:**
Ch. VI ..... 25650

**38 CFR**

17 ..... 26148
71 ..... 26148

**40 CFR**

52.....24372, 25178
180.....25236, 25240
1042.....25246

**Proposed Rules:**

52 .....24421, 24846, 25652
60.....24976
63.....24976
180.....25281

**42 CFR**

482.....25550
485.....25550

**Proposed Rules:**

412.....25788
413.....25788
476.....25788
482.....25460
485.....25460
491.....25460
494.....25460

**47 CFR**

0.....24376, 24383
1.....24376, 24383
64.....24393

**Proposed Rules:**

0.....24434
1.....24434
64.....24437, 24442
73.....24846

**48 CFR**

211.....25565
216.....25566
223.....25569
237.....25565
252.....25566, 25569

**Proposed Rules:**

4.....24443
8.....24443
17.....24443
37.....24443
52.....24443
1809.....25656
1812.....25657
1828.....25657
1852.....25657

**49 CFR**

195.....25576
395.....25588
451.....24402

**50 CFR**

17.....25590, 25593
218.....25480
660.....25246
679.....24403, 24404

**Proposed Rules:**

17.....25150, 26086
226.....25660
648.....24444
679.....25295

## LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

**S. 307/P.L. 112–11**
To designate the Federal building and United States courthouse located at 217 West King Street, Martinsburg, West Virginia, as the "W. Craig Broadwater Federal Building and United States Courthouse". (Apr. 25, 2011; 125 Stat. 213)

**S.J. Res. 8/P.L. 112–12**
Providing for the appointment of Stephen M. Case as a citizen regent of the Board of Regents of the Smithsonian Institution. (Apr. 25, 2011; 125 Stat. 214)

**Last List April 19, 2011**

## Public Laws Electronic Notification Service (PENS)

**PENS** is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

**Note:** This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.