

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 414, and 424

[CMS-1540-F]

RIN 0938-A016

**Medicare Program; Inpatient Rehabilitation Facility
Prospective Payment System for Federal Fiscal Year 2007;
Certain Provisions Concerning Competitive Acquisition for
Durable Medical Equipment, Prosthetics, Orthotics, and
Supplies (DMEPOS); Accreditation of DMEPOS Suppliers**

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

ACTION: Final rule.

SUMMARY: This final rule will update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2007 (for discharges occurring on or after October 1, 2006 and on or before September 30, 2007) as required under section 1886(j)(3)(C) of the Social Security Act (the Act).

We are revising existing policies regarding the prospective payment system within the authority granted under section 1886(j) of the Act. In addition, we are revising the current regulation text to reflect the changes

enacted under section 5005 of the Deficit Reduction Act of 2005.

This final rule will also establish certain requirements related to competitive acquisition for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and establish accreditation of DMEPOS suppliers as required under section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

EFFECTIVE DATES: The regulatory changes to part 412 of 42 CFR are effective October 1, 2006. The regulatory changes to part 414 of 42 CFR, other than § 414.406(e), are effective [**OFR: Insert date 30 days after display**]. The regulatory changes to part 424 of 42 CFR are effective [**OFR: Insert date 60 days after display**]. The updated IRF prospective payment rates are effective October 1, 2006, for discharges occurring on or after October 1, 2006 and on or before September 30, 2007 (that is, during FY 2007).

FOR FURTHER INFORMATION CONTACT:

Pete Diaz, (410) 786-1235, for information regarding the IRF PPS 75 percent rule.

Susanne Seagrave, (410) 786-0044, for information regarding the new IRF PPS payment policies.

Zinnia Ng, (410) 786-4587, for information regarding the wage index and the IRF prospective payment rate

calculation.

Sandra Bastinelli, (410) 786-3630, for information regarding accreditation of DMEPOS suppliers.

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Linda Smith, (410) 786-5650, for information regarding the DMEPOS quality standards.

Michael Keane, (410) 786-4495, for information on DMEPOS competitive bidding implementation contractors.

Alexis Meholic, (410) 786-2300, for issues related to education and outreach under the DMEPOS competitive bidding program.

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Regulation Text

Addendum

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding terms in alphabetical order below.

ADC Average Daily Census

ASCA Administrative Simplification Compliance Act of 2002, Pub. L. 107-105

BBA Balanced Budget Act of 1997, Pub. L. 105-33

BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113

BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106-554

CBA Competitive Bidding Area

CBIC Competitive Bidding Implementation Contractor

CBSA Core-Based Statistical Area

CCMO CMS Consortium Contractor Management Officer

CCR Cost-to-Charge Ratio

CFR Code of Federal Regulations

CMG Case-Mix Group

CY Calendar Year

DMERC Durable Medical Equipment Regional Carrier

DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

DRA Deficit Reduction Act of 2005, Pub. L. 109-171

DRG Diagnosis-Related Group

DSH Disproportionate Share Hospital

ECI Employment Cost Indexes

FI	Fiscal Intermediary
FR	Federal Register
FTE	Full-Time Equivalent
FY	Federal Fiscal Year
GDP	Gross Domestic Product
HCPCS	Healthcare Common Procedure Coding System
HHH	Hubert H. Humphrey Building
HIPAA	Health Insurance Portability and Accountability Act, Pub. L. 104-191
HIT	Health Information Technology
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IFMC	Iowa Foundation for Medical Care
IIC	Inflation Indexed Charge
IPPS	Inpatient Prospective Payment System
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF PPS	Inpatient Rehabilitation Facility Prospective Payment System
IRVEN	Inpatient Rehabilitation Validation and Entry
LCD	Local Coverage Determination
LIP	Low-Income Percentage
MEDPAR	Medicare Provider Analysis and Review

MLN	Medicare Learning Network
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173)
MSA	Metropolitan Statistical Area
NAICS	North American Industrial Classification System
NCMRR	National Center for Medical Rehabilitation Research
NIH	National Institutes of Health
NSC	National Supplier Clearinghouse
OCI	Organizational and Consultant Conflicts of Interest
OIG	Office of Inspector General
OMB	Office of Management and Budget
PAC	Post Acute Care
PAI	Patient Assessment Instrument
PAOC	Program Advisory and Oversight Committee
PPS	Prospective Payment System
RAND	RAND Corporation
RFB	Request for Bids
RFA	Regulatory Flexibility Act, Pub. L. 96-354
RIA	Regulation Impact Analysis
RIC	Rehabilitation Impairment Category
RO	Regional Office
RPL	Rehabilitation, Psychiatric, and Long-Term Care

Hospital Market Basket

SCHIP State Children's Health Insurance Program

SIC Standard Industrial Code

TEFRA Tax Equity and Fiscal Responsibility Act of 1982,
Pub. L. 97-248

I. Background

A. Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)

We received approximately 58 timely items of correspondence on the FY 2007 Inpatient Rehabilitation Facility Prospective Payment System proposed rule (71 FR 28106, May 15, 2006). Summaries of the public comments and our responses to those comments are set forth below under the appropriate section heading of this final rule.

1. Historical Overview of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) for Fiscal Years (FYs) 2002 through 2006.

Section 4421 of the Balanced Budget Act of 1997 (BBA, Pub. L. 105-33), as amended by section 125 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106-113), and by section 305 of the Medicare,

Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106-554), provides for the implementation of a per discharge prospective payment system (PPS), through section 1886(j) of the Social Security Act (the Act), for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (hereinafter referred to as IRFs).

Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs) but not costs of approved educational activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the August 7, 2001 final rule (66 FR 41316) as revised in the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for fiscal years (FYs) 2002 through 2006.

Under the IRF PPS from FY 2002 through FY 2005, as described in the August 7, 2001 final rule, the Federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases,

cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the Federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget neutral conversion factor). For a detailed discussion of the budget neutral conversion factor, please refer to our August 1, 2003 final rule (68 FR 45674, 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted Federal prospective payment rates. Under the IRF PPS from FYs 2002 through 2005, we then applied

adjustments for geographic variations in wages (wage index), the percentage of low-income patients, and location in a rural area (if applicable) to the IRF's unadjusted Federal prospective payment rates. In addition, we made adjustments to account for short-stay transfer cases, interrupted stays, and high cost outliers.

For cost reporting periods that began on or after January 1, 2002 and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the Federal IRF PPS rate and the payment that the IRF would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the Federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the Federal IRF PPS rate.

In the FY 2006 IRF PPS final rule (70 FR 47880), we implemented refinements that became effective for discharges beginning on or after October 1, 2005. We published correcting amendments to the FY 2006 IRF PPS

final rule in the **Federal Register** on September 30, 2005 (70 FR 57166). Any reference to the FY 2006 IRF PPS final rule in this rule also includes the provisions effective in the correcting amendments.

In the FY 2006 final rule (70 FR 47880 and 70 FR 57166), we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements were based on analyses by the RAND Corporation (RAND), a non-partisan economic and social policy research group, using calendar year 2002 and FY 2003 data. These were the first significant refinements to the IRF PPS since its implementation. In conducting the analysis, RAND used claims and clinical data for services furnished after the implementation of the IRF PPS. These newer data sets were more complete, and reflected improved coding of comorbidities and patient severity by IRFs. The researchers were able to use new data sources for imputing missing values and more advanced statistical approaches to complete their analyses. The RAND reports supporting the refinements made to the IRF PPS are available on the CMS Web site at:

http://www.cms.hhs.gov/InpatientRehabFacPPS/09_Research.asp

The final key policy changes, effective for discharges occurring on or after October 1, 2005, are discussed in detail in the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166). The following is a brief summary of the key policy changes:

- We adopted the Office of Management and Budget's (OMB's) Core-Based Statistical Area (CBSA) market area definitions in a budget neutral manner. We made this geographic adjustment using the most recent final wage data available (that is, pre-reclassification and pre-floor hospital wage index based on FY 2001 hospital wage data). In addition, we implemented a budget-neutral 3-year hold harmless policy for IRFs that were considered rural in FY 2005, but became urban in FY 2006 under the CBSA definitions, as described in the FY 2006 IRF PPS final rule (70 FR 47880, 47923 through 47925).
- We also implemented a payment adjustment to account for changes in coding that did not reflect real changes in case mix. Thus, we reduced the standard payment amount by 1.9 percent to account for these changes in coding following implementation of the IRF PPS. Our contractors conducted a series of analyses to identify real case mix change over time and the

effect of this change on aggregate IRF PPS payments.

A detailed discussion of the analysis and research

appears in the FY 2006 IRF PPS final rule

(70 FR 47880).

- In addition, we made modifications to the CMGs, tier comorbidities, and relative weights in a budget-neutral manner. The final rule included a number of adjustments to the IRF classification system that are designed to improve the system's ability to predict IRF costs. The data indicated that moving or eliminating some comorbidity codes from the tiers, redefining the CMGs, and other minor changes to the system would improve the ability of the classification system to ensure that Medicare payments to IRFs continue to be aligned with the costs of care. These refinements resulted in 87 CMGs using Rehabilitation Impairment Categories (RICs), functional status (motor and cognitive scores), and age (in some cases, cognitive status and age may not be factors in defining CMGs). The five special CMGs remained the same as they had been before FY 2006 and continue to account for very short stays and for patients who expired in the IRF.
- In addition, we implemented a new teaching status

adjustment for IRFs, similar to the one adopted for inpatient psychiatric facilities. We implemented the teaching status adjustment in a budget neutral manner.

- We also revised and rebased the market basket. We finalized the use of a new market basket reflecting the operating and capital cost structures for rehabilitation, psychiatric, and long term care (RPL) hospitals to update IRF payment rates. The RPL market basket excludes data from cancer hospitals, children's hospitals, and religious non-medical institutions. In addition, we rebased the market basket to account for 2002-based cost structures for RPL hospitals. Further, we calculated the labor-related share using the RPL market basket.
- In addition, we updated the rural adjustment (from 19.14 percent to 21.3 percent), the low-income percentage (LIP) adjustment (from an exponent of 0.484 to an exponent of 0.6229), and the outlier threshold amount (from \$11,211 to \$5,129, as further revised in the FY 2006 IRF PPS correction notice (70 FR 57166, 57168)). We implemented the changes to the rural and LIP adjustments in a budget neutral manner.

Since the implementation of the IRF PPS, we have maintained a CMS Web site as a primary information resource

for the IRF PPS. The Web site URL is <http://www.cms.hhs.gov/InpatientRehabFacPPS/> and may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

2. Requirements for Updating the IRF PPS Rates

On August 7, 2001, we published a final rule titled "Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities" in the **Federal Register** (66 FR 41316) that established a PPS for IRFs as authorized under section 1886(j) of the Act and codified at subpart P of part 412 of the Medicare regulations. In the August 7, 2001 final rule, we set forth the per discharge Federal prospective payment rates for FY 2002, which provided payment for inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs) but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IRF PPS. The provisions of the August 7, 2001 final rule were effective for cost reporting periods beginning on or after January 1, 2002. On July 1, 2002, we published a correcting amendment to the August 7, 2001 final rule in the **Federal Register** (67 FR 44073). Any references to the

August 7, 2001 final rule in this final rule include the provisions effective in the correcting amendment.

Section 1886(j)(5) of the Act and 42 CFR 412.628 of the regulations require the Secretary to publish in the **Federal Register**, on or before the August 1 that precedes the start of each new FY, the classifications and weighting factors for the IRF CMGs and a description of the methodology and data used in computing the prospective payment rates for the upcoming FY. On August 1, 2002, we published a notice in the **Federal Register** (67 FR at 49928) to update the IRF Federal prospective payment rates from FY 2002 to FY 2003 using the methodology as described in §412.624. As stated in the August 1, 2002 notice, we used the same classifications and weighting factors for the IRF CMGs that were set forth in the August 7, 2001 final rule to update the IRF Federal prospective payment rates from FY 2002 to FY 2003. We continued to update the prospective payment rates in accordance with the methodology set forth in the August 7, 2001 final rule for each succeeding FY up to and including FY 2005. For FY 2006, however, we published a final rule that revised several IRF PPS policies (70 FR 47880), as summarized in section I.A.1 of this final rule. The provisions of the FY 2006 IRF PPS final rule became effective for discharges occurring on or

after October 1, 2005.

On May 15, 2006, we published a proposed rule in the **Federal Register** (71 FR 28106) to update the IRF Federal prospective payment rates from FY 2006 to FY 2007. In this final rule for FY 2007, we update the IRF Federal prospective payment rates. In addition, we update the outlier threshold amount and the cost-to-charge ratio ceilings from FY 2006 to FY 2007. We are also implementing a 2.6 percent reduction to the FY 2007 standard payment amount to account for changes in coding practices that do not reflect real changes in case mix. (See section V.A of this final rule for further discussion of the reduction of the standard payment amount to account for coding changes.)

We are also implementing revisions to the tier comorbidities and the relative weights to ensure that IRF PPS payments reflect, as closely as possible, the costs of caring for patients in IRFs. (See section IV for a detailed discussion of these changes.) The FY 2007 Federal prospective payment rates are effective for discharges occurring on or after October 1, 2006 and on or before September 30, 2007.

In addition, we are revising the regulation text in §412.23(b)(2)(i) and §412.23(b)(2)(ii) pursuant to our authority in section 5005 of the Deficit Reduction Act of

2005 (DRA, Pub. L. 109-171) and section 1886(d)(1)(B) of the Act. Section 5005 of the DRA required that we revise the applicable percentages stipulated in the May 7, 2004 final rule (69 FR 25752). The effect of this change prolongs by an additional year the duration of the phased transition to the full 75 percent threshold established in current regulation text. In addition, under the authority in section 1886(d)(1)(B) of the Act, we are similarly extending by an additional year the use of comorbid conditions that meet the criteria outlined in the regulations to count for purposes of determining compliance with the classification criteria in §412.23(b)(2)(i).

3. Operational Overview of the Current IRF PPS

As described in the August 7, 2001 final rule and subsequent rules, upon the admission and discharge of a Medicare Part A fee-for-service patient, the IRF is required to complete the appropriate sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI). Generally, the encoded IRF-PAI software product includes patient grouping programming called the GROUPER software. The GROUPER software uses specific Patient Assessment Instrument (PAI) data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The GROUPER software produces a five-digit CMG number. The first digit is an alpha-character that indicates the comorbidity tier. The last four digits represent the distinct CMG number. (Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the GROUPER software, are available on the CMS Web site at http://www.cms.hhs.gov/InpatientRehabFacPPS/06_Software.Asp.)

Once a patient is discharged, the IRF completes the Medicare claim (UB-92 or its equivalent) using the five-digit CMG number and sends it to the appropriate Medicare fiscal intermediary (FI). 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). For a detailed discussion on this issue and additional legal citations, please visit the electronic billing & electronic data interchange (EDI) transactions Web site at: <http://www.cms.hhs.gov/ElectronicBillingEDITrans/>.

The Medicare FI processes the claim through its software system. This software system includes pricing programming called the PRICER software. The PRICER

software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the new teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

4. Summary of Revisions to the IRF PPS for FY 2007

In this final rule, we make the following revisions and updates:

- Update the relative weight and average length of stay tables based on re-analysis of the data by CMS and our contractor, the RAND Corporation, as discussed in section IV of this final rule. This update will be reflected in the IRF GROUPER software and other applicable CMS publications.

- Reduce the standard payment amount by 2.6 percent to account for coding changes that do not reflect real changes in case mix, as discussed in section V.A of this final rule.

- Update the FY 2007 IRF PPS payment rates by the market basket, as discussed in section V.B of this final rule.
- Update the FY 2007 IRF PPS payment rates by the labor related share, the wage indexes, and the second year of the hold harmless policy in a budget neutral manner, as discussed in section V.C of this final rule.
- Update the outlier threshold for FY 2007 to \$5,534, as discussed in section VI.A of this final rule.
- Update the urban and rural national cost-to-charge ratio ceilings for purposes of determining outlier payments under the IRF PPS and clarify the methodology described in the regulation text, as discussed in section VI.B of this final rule.
- Revise the regulation text at §412.23(b)(2)(i) and §412.23(b)(2)(ii) in the following manner so that the compliance thresholds reflect section 5005 of the DRA: (1) For cost reporting periods starting on or after July 1, 2006, and before July 1, 2007, the compliance threshold is 60 percent. (2) For cost reporting periods starting on or after July 1, 2007 and before July 1, 2008, the compliance threshold is 65 percent. (3) For cost reporting periods starting on or after July 1, 2008, the compliance threshold

is 75 percent. In addition, comorbidities may not be used to determine if the 75 percent compliance threshold is met. However, comorbidities meeting the criteria outlined in the regulations may be used to determine if the applicable compliance threshold is met for cost reporting periods beginning on or after July 1, 2004 and before July 1, 2008.

B. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

On May 1, 2006, we issued a proposed rule to implement the Medicare DMEPOS Competitive Bidding Program and other issues (71 FR 25654). To ensure timely implementation of the Medicare DMEPOS Competitive Bidding Program, we are choosing to respond in this final rule to comments submitted on certain provisions of the May 1, 2006 proposed rule. These provisions include DMEPOS competitive bidding implementation contractors, DMEPOS competitive bidding education and outreach, quality standards for DMEPOS suppliers, and accreditation of DMEPOS suppliers. We received approximately 600 timely comments on these provisions of the May 1, 2006 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate section headings of this final rule.

1. The Medicare DMEPOS Competitive Bidding Program

Section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108-173) amended section 1847 of the Act to require the Secretary to establish and implement programs under which competitive bidding areas are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items for which payment is made under Part B (the "Medicare DMEPOS Competitive Bidding Program"). Section 1847(a)(2) of the Act provides that the items and services that may be furnished under the competitive bidding programs include certain DME and associated supplies, enteral nutrition and associated supplies, and off-the-shelf orthotics. In addition, section 1847 of the Act specifies the requirements and conditions for implementation of the Medicare DMEPOS Competitive Bidding Program. Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost.

2. Implementation Contractors

Section 1847(b)(9) of the Act provides that the Secretary may contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program.

Section 1847(a)(1)(C) of the Act also authorizes the Secretary to waive provisions of the Federal Acquisition Regulation (FAR) as necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and other provisions as the Secretary determines appropriate.

In the May 1, 2006 proposed rule (71 FR 25661), we proposed to designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program (proposed §414.406(a)). We also discussed the six primary functions of the program (see 71 FR 25661), which include overall oversight and decision-making, operation design functions (including the design of both bidding and outreach material templates, as well as program processes), bidding and evaluation, access and quality monitoring, outreach and education, and claims processing. We respond to comments on our proposal in section X.A of this preamble.

3. Quality Standards for Suppliers of DMEPOS

Section 302(a)(1) of the MMA added section 1834(a)(20) to the Act, which requires the Secretary to establish and implement quality standards for suppliers of certain items,

including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the DMEPOS quality standards in order to furnish any item for which Part B makes payment, and also in order to receive or retain a supplier billing number used to submit claims for reimbursement for any such item for which payment can be made by Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these DMEPOS quality standards to suppliers of the following items for which we deem the standards to be appropriate:

- Covered items, as defined in section 1834(a)(13), for which payment may be made under section 1834(a);
- Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4); and
- Items described in section 1842(s)(2) of the Act, which include medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine.

Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the DMEPOS quality standards by program instructions or otherwise after consultation with representatives of relevant parties. After consulting with such representatives, including the Program Advisory and Oversight Committee (PAOC) (please see 71 FR 25658 for a discussion of this committee) and a wide range of other stakeholders, we published the draft quality standards on the CMS Web site in September 2005 (see <http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>) and provided for a 60-day public comment period. We received more than 5,600 public comments on the draft DMEPOS quality standards. After careful consideration of all comments, these quality standards will be published shortly on the CMS web site. They will appear on the CMS Web site at <http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>. The quality standards will become effective for use as part of the accreditation selection process when posted on the website. All suppliers of DMEPOS and other items to which section 1834(a)(20) of the Act applies will be required to meet the DMEPOS quality standards established under that section. Finally, section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the DMEPOS quality standards specified by the Secretary under section

1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program.

4. Accreditation for Suppliers of DMEPOS and Other Items

Section 1834(a)(20)(B) of the Act requires the Secretary, notwithstanding section 1865(b) of the Act, to designate and approve one or more independent accreditation organizations to apply the DMEPOS quality standards established under section 1834(a)(20) of the Act to suppliers of DMEPOS and other items. The Medicare program currently contracts with State agencies to perform survey and review functions for providers and suppliers to approve their participation in or coverage under the Medicare program. Additionally, section 1865(b) of the Act sets forth the general procedures for CMS to designate national accreditation organizations to deem providers or suppliers to meet Medicare conditions of participation or coverage if they are accredited by a national accreditation organization approved by CMS. Many types of providers and suppliers have a choice between having the State agency or the CMS-approved accreditation organization survey them. If the supplier selects the CMS-approved accreditation organization and is in compliance with the accreditation organization standards, it is generally deemed to meet the

Medicare conditions of participation or coverage. We are responsible for the oversight and monitoring of the State agencies and the approved accreditation organizations. The procedures, implemented by the Secretary, for designating private and national accreditation organizations and the Federal review process for accreditation organizations appear in regulations at 42 CFR parts 422 (for Medicare Advantage organizations) and 488 (for most providers and suppliers). To accommodate suppliers that want to participate in the Medicare DMEPOS Competitive Bidding Program, we will phase-in the accreditation process and give preference to accreditation organizations that prioritize their surveys to accredit suppliers in the selected MSAs and competitive bidding areas. We will provide further guidance in a **Federal Register** notice on the submission procedures for accreditation.

5. Summary of DMEPOS Provisions

This final rule responds to public comments on the following provisions of the May 1, 2006 proposed rule (71 FR 25654):

- Requirements for competitive bidding implementation contractors, as discussed in section X.A of this final rule.

- Our plans for DMEPOS competitive bidding education and outreach, as discussed in section X.B of this final rule.
- Issues related to the DMEPOS quality standards for DMEPOS suppliers, as discussed in section X.C of this final rule.
- Accreditation requirements for DMEPOS suppliers as discussed in section X.D of this final rule.

II. Provisions of the Proposed Rule

A. IRF PPS

In the FY 2007 IRF PPS proposed rule (71 FR 28106), we proposed to make revisions to the regulation text in order to implement the proposed policy changes for IRFs for FY 2007 and subsequent fiscal years. Specifically, we proposed to make conforming changes in 42 CFR part 412. These proposed revisions and other proposed changes are discussed in detail below.

1. Section 412.23 Excluded hospitals: Classifications.

As discussed in section VI of the FY 2007 IRF PPS proposed rule (71 FR 28106), we proposed to revise the regulation text in paragraphs (b)(2)(i) and (b)(2)(ii) to reflect the applicable percentages specified in this section as amended by the DRA. To summarize, for cost reporting periods--

(a) Beginning on or after July 1, 2005 and before July 1, 2007, the hospital has served an inpatient population of whom at least 60 percent;

(b) Beginning on or after July 1, 2007 and before July 1, 2008, the hospital has served an inpatient population of whom at least 65 percent; and

(c) Beginning on or after July 1, 2008, the hospital has served an inpatient population of whom at least 75 percent require intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b) (2) (iii) of this section.

Under the proposal to revise the transition timeframes in order to implement the DRA provision, a facility would not have to meet the 75 percent compliance threshold until its first cost reporting period beginning on or after July 1, 2008. In addition to the above DRA requirements pertaining to the applicable compliance percentage requirements under §412.23(b) (2), we proposed to permit a comorbidity that meets the criteria as specified in §412.23(b) (2) (i) to continue to be used to determine the compliance threshold for cost reporting periods that begin before July 1, 2008. However, for cost reporting periods beginning on or after July 1, 2008, a comorbidity specified in §412.23(b) (2) (i) cannot be used to determine compliance

at the 75 percent threshold.

2. Section 412.624 Methodology for calculating the Federal prospective payment rates.

In section IV of the FY 2007 IRF PPS proposed rule, we proposed to revise the current regulation text in paragraph (e) (5) to clarify that the cost-to-charge ratio for IRFs is a single overall (combined operating and capital) cost-to-charge ratio. We wish to emphasize that we follow the methodology described in §412.84(i) and §412.84(m) except that the IRF PPS uses a single overall (combined operating and capital) cost-to-charge ratio, and uses national averages instead of statewide averages.

3. Additional Proposed Changes

- Update the tier comorbidities, the relative weights, and the average length of stay tables based on a reconsideration of the data used in the FY 2006 IRF classification refinements, as discussed in section II of the FY 2007 IRF PPS proposed rule (71 FR 28106). This update will be reflected in the IRF GROUPER software and the FY 2007 payment rates.
- Reduce the FY 2007 standard payment amount by 2.9 percent to account for coding changes when the IRF PPS was implemented that do not reflect real

changes in case mix, as discussed in detail in section III.A of the FY 2007 IRF PPS proposed rule (71 FR 28106).

- Update payment rates for rehabilitation facilities using the IRF market basket, IRF labor-related share, and CBSA urban and rural wage indexes, as discussed in sections III.B and C of the FY 2007 IRF PPS proposed rule (71 FR 28106).
- Update the outlier threshold amount for FY 2007 to \$5,609, as discussed in section IV.A of the FY 2007 IRF PPS proposed rule (71 FR 28106).
- Update the national average urban and rural cost-to-charge ratios (CCR) used for new IRFs, IRFs whose overall CCR is in excess of 3 standard deviations above the national geometric mean, and IRFs for whom accurate data are not available to calculate a CCR, as discussed in detail in section IV.B of the FY 2007 IRF PPS proposed rule (71 FR 28106).

B. DMEPOS

On May 1, 2006, we published in the **Federal Register** (71 FR 23654) a proposed rule that would, in part, implement the Medicare DMEPOS Competitive Bidding Program

for certain DMEPOS items, as required by sections 1847(a) and (b) of the Social Security Act (the Act). As indicated in section I.B of this final rule, to ensure timely implementation of the Medicare DMEPOS Competitive Bidding Program, we are choosing to respond to comments on the following proposals in the May 1, 2006 proposed rule. In summary, we proposed to--

- Designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program (proposed §414.406(a)).
- Implement an outreach and education plan to ensure the effective implementation of the Medicare DMEPOS Competitive Bidding Program.
- Establish requirements for accreditation of DMEPOS suppliers.

In addition, we are clarifying in this final rule certain issues related to the establishment of quality standards for suppliers of certain DMEPOS items, which will be applied by recognized independent accreditation organizations under section 1834(a)(20) of the Act.

These provisions are described in detail in sections X.A. through I of this preamble.

III. Analysis of and Response to Public Comments

A. IRF PPS

In response to the publication of the FY 2007 IRF PPS proposed rule, we received approximately 58 timely items of correspondence from the public. We received numerous comments from various trade associations and major organizations. Comments also originated from inpatient rehabilitation facilities, members of Congress, health care industry organizations, State health departments, and health care consulting firms. The following discussion, arranged by subject area, includes a summary of the public comments that we received, and our responses to the comments appear under the appropriate heading.

B. DMEPOS

We received approximately 600 pieces of correspondence on a timely basis that contained comments on the provisions of the May 1, 2006 proposed rule (71 FR 25654) that are included in this final rule. The remainder of this preamble sets forth a detailed discussion of the proposed provisions concerning implementation contractors, education and outreach, and accreditation; a summary of the public comments received on each subject area; our responses to those comments; and a presentation of the final policies. This preamble also contains a discussion of certain issues

relating to the quality standards that will be applied by the independent accrediting organizations.

IV. Refinements to the IRF Patient Classification System

A. Changes to the Existing List of Tier Comorbidities

The IRF PPS uses a patient's principal diagnosis or impairment to classify the patient into a rehabilitation impairment category (RIC), and then uses the patient's comorbidities (secondary diagnoses) to determine whether to classify the patient into a higher-paying tier. In the FY 2007 proposed rule (71 FR 28106), we proposed revisions to the tier comorbidities in the IRF GROUPER for FY 2007 to ensure that IRF PPS payments continue to reflect as accurately as possible the costs of care. In addition, we proposed to indicate ongoing changes to the IRF GROUPER software to reflect the most current national coding guidelines, by posting a complete ICD-9 table (including new, discontinued, and modified codes) on the IRF PPS Web site, because we realized that we did not have a mechanism for ensuring that the IRF GROUPER would reflect the latest guidelines. We also proposed to continue to report the complete list of ICD-9 codes associated with the tiers in the IRF GROUPER documentation, which is also posted on the IRF PPS Web site.

We received several comments on the proposed changes to the existing list of tier comorbidities, which are summarized below.

Comment: Comments were generally favorable regarding our proposed revisions to the existing list of tier comorbidities. In particular, several commenters expressed support for our proposed deletion of certain category codes, which they indicated would increase clarity and accuracy in coding. Further, several commenters supported our proposal to continue to update the IRF GROUPER to reflect ICD-9-CM national coding guidelines, and to make any substantive changes to the tier comorbidities (that is, changes other than those that merely ensure that the list of tier comorbidities continues to reflect the annual updates to the ICD-9 national coding guidelines) through notice and comment procedures. These commenters also supported our proposal to update Appendix C to reflect current policies.

Response: We agree that our proposal to delete certain category codes should help to eliminate any confusion that providers might have experienced regarding the appropriate codes to use in recording patient comorbidities.

We also agree with the commenters that updating Appendix C each year, and making it a Web-based document rather than including it in the IRF regulations, will provide a more comprehensive solution that will allow providers to stay informed of any changes to the IRF GROUPER

as soon as they occur. Any document, such as Appendix C, that contains such an extensive list of ICD-9 codes runs the risk of becoming out-of-date quickly when it is published in regulations. We believe that making the document available on the IRF PPS Web site

(<http://www.cms.hhs.gov/InpatientRehabFacPPS/>) will make it easier for CMS to give providers the most current information and, more importantly, will allow providers easier access to the latest information.

Comment: Several commenters expressed reservations about particular revisions that we had proposed. In particular, several commenters asked that CMS retain ICD-9 codes 453.40, 453.41, and 453.42 (various types of venous thrombosis) on the list of tier comorbidities for which providers receive additional payments because of the increased costs associated with these comorbidities, and one commenter asked that we retain ICD-9 codes 799.01 and 799.02 for similar reasons. One commenter also noted recent increases in the rate at which providers are using ICD-9 code 453.41 and asked that CMS delay deleting this code from the IRF grouper until the underlying clinical reasons for its recent increased use could be determined. One commenter requested that the original ICD-9 code (453.8) associated with codes 453.40, 453.41, and 453.42 be added to the list of tier comorbidities in the IRF GROUPER.

Response: In Appendix C of the August 7, 2001 final rule (66 FR 41316, 41414 through 41427), we provided the

list of comorbidity codes to be used in the original IRF GROUPER, based on the statistical analysis conducted by RAND for CMS in developing the IRF PPS. On October 1, 2004, the ICD-9-CM Coordination and Maintenance Committee created ICD-9 codes 453.40, 453.41, and 453.42 to represent more specific clinical conditions related to the clinical condition associated with ICD-9 code 453.8 (Venous Thrombosis). Effective October 2004, we inadvertently added codes 453.40 (Ven Embol Thrmbs unspec DP vsls lower extremity), 453.41 (Ven Embol Thrmbs DP vsls prox lower extremity), and 453.42 (Ven Embol Thrmbs DP vsls distal lower extremity) to the IRF GROUPER, even though code 453.8 was never included in the IRF payment algorithm, and therefore was not listed in Appendix C of the August 7, 2001 final rule. The addition of these codes to the IRF GROUPER was not based on any evidence that these codes should have been included on the list, but resulted instead from a simple miscommunication.

Similarly, ICD-9 codes 799.01 (Asphyxia) and 799.02 (Hypoxemia) were created in October 2005 in association with code 799.0. However, code 799.0 (Asphyxia) was never included in the IRF payment algorithm, and therefore was not listed in Appendix C of the August 7, 2001 final rule. Thus, codes 799.01 and 799.02 were also inadvertently added through a simple miscommunication, and the addition of these codes to the IRF GROUPER was not based on any evidence that these codes should have been included on the list.

RAND's regression analysis of the tier comorbidities for both the FY 2002 and FY 2006 final rules focused on the additional costs that an IRF would be expected to incur in caring for a patient with a particular comorbidity (using FY 2003 data). Neither RAND's statistical analysis for the FY 2002 final rule, nor the subsequent statistical analysis for the FY 2006 final rule, showed that the additional costs of the comorbidities associated with ICD-9 codes 453.8, 453.40, 453.41, 453.42, 799.0, 799.01, or 799.02 are sufficient to warrant inclusion in a tier. In addition, RAND sought advice from a technical expert panel that it convened. The technical expert panel reviewed all of RAND's findings regarding the tier comorbidities and generally agreed with RAND's findings and recommendations. RAND did not recommend that we add these codes to the IRF GROUPER.

Further, since code 453.41 was first approved in October 2004, we do not believe it is surprising that use of this code increased in 2005, especially because providers were made more aware of the code due to its inadvertent inclusion in the IRF GROUPER.

Thus, we are finalizing our decision to delete ICD-9 codes 453.40, 453.41, 453.42, 799.01, and 799.02 from the IRF GROUPER, and we are not adding code 453.8. However, we will continue monitoring the costs associated with various patient comorbidities. If future analyses indicate that any of these ICD-9 codes should be included in one of the tiers in the IRF GROUPER, we will consider adding them through

notice and comment procedures.

Comment: One commenter suggested that we consider adding ICD-9 code 282.69 (other sickle cell disease with crisis) to the IRF GROUPER because the commenter believes that this code should be treated as a pair with code 282.68 (other sickle cell disease w/o crisis), which we proposed to add to the IRF GROUPER for FY 2007.

Response: We agree with the commenter, and we note that code 282.69 is already included as one of the comorbidities that generates an additional tier 3 payment in the IRF GROUPER. In fact, this code has always been included in the IRF payment algorithm, and is therefore listed in Appendix C of the August 7, 2001 final rule (66 FR 41423). We are not proposing any changes regarding code 282.69. For FY 2007, we will add code 282.68.

Comment: Several commenters recommended that CMS publish the final changes to the tier comorbidities in the IRF-PAI training manual and in Appendix C.

Response: We agree with the commenters' recommendation and will update both the IRF-PAI training manual and Appendix C with the most current list of tier comorbidities for FY 2007.

In reviewing the refinements that we made to the tier comorbidities for FY 2006, we realized that we did not have an explicit mechanism for updating the IRF GROUPER to account for annual changes to the ICD-9-CM national coding

guidelines or to alert providers to these changes. Thus, we believe that the best way to accomplish both of these goals, and to ensure that providers have access to the most up-to-date IRF GROUPER information possible is to make the documents containing the final list of ICD-9 codes used in the IRF GROUPER Web-based, rather than publishing each technical update in regulation. The ICD-9 code updates might occur more frequently than CMS publishes an IRF rule in the **Federal Register**, so it would be impractical to keep Appendix C updated based on annual ICD-9 national coding guideline changes if we were to try to publish Appendix C in the Federal Register each time Appendix C is updated to reflect new codes. We believe a Web-based product will allow providers to have the most convenient and timely possible access to the latest available information. Therefore, both updated documents will be available on the IRF PPS Web site (located at <http://www.cms.hhs.gov/InpatientRehabFacPPS/>) before October 1, 2006.

To clarify, as discussed in the FY 2007 IRF PPS proposed rule (71 FR 28106, 28111), we will update these Web-based documents regularly to reflect changes in the ICD-9 national coding guidelines that are technical in nature. For example, the ICD-9 national coding guidelines added ICD-9 codes 341.20 through 341.22 for October 2006 to correspond to codes 323.8 and 323.9 that are currently in the IRF Grouper. Thus, we will add codes 341.20 through 341.22 to

the IRF Grouper and to Appendix C on the IRF PPS Web site as soon as the changes become effective. However, any substantive changes to the comorbid conditions on the list of tier comorbidities in the IRF GROUPER will be proposed through notice and comment procedures. Thus, hypothetically speaking, if we were to discover later through our ongoing analysis of the IRF classification and payment systems that one (or possibly more than one) of these ICD-9 codes does not belong on the list of tier comorbidities--either because it does not substantially increase the IRFs' costs of caring for patients with that comorbidity, or because it is not clinically relevant as discussed in the August 7, 2001 final rule--then we would later propose to delete this code (or codes) through notice and comment procedures. To reiterate, this is only a hypothetical example. We have no intent to delete codes 341.20 through 341.22 at this time.

The finalized list of tier comorbidities for FY 2007 that we are posting on the IRF PPS Web site and in the IRF GROUPER documentation as of October 1, 2006 will generally reflect the August 7, 2001 final rule (66 FR 41316, 41414 through 41427) as modified by the tier comorbidity changes adopted in this final rule, as well as changes adopted due to ICD-9 national coding guideline updates. This version will constitute the baseline for any future updates to the tier comorbidities.

Comment: One commenter expressed confusion over the listing of ICD-9 code 250.01 in the FY 2006 IRF GROUPER,

while the FY 2006 IRF PPS final rule indicated that CMS was adding code 250.1, which was not listed in the FY 2006 IRF GROUPER.

Response: On September 30, 2005, we published a correction notice (70 FR 57166) that implemented some technical corrections to the FY 2006 IRF PPS final rule. One of these technical corrections was to change code 250.1 to 250.01.

Comment: One commenter requested that CMS add an ICD-9 code that represents the condition HYPOALBUMINEMIA to the list of tier comorbidities to account for the added costs of patients with this condition.

Response: We would need to conduct further statistical analysis to determine whether this condition should be included in the list of tier comorbidities. We will take the commenter's recommendation into consideration for the future.

Final Decision: After carefully considering all of the comments that we received on the proposed changes to the existing list of tier comorbidities, we are finalizing our decision to implement all of the changes as proposed, including the additions listed in Table 1, the deletions listed in Table 2, and the movement of the codes listed in Table 3 from tier 2 to tier 3.

Table 1: ICD-9 codes that we will add to the IRF PPS GROUPER

ICD-9-CM	ICD-9-CM Label	Tier	RIC Exclusion
466.11	ACU BRONCHOLITIS D/T RSV	3	15
466.19	ACU BRNCHLTS D/T OTH ORG	3	15
282.68	OTH SICKLE-CELL DISEASE W/O CRISIS	3	None
567.29	OTH SUPPURATIVE PERITONITIS	3	None

Table 2: ICD-9 codes that we will delete from the IRF PPS GROUPER

ICD-9-CM	ICD-9-CM Label	Tier
453.40	VEN EMBOL THRMBS UNSPEC DP VSLS LWR EXTREM	3
453.41	VEN EMBOL THRMBS DP VSLS PROX LWR EXTREM	3
453.42	VEN EMBOL THRMBS DP VSLS DIST LWR EXTREM	3
799.01	ASPHYXIA	3
799.02	HYPOXEMIA	3

Table 3: ICD-9 codes that we will move from tier 2 to tier 3 in the IRF PPS GROUPER

ICD-9-CM	ICD-9-CM Label	Tier	RIC Exclusion
112.4	CANDIDIASIS OF LUNG	3	15
112.5	DISSEMINATED CANDIDIASIS	3	None
112.81	CANDIDAL ENDOCARDITIS	3	14
112.83	CANDIDAL MENINGITIS	3	03, 05
112.84	CANDIDAL ESOPHAGITIS	3	None

ICD-9-CM	ICD-9-CM Label	Tier	RIC Exclusion
785.4	GANGRENE	3	10,11
995.90	SIRS NOS	3	None
995.91	SIRS INF W/O ORG DYS	3	None
995.92	SIRS INF W ORG DYS	3	None
995.93	SIRS NON-INF W/O ORG DYS	3	None
995.94	SIRS NON-INF W ORG DYS	3	None

B. Changes to the Case-Mix Group (CMG) Relative Weights

As specified in §412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. (For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1.) Relative weights account for the variance in cost per discharge and resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care as well as provider efficiency. In the FY 2007 IRF PPS proposed rule (71 FR 28106), we proposed to update the relative weights for FY 2007 based on a revised analysis of the data used to construct the relative weights for FY 2006, which had revealed certain minor discrepancies.

We received numerous comments on the proposed changes to the CMG relative weights, which are summarized below.

Comment: Numerous commenters expressed concern that

the proposed CMG relative weights for FY 2007 were based on the same FY 2003 data used to compute the FY 2006 CMG relative weights. These commenters asked that CMS recalculate the CMG relative weights for FY 2007 using the latest available data.

Response: We asked RAND to recalculate the CMG relative weights for FY 2007 to correct some minor discrepancies found in the tier comorbidities used in the analysis of the FY 2006 relative weights. After we published the FY 2006 IRF PPS final rule (70 FR 47880), we conducted a post-implementation review to ensure that the FY 2006 revisions were implemented correctly. Because the revisions for FY 2007 are merely designed to resolve some of the minor discrepancies identified in this post-implementation review and not to implement additional refinements, we believe it is appropriate to continue to use the same data that we used for the FY 2006 IRF PPS final rule. We agree that, in the future, any rebasing or recalibration of the system should be done using the most current available data.

Comment: Several commenters requested copies of the updated RAND analysis that produced the revised CMG relative weights for FY 2007.

Response: The updated analysis that RAND performed in recalculating the CMG relative weights for this final rule was identical to its analysis for the FY 2002 and FY 2006 IRF PPS final rules, with the exception of correcting some

of the minor discrepancies in the data used in the FY 2006 analysis. For a detailed description of the methodology that RAND used to calculate the CMG relative weights for the FY 2002, FY 2006, and current final rules, please refer to pages 41351 through 41353 of the August 7, 2001 final rule (66 FR 41316). The data that RAND used for the FY 2006 and FY 2007 CMG relative weight calculations are the FY 2003 IRF MEDPAR data merged with the FY 2003 IRF-PAI and cost report data. The analysis that RAND conducted for us for FY 2007 produced the updated CMG relative weight and average length of stay figures displayed in Table 4 of this final rule.

Comment: We received some comments expressing concerns about the accuracy of the average length of stay values. One commenter suggested that the average length of stay values for the different tiers should be proportional to payment and that, for example, the average length of stay values for tier 1 (the highest paying tier) should always be higher than the average lengths of stay for tiers 2 and 3 and the "no comorbidity" tier. Another commenter asked that we re-examine the average length of stay value for the traumatic spinal cord injury patients in tier 1 to ensure that it is consistent with medical practice, stating that these patients require relatively long rehabilitation periods.

Response: We have reviewed the average length of stay values, in general and for the traumatic spinal cord injury CMGs in particular, and we believe they are correct. The

average length of stay values shown in Table 4 are entirely driven by the data. Whereas we impose a constraint on the CMG relative weights under which the relative weight for a higher-paying tier can never be lower than the relative weight for a lower-paying tier, we do not constrain the average length of stay values. They represent the average number of days that patients in a given CMG and tier were in an IRF.

As we indicated in the FY 2006 IRF PPS final rule (70 FR 47901), the relative weights for each of the CMGs and tiers represent the relative costliness of patients in those CMGs and tiers compared with patients in other CMGs and tiers. The average length of stay for each CMG and tier, however, represents the average number of days that patients in that CMG and tier were treated in IRFs, based on the FY 2003 data. We determine IRF PPS payments on a per-discharge basis, meaning that providers receive a pre-determined payment amount according to an individual patient's CMG and tier classification, regardless of the number of days that patient is treated in the IRF. The only exceptions to this general policy are for very short-stay cases and for certain transfer cases. Because payments are made on a per-discharge basis, there is not necessarily a correlation between the number of days a patient is treated in an IRF and the payment amount for that patient. If, for example, the relative weight for a particular CMG in tier 1 is higher than the relative weight for that same CMG in the "no

comorbidity" tier, this means that cases in that CMG in tier 1 are expected to be more costly for the IRF to treat than cases in that CMG in the "no comorbidity" tier. However, the average length of stay of patients in that CMG in tier 1 might sometimes actually be lower than the average length of stay of patients in that CMG in the "no comorbidity" tier; for example, the "tier 1" patients could require significantly more intensive treatment for a shorter period of time, while the "no comorbidity" patients could require less intensive treatment over a longer period of time. Thus, the relative weights may not bear a proportional relationship to the average length of stay values.

We do not require IRFs to treat the average length of stay values as goals or targets for particular cases. IRFs are generally free to treat particular patients for as few or as many days as is medically appropriate. We encourage IRFs to admit patients for the length of time that results in the best quality of care for the patient.

Final Decision: After carefully reviewing all of the comments that we received on the proposed changes to the CMG relative weights, we are finalizing our decision to update the CMG relative weights and the average length of stay values for FY 2007, as shown in Table 4.

Table 4: FY 2007 IRF PPS Relative Weights and Average Lengths of Stay for Case-Mix Groups

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0101	Stroke M>51.05	0.7707	0.7303	0.6572	0.6347	8	11	9	9
0102	Stroke M>44.45 and M<51.05 and C>18.5	0.9493	0.8995	0.8095	0.7818	11	15	11	10
0103	Stroke M>44.45 and M<51.05 and C<18.5	1.1192	1.0605	0.9544	0.9218	14	13	12	12
0104	Stroke M>38.85 and M<44.45	1.1885	1.1260	1.0134	0.9787	13	14	13	13
0105	Stroke M>34.25 and M<38.85	1.4261	1.3512	1.2161	1.1745	16	17	16	15
0106	Stroke M>30.05 and M<34.25	1.6594	1.5722	1.4150	1.3666	18	20	18	18
0107	Stroke M>26.15 and M<30.05	1.9150	1.8145	1.6330	1.5771	21	23	21	20
0108	Stroke M<26.15 and A>84.5	2.2160	2.0997	1.8897	1.8250	28	29	25	24
0109	Stroke M>22.35 and M<26.15 and A<84.5	2.1998	2.0843	1.8758	1.8116	23	26	24	23
0110	Stroke M<22.35 and A<84.5	2.6287	2.4907	2.2416	2.1649	30	33	28	27
0201	Traumatic brain injury M>53.35 and C>23.5	0.8143	0.6806	0.6080	0.5647	10	9	9	8

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5	1.0460	0.8743	0.7810	0.7254	12	10	11	9
0203	Traumatic brain injury M>44.25 and C<23.5	1.2503	1.0450	0.9335	0.8671	15	15	12	12
0204	Traumatic brain injury M>40.65 and M<44.25	1.3390	1.1192	0.9998	0.9287	15	16	13	13
0205	Traumatic brain injury M>28.75 and M<40.65	1.6412	1.3718	1.2254	1.1382	17	18	16	15
0206	Traumatic brain injury M>22.05 and M<28.75	2.1445	1.7924	1.6011	1.4873	23	22	21	20
0207	Traumatic brain injury M<22.05	2.7664	2.3122	2.0655	1.9185	35	29	26	25
0301	Non-traumatic brain injury M>41.05	1.1394	0.9533	0.8552	0.7772	12	12	11	10
0302	Non-traumatic brain injury M>35.05 and M<41.05	1.4875	1.2446	1.1164	1.0147	14	16	14	13
0303	Non-traumatic brain injury M>26.15 and M<35.05	1.7701	1.4810	1.3285	1.2074	20	19	17	16
0304	Non-traumatic brain injury M<26.15	2.4395	2.0410	1.8309	1.6640	32	25	23	21
0401	Traumatic spinal cord injury M>48.45	0.9587	0.8456	0.7722	0.6858	12	12	11	10
0402	Traumatic spinal cord injury M>30.35 and M<48.45	1.3256	1.1691	1.0676	0.9482	18	16	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35	2.3069	2.0347	1.8580	1.6502	22	24	24	22
0404	Traumatic spinal cord injury M<16.05 and A>63.5	4.1542	3.6639	3.3458	2.9717	51	46	41	37
0405	Traumatic spinal cord injury M<16.05 and A<63.5	3.1371	2.7668	2.5266	2.2441	33	37	33	28

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0501	Non-traumatic spinal cord injury M>51.35	0.7648	0.6455	0.5687	0.5071	9	8	8	7
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35	1.0262	0.8661	0.7630	0.6804	13	12	11	9
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15	1.3596	1.1476	1.0109	0.9014	15	15	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25	1.6984	1.4335	1.2628	1.1260	21	19	16	15
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25	2.0171	1.7025	1.4997	1.3373	23	22	19	18
0506	Non-traumatic spinal cord injury M<23.75	2.7402	2.3128	2.0374	1.8167	29	28	26	23
0601	Neurological M>47.75	0.8991	0.7330	0.7019	0.6522	11	10	9	9
0602	Neurological M>37.35 and M<47.75	1.1968	0.9757	0.9342	0.8682	13	13	13	12
0603	Neurological M>25.85 and M<37.35	1.5326	1.2495	1.1965	1.1118	17	17	15	15
0604	Neurological M<25.85	1.9592	1.5973	1.5295	1.4213	22	20	21	19
0701	Fracture of lower extremity M>42.15	0.9028	0.7717	0.7338	0.6617	12	11	10	9
0702	Fracture of lower extremity M>34.15 and M<42.15	1.1736	1.0033	0.9539	0.8602	13	14	13	12
0703	Fracture of lower extremity M>28.15 and M<34.15	1.4629	1.2506	1.1890	1.0722	16	17	16	14
0704	Fracture of lower extremity M<28.15	1.7969	1.5361	1.4605	1.3170	20	20	19	18
0801	Replacement of lower extremity joint M>49.55	0.6537	0.5504	0.5131	0.4607	7	7	7	6

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0802	Replacement of lower extremity joint M>37.05 and M<49.55	0.8542	0.7193	0.6704	0.6020	10	10	9	8
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5	1.2707	1.0700	0.9974	0.8956	15	15	13	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5	1.1040	0.9296	0.8665	0.7781	13	12	12	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65	1.3927	1.1727	1.0931	0.9816	17	16	14	13
0806	Replacement of lower extremity joint M<22.05	1.6723	1.4082	1.3126	1.1787	18	19	17	15
0901	Other orthopedic M>44.75	0.8425	0.7641	0.6868	0.6120	10	11	10	9
0902	Other orthopedic M>34.35 and M<44.75	1.1088	1.0057	0.9039	0.8056	13	13	12	11
0903	Other orthopedic M>24.15 and M<34.35	1.4638	1.3277	1.1934	1.0635	18	19	16	15
0904	Other orthopedic M<24.15	1.8341	1.6636	1.4952	1.3325	25	23	21	19
1001	Amputation, lower extremity M>47.65	0.9625	0.8879	0.7957	0.7361	11	11	11	10
1002	Amputation, lower extremity M>36.25 and M<47.65	1.2709	1.1724	1.0507	0.9719	14	15	14	13
1003	Amputation, lower extremity M<36.25	1.7876	1.6491	1.4779	1.3671	19	22	19	18

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
1101	Amputation, non-lower extremity M>36.35	1.2554	1.0482	0.9225	0.8496	14	15	12	11
1102	Amputation, non-lower extremity M<36.35	1.8824	1.5717	1.3832	1.2739	19	19	18	17
1201	Osteoarthritis M>37.65	1.0177	0.8785	0.8182	0.7405	11	12	11	10
1202	Osteoarthritis M>30.75 and M<37.65	1.3168	1.1367	1.0586	0.9581	15	16	14	13
1203	Osteoarthritis M<30.75	1.6241	1.4020	1.3057	1.1817	21	19	17	16
1301	Rheumatoid, other arthritis M>36.35	1.0354	0.9636	0.8511	0.7429	12	13	11	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35	1.4321	1.3327	1.1772	1.0275	15	18	15	14
1303	Rheumatoid, other arthritis M<26.15	1.8250	1.6984	1.5002	1.3094	22	21	20	18
1401	Cardiac M>48.85	0.8160	0.7351	0.6534	0.5861	10	9	9	8
1402	Cardiac M>38.55 and M<48.85	1.1038	0.9944	0.8839	0.7928	12	13	12	11
1403	Cardiac M>31.15 and M<38.55	1.3705	1.2347	1.0975	0.9844	16	16	14	13
1404	Cardiac M<31.15	1.7370	1.5649	1.3910	1.2477	21	20	18	16
1501	Pulmonary M>49.25	0.9986	0.8870	0.7793	0.7399	11	13	10	10
1502	Pulmonary M>39.05 and M<49.25	1.2661	1.1246	0.9880	0.9381	13	15	12	12
1503	Pulmonary M>29.15 and M<39.05	1.5457	1.3730	1.2062	1.1453	16	16	15	15
1504	Pulmonary M<29.15	2.0216	1.7957	1.5775	1.4979	26	21	20	18
1601	Pain syndrome M>37.15	1.0070	0.8550	0.7774	0.6957	12	11	10	10
1602	Pain syndrome M>26.75 and M<37.15	1.3826	1.1739	1.0673	0.9552	15	17	14	13

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
1603	Pain syndrome M<26.75	1.7025	1.4455	1.3143	1.1762	19	19	18	16
1701	Major multiple trauma without brain or spinal cord injury M>39.25	0.9818	0.9641	0.8479	0.7368	12	12	11	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25	1.2921	1.2688	1.1158	0.9696	14	16	15	13
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05	1.5356	1.5080	1.3262	1.1524	17	20	18	16
1704	Major multiple trauma without brain or spinal cord injury M<25.55	1.9246	1.8899	1.6620	1.4443	26	26	22	19
1801	Major multiple trauma with brain or spinal cord injury M>40.85	1.1920	0.9866	0.8243	0.7342	15	13	13	10
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85	1.9058	1.5774	1.3179	1.1738	19	21	18	16
1803	Major multiple trauma with brain or spinal cord injury M<23.05	3.4302	2.8391	2.3721	2.1127	43	33	30	27
1901	Guillian Barre M>35.95	1.2399	1.0986	1.0965	0.9350	14	13	14	12
1902	Guillian Barre M>18.05 and M<35.95	2.3194	2.0552	2.0512	1.7491	27	25	25	23
1903	Guillian Barre M<18.05	3.3464	2.9651	2.9593	2.5235	37	39	31	33
2001	Miscellaneous M>49.15	0.8734	0.7381	0.6735	0.6084	10	10	9	8
2002	Miscellaneous M>38.75 and M<49.15	1.1447	0.9674	0.8827	0.7975	12	13	12	11

CMG	CMG Description (M=motor, C=cognitive, A=age)	Relative Weights				Average Length of Stay			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
2003	Miscellaneous M>27.85 and M<38.75	1.4777	1.2488	1.1395	1.0294	16	16	15	14
2004	Miscellaneous M<27.85	1.9716	1.6662	1.5204	1.3735	25	22	20	18
2101	Burns M>0	2.1842	2.1842	1.6606	1.4587	27	24	20	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.2201				2
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.6351				8
5102	Expired, orthopedic, length of stay is 14 days or more				1.5985				22
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.7203				8
5104	Expired, not orthopedic, length of stay is 16 days or more				1.8784				24

V. FY 2007 IRF Federal Prospective Payment Rates

A. Reduction of the Standard Payment Amount to Account
for Coding Changes

According to research conducted by the RAND Corporation under contract with CMS, changes in provider coding practices increased Medicare payments to IRFs between 1999 and 2002 by at least 1.9 percent and as much as 5.8 percent. (We note that RAND revised its report in

late 2005 to reflect an upper bound (high-end estimate) of 5.9 percent, instead of the 5.8 percent that we reported in the FY 2006 IRF PPS proposed and final rules. However, because our FY 2006 proposed rule refers to a 5.8 percent upper bound, we will continue to use the 5.8 percent figure for this final rule.) In the FY 2007 proposed rule (71 FR 28106), we proposed to apply a 2.9 percent reduction to the standard payment amount for FY 2007 to adjust for changes in coding that, according to RAND's research, did not reflect real changes in IRF case mix. This proposed reduction would be in addition to the 1.9 percent adjustment implemented for FY 2006 and would result in a total adjustment of 4.8 percent ($1.9 + 2.9 = 4.8$), which still falls well within the range that RAND estimated.

However, we stated in the proposed rule that we were continuing to analyze the data and, therefore, the specific amount of the final payment adjustment was subject to change for this final rule based on the results of the ongoing analysis. As noted below, we also received a significant number of comments that uniformly recommended no reduction for FY 2007. Accordingly, we have revised the amount of the proposed reduction for this final rule, as discussed below, and will implement a reduction of 2.6 percent.

Public comments and our responses on the proposed reduction of the standard payment amount to account for coding changes are summarized below.

Comment: The majority of commenters expressed significant concerns about the proposed 2.9 percent reduction to the standard payment amount for FY 2007, and all who commented on this proposal indicated that CMS should not implement any reduction to the standard payment amount for FY 2007. Although they expressed a number of specific concerns (which we address separately below), the commenters generally indicated that IRFs are currently experiencing a significant amount of volatility and, for this reason, CMS should not implement an additional reduction to the standard payment amount for FY 2007. Further, many commenters asserted that RAND expressed more confidence in the findings at the low end of its estimated range (1.9 percent), and that CMS had already used RAND's analysis to justify the 1.9 percent coding adjustment for FY 2006. Several commenters also questioned CMS' conclusion that real case mix in IRFs had not increased substantially.

Response: In light of recent changes to the IRF PPS that affect utilization trends, including the phase-in of the IRF 75 percent rule compliance percentage, we have

chosen to take an incremental approach to adjusting for changes in coding that do not reflect real changes in case mix. In the FY 2006 final rule (70 FR 47880), we implemented a 1.9 percent reduction to the standard payment amount, and noted that it was the "lowest possible amount of change attributable to coding changes," as determined by RAND's analysis. In that final rule, we decided to implement the lowest possible amount to account for the possibility that some of the observed changes may have been attributable to factors other than coding changes or could be temporary changes associated with the transition to a new payment system. However, we indicated that we would continue to review the need for any further reduction in the standard payment amount in subsequent years as part of our overall monitoring and evaluation of the IRF PPS.

Based on our continued review, we believe a further reduction is warranted. Since publication of the FY 2006 final rule, we have continued our fiscal oversight of the IRF PPS and have conducted detailed analyses of IRF payment and utilization practices. We re-examined RAND's analysis of the 1999 and 2002 data (contained in RAND's report entitled "Preliminary Analyses of Changes in Coding and Case Mix Under the Inpatient Rehabilitation Facility Prospective Payment System"). We believe it is appropriate

to base our decision to implement a further reduction on RAND's analysis because the additional adjustment is intended to reflect more fully the impact of coding changes (that do not reflect real changes in case mix) from the same period for which we implemented the 1.9 percent reduction in FY 2006 (that is, 2002).

We disagree with the commenters who believe that the lower end of RAND's estimate is more valid than the higher end. We further believe that our decision for FY 2006 to make an adjustment of 1.9 percent is indicative only of our intent to adjust incrementally for coding changes, and is not an indication that the higher end of the estimate is less valid than the lower. Indeed, in contrast to some of the commenters, we find it compelling that RAND found that coding changes accounted for *at least* 1.9 percent of the increases in payment in 2002. In our view, this means that the actual amount was likely somewhat higher than 1.9 percent. As we discussed in the FY 2006 final rule, a separate analysis by RAND found that if all IRFs had been paid based on 100 percent of the IRF PPS payment rates throughout all of 2002, PPS payments during 2002 would have been 17 percent higher than IRFs' costs. We stated that we believed this suggested that we could have proposed a reduction greater than 1.9 percent. We continue to believe

this is the case. Further, if RAND's analysis did not support a conclusion that coding change likely accounted for more than 1.9 percent of the increase in payments, RAND would not have provided a range of estimates. However, RAND reported that IRF payments were at least 1.9 percent and as much as 5.8 percent higher than expected as a result of changes in coding that did not reflect real changes in case mix.

As the commenters noted, several portions of RAND's report discuss the difficulty of estimating with precision the amount of change in case mix that is real and the amount that is a result of changes in coding that do not reflect real changes in case mix. However, we believe this discussion was merely an acknowledgement of the complexity of the analysis, and did not represent a lack of confidence in the upper end of RAND's estimated range (1.9 to 5.8 percent).

Further, the technical expert panel (consisting of representatives from industry groups, other government entities, academia, and other researchers) that RAND assembled to advise it on its methodology and review its findings expressed general agreement with RAND's analytical approaches. We have also carefully reviewed RAND's report, and we continue to believe that the analyses that support

both the upper- and lower- bounds of RAND's range of estimates are analytically sound. In particular, we believe the approach that RAND used in examining IRF patients' acute care hospital records before admission to the IRF provides a good indication of IRF patients' acuity because the vast majority of IRF patients are referred to the IRF from the acute care hospital setting. As detailed in RAND's report, most of the changes in case mix that RAND documented from the acute care hospital records indicated that IRF patients should have been less costly to treat in 2002 than in 1999. This analysis produced RAND's upper-bound estimate that as much as 5.8 percent of the changes in aggregate payments were a result of changes in coding that did not reflect real changes in case mix. For the reasons discussed in its report, RAND acknowledged that the 5.8 percent estimate was an upper-bound estimate and that, therefore, the actual change in aggregate payments as a result of coding change was likely lower than this. However, we believe it is an incorrect interpretation of RAND's results to suggest that RAND only expressed confidence in its 1.9 percent estimate. If RAND had believed that 1.9 percent was the final result of its analysis, RAND would have recommended that CMS implement a coding adjustment of exactly 1.9 percent, not at least 1.9

percent, and would not have given a range of up to 5.8 percent. We interpret the 1.9 percent figure to be a floor for our adjustment for coding changes that do not reflect real changes in case mix, rather than an upper limit for such an adjustment.

As noted previously, we initially chose to adopt a conservative approach by implementing only a 1.9 percent adjustment for FY 2006, even though we believe that RAND's analysis suggested that the actual effects of coding changes that do not reflect a real change in case mix were likely larger than 1.9 percent. We chose this more conservative approach for FY 2006 because we believed that an incremental approach to implementing the payment reduction was appropriate in view of all of the other recent Medicare policy changes, such as the phase in of the 75 percent rule compliance percentage. We continue to favor an incremental approach, for this same reason. However, as described in the FY 2007 proposed rule and for the reasons described below, we are convinced that an additional coding adjustment is needed to adjust the impact of coding changes not related to real changes in case mix. As part of our ongoing assessment, we examined a recent MedPAC analysis of trends in IRF costs that we believe indicates that case mix changes had a lower impact on

payment than we initially thought, and therefore that coding changes had a larger impact on payments than we initially thought. In its March 2006 report, MedPAC reported that IRFs' cost increases in 2003 and 2004 (2.4 percent and 3.6 percent respectively) lagged far behind payment increases. During 2002 and 2003, MedPAC reported that IRF PPS payments were increasing at a rate of "more than 10 percent per year." From this, MedPAC concluded that "payments have far outpaced cost growth" during the first years of the IRF PPS. We believe that the relatively low cost increases that MedPAC found suggest that case mix was not increasing as rapidly as IRF PPS payments, because if case mix had been increasing substantially, this would have led to rapidly rising costs.

As we discussed in the proposed rule, we also analyzed changes in the distribution of patients across the four IRF payment tiers from calendar year 2002 through calendar year 2005. The purpose of this analysis was to evaluate whether an additional adjustment was needed to eliminate the effects of coding changes that do not represent real changes in case mix from payments in the initial implementation year of the IRF PPS, and we analyzed the calendar year 2002 through calendar year 2005 data because it was the most complete post-PPS data available. For

determining IRF PPS payments, we classify patients into one of four tiers within a CMG, based on the presence of any relevant comorbidities. One of the tiers contains patients with no relevant comorbidities. The other three tiers contain patients with increasingly costly comorbidities. For this reason, an IRF will receive higher payments for patients in one of the three more-costly tiers than for patients in the "no comorbidity" tier.

As indicated in Table 6 of the proposed rule, we found that the proportion of IRF patients in the lowest-paying tier (the tier for patients with "no comorbidities") decreased by 6 percentage points between calendar years 2002 and 2005. Conversely, the proportion of patients in each of the three higher-paying tiers increased each year. As we indicated previously, we do not believe real case mix was increasing substantially, because MedPAC's findings indicate that costs were not rising as rapidly as we would have expected if case mix had been increasing significantly during this period. Thus, we believe this potential disparity lends further support to the conclusion that a substantial portion of the unexpected increase in IRF payments when we first implemented the IRF PPS was a result of changes in provider coding practices that do not reflect real changes in case mix. We believe the MedPAC and CMS

analyses, taken together, combined with our interpretation of the RAND report suggesting that the amount of coding change likely represented more than 1.9 percent of the aggregate payment increases, suggest that our FY 2006 decision to reduce the standard payment by only 1.9 percent, the lowest possible amount, was a very conservative approach. As we indicated previously, we intended to take a conservative approach for FY 2006 because we believed, and continue to believe, that an incremental approach to the coding adjustment is best given the other recent Medicare policy changes that we have implemented for IRFs. As part of that incremental approach, we believe making the additional adjustment for FY 2007 is warranted based on the mandate of Section 1886(j)(2)(C)(ii) of the Act.

Comment: Many commenters expressed specific concerns about the effects of the recent phase-in of the 75 percent rule compliance percentage, including concerns that the enforcement of the 75 percent rule was having a larger effect on the population of patients being admitted to IRFs than CMS's 75 percent rule impact analysis would have predicted. These commenters indicated that it would be inappropriate to implement any reduction to the standard payment amount to account for coding changes, not only for

FY 2007 but also until the 75 percent rule is fully phased in and CMS has had an opportunity to analyze the data that reflect the full phase-in of the compliance percentage.

Response: We do not agree with the commenters that CMS should delay the implementation of a reduction to the standard payment amount to account for coding changes that do not reflect real changes in case mix that occurred when we first began implementing the IRF PPS, as required by statute and for the reasons outlined immediately above. For FY 2006, we implemented a very conservative adjustment of 1.9 percent in recognition that IRFs' current cost structures may be changing as they strive to comply with other recent Medicare policy changes, such as the 75 percent rule. As described in further detail below, in further recognition of these changes and in response to comments, we are lowering our proposed reduction from 2.9 percent to 2.6 percent. However, the 75 percent rule and the reduction to the standard payment amount to account for coding change involve separate statutory mandates. The purpose of the 75 percent rule is to adhere to the statutory requirement to differentiate IRF facilities from IPPS hospitals and other types of inpatient hospital facilities. The purpose of the reduction to the standard payment amount is to adhere to the statutory requirement to

adjust the standard payment amount to account for changes in coding that affect aggregate payments and do not reflect real changes in case mix. We believe that the statute requires us to establish policies for both purposes.

The impact analysis contained in the May 7, 2004 IRF classification criteria final rule used the best available data to estimate the effects of the revised regulations. However, although we strive to be as accurate as possible in our estimation of the effects of the policies we implement, an impact analysis is always a projection of what we believe will happen in the future based on historical data, and therefore uncertain. Because we understand the commenters' concerns regarding the effects of the 75 percent rule on beneficiaries and on providers, we are continuing our close monitoring of the impact of the multi-year phase in of the 75 percent rule compliance percentage on beneficiaries' access to IRF services and on IRFs' costs of treating various types of patients. As detailed in CMS' November 30, 2005 memorandum entitled "Inpatient Rehabilitation Facility PPS and the 75 Percent Rule," (available on the IRF PPS Web site at <http://www.cms.hhs.gov/InpatientRehabFacPPS/>), our analysis indicates that the effects of the 75 percent rule have been focused on a few specific conditions, but have resulted in

improved access to care for certain types of patients, such as those being treated for a stroke, for which IRF services can be particularly beneficial.

As discussed in detail in the IRF classification criteria final rule (69 FR 25752), published May 7, 2004, we implemented a phase-in schedule for the 75 percent compliance threshold to give providers ample time to adjust their admission practices to comply with the full threshold. Further, as discussed in section VII of this final rule, in accordance with section 5005 of the DRA, we are revising the compliance thresholds that must be met for certain cost reporting periods, which effectively allows providers an additional cost reporting period to meet the 60 percent compliance threshold and delays the full phase-in of the 75 percent compliance threshold. In addition, patient comorbidities will continue to be used to determine compliance for an additional cost reporting period, until the full 75 percent compliance threshold becomes effective. Thus, we believe that both of these measures, along with our decision to implement a 2.6 percent reduction instead of a 2.9 percent reduction, will ease the transition for providers by allowing them more time to adjust their practices to comply with the regulations.

Comment: Some commenters expressed concerns about the

local coverage determinations (LCDs) being used by some of the fiscal intermediaries in denying some IRF claims. They said that these policies were creating instability in the system that would be intensified by the imposition of the additional reduction to the standard payment amount for FY 2007.

Response: Because LCDs were not discussed in the proposed rule, a substantive discussion of LCD policies is outside the scope of this final rule. However, to the extent that the commenters believe CMS should delay implementation of the reduction to the standard payment amount for FY 2007 because of the LCD issues, we disagree with the commenters. We continue to believe that we have an obligation to implement a reduction to the standard payment amount to account for coding changes that do not reflect real changes in case mix that occurred when we first began implementing the IRF PPS, as required by statute and for the reasons outlined above. We will continue to monitor the effects of the LCDs closely and will take these effects into account in our ongoing analyses of IRF payment policies. We note that the FIs have discretion in formulating and implementing the most appropriate LCDs for their areas, as long as they are not inconsistent with the national policies defined by CMS, and

we fully support their efforts in this regard.

Comment: Numerous commenters questioned why CMS was using older data to support the proposed reduction to the standard payment amount for FY 2007. They asked CMS to collect and analyze FY 2005 and FY 2006 data (which would be representative of the changes under the 75 percent rule) before implementing any reductions in payments.

Response: We agree with the commenters that it will be important to continue to analyze the most current available data over the coming years, especially when complete data from the full phase-in of the 75 percent rule become available, to ensure that IRF payments continue to reflect as closely as possible the costs of care in IRFs. If our analysis of this data shows that additional refinements need to be made to the system, we will propose them in the future. However, we do not believe that this precludes us from making current refinements to the system that adjust payments for the effects of coding changes (that do not reflect real changes in case mix) that occurred when the IRF PPS was first implemented, for the reasons described in detail above.

Comment: Several commenters incorrectly cited a 16 percent behavioral offset that was implemented at the start of the IRF PPS, which they believed had already accounted

for the expected changes in IRF payments due to changes in coding. These commenters suggested that this behavioral offset eliminated the need for the FY 2006 and FY 2007 coding adjustments.

Response: As described in the August 7, 2001 final rule (66 FR 41316, 41366 through 41367), we applied a 1.16 percent (not 16 percent) behavioral offset to IRF PPS payments to account for the inherent incentives of a discharge-based prospective payment system to discharge patients earlier than under the previous cost-based IRF payment system. In that final rule, we expressed our expectation that reductions in IRF lengths of stay under the IRF PPS would lead to lower costs for the facilities and that, in the absence of a behavioral offset, payments would be too high because they would continue to reflect IRFs' higher costs with the longer lengths of stay under the previous payment system. We have, in fact, observed rapid decreases in lengths of stay for IRF patients since we implemented the IRF PPS.

In addition, as explained in detail in RAND's report titled "Preliminary Analyses of Changes in Coding and Case Mix Under the Inpatient Rehabilitation Facility Prospective Payment System" (available on RAND's website at <http://www.rand.org/publications/TR/TR213/>), RAND accounted

for the 1.16 percent behavioral offset adjustment when estimating the amount of observed case mix change that was a result of real case mix change and the amount that was a result of coding changes that do not reflect real changes in case mix. The range of estimates for the amount of case mix and coding change that RAND developed (1.9 percent to 5.8 percent) contains an adjustment to account for this behavioral offset.

Comment: Several commenters stated that one effect of the FY 2006 refinements to the IRF classification system was to lower IRF payments by 2.2 percent, and recommended that CMS restore 2.2 percent to the IRF PPS payments for FY 2007.

Response: As described in detail in the FY 2006 IRF PPS final rule (70 FR 47880, 47886 through 47904), we implemented several refinements to the IRF classification system for FY 2006, based on analysis conducted by RAND, to ensure that payments are aligned as closely as possible with the costs of care in IRFs. The FY 2006 refinements included a redefinition of the IRF case mix groups (CMGs), so that the new CMGs were based on the most current and complete post-PPS data available. We implemented these revisions in a budget-neutral manner, so that aggregate payments to providers were not estimated to increase or

decrease as a result of these refinements. However, in the impact section of the FY 2006 IRF PPS final rule, we discussed the redistribution of payments that we estimated would occur in FY 2006 as a result of the implementation of these refinements. We estimated that some providers would experience increases in payments and that some providers would experience decreases in payments as a result of these refinements.

Many of the commenters cited a report titled "Evaluation of the Proposed Coding Adjustment to the Standardized Payment Amount for FY 2007," prepared by the Lewin Group for the HealthSouth Corporation in July 2006, as the source of the 2.2 percent estimate of the decrease in payments resulting from the FY 2006 IRF classification refinements. The report contained two separate analyses of changes in IRFs' case mix indexes (CMIs) between 2002 and 2006 that the authors of the report believe are due to the changes to the classification system that we implemented for FY 2006. The first analysis did not use the same methodology for computing the CMI that RAND and CMS use, and the authors of the report indicated that they had less confidence in this analysis for that reason. The second analysis, from which Lewin's 2.2 percent estimate is derived, used the same methodology that RAND and CMS use to

calculate the CMI, but the analysis used IRF-PAI data from only 592 facilities (out of a total of about 1,240 IRFs nationwide). Lewin obtained data on these 592 facilities from the database maintained by the Uniform Data System for Medical Rehabilitation (UDS_{mr}).

In contrast, our estimates of the effects of the FY 2006 refinements to the classification system are based on analysis of 1,188 IRFs nationwide, for which we had complete data at the time that we were conducting the impact analysis for the FY 2006 IRF PPS final rule. We believe that our estimates of the effects of the FY 2006 refinements are more representative of the effects on the industry than Lewin's analysis because our database includes all IRFs for which we were able to match claims and IRF-PAI data. As illustrated in the first row of column 7 in Table 13 of the IRF PPS final rule, we estimated that aggregate payments to all IRFs would neither increase nor decrease as a result of the FY 2006 refinements to the IRF classification system, because we implemented these changes in a budget neutral manner, as described in detail in that final rule. However, in that final rule, we also indicated that we estimated that the refinements to the classification system would result in some redistribution of payments among different types of

providers, with some groups estimated to experience payment increases and some groups estimated to experience payment decreases. For example, we estimated that these refinements could result in an estimated 2.7 percent decrease in payments to rural providers in the Pacific region and an estimated 2.6 percent increase in payments to rural providers in the Mountain region. In Table 13 of the FY 2006 IRF PPS final rule, we provide additional information on the estimated effects on IRF PPS payments of the policy changes implemented in that final rule.

In contrast to our analysis, the report by the Lewin Group suggested that the refinements to the classification system resulted in an across-the-board decrease to aggregate IRF payments of about 2.2 percent because, they contend, the refinements caused a decrease in IRFs' CMIs. To assist CMS in analyzing the differences between CMS' impact analysis and the findings contained in Lewin's report, UDS_{mr} gave CMS the provider numbers for 589 of the facilities that Lewin used in the analysis on which Lewin's 2.2 percent estimate is based. Out of these 589 facilities, we were able to match 551 to our IRF database. Some of the 38 provider numbers that did not match appeared to be Medicare provider numbers for skilled nursing facilities, acute care hospital facilities, or other types

of providers. We repeated the same analysis that we had conducted for the FY 2006 IRF PPS final rule, as detailed on pages 47944 through 47952 of that final rule, with the 551 provider numbers that we could match. From this analysis, we determined that these 551 IRFs were more likely to experience expected decreases in payment as a result of the FY 2006 refinements to the classification system than the other IRFs in our database. However, we found that other IRFs experienced corresponding increases in payments as a result of the FY 2006 classification refinements. Thus, we disagree with the Lewin report's finding that the FY 2006 classification refinements reduced IRF payments across the board by 2.2 percent, and believe that the impact analysis we published in the FY 2006 IRF PPS final rule continues to represent our best estimate of the effects of these changes. However, when we have complete data from FY 2006 to analyze, we will revisit our analysis and determine whether additional refinements to the system are necessary in the future.

Comment: Several commenters expressed concerns that the revised average length of stay values in the FY 2006 IRF PPS final rule may have affected payments for short-stay transfer cases and thereby contributed to a reduction in IRF payments. These commenters urged CMS to take this

into account when considering whether an additional reduction to the standard payment amount is necessary for FY 2007.

Response: The average length of stay values published in the FY 2006 IRF PPS final rule (70 FR 47880, 47902 through 47904) and in section IV.B of this final rule are not used to determine payments to IRFs other than to determine payments for short-stay transfer cases. These values are entirely driven by the data that providers submit, and have been falling consistently in recent years as the average number of days that patients spend in IRFs continues to decline. The overall decline in the average length of stay values likely has resulted in fewer cases qualifying for the per diem short-stay transfer payments, meaning that more cases have likely received the full CMG payments rather than the per diem payments.

Because the average length of stay values that we estimate are entirely data-driven, then, we believe that any changes in payments that result from updated average length of stay values are appropriately reflecting changes in the costs of care in IRFs.

Comment: Several commenters suggested that the FY 2006 refinements should serve as a new baseline for evaluating payments in the system, and that CMS should wait

until the data are available to assess how providers respond to the FY 2006 changes before implementing an additional coding adjustment.

Response: As the commenters suggested, the FY 2006 refinements were intended to establish a new baseline for payments in the system, and we will be analyzing this new data for FY 2006 and beyond as part of our ongoing monitoring of the system to ensure that payments reflect as closely as possible the costs of caring for patients in IRFs. However, because, as noted above, the statute requires us to adjust payment rates for IRF services if we determine that changes in coding (that do not reflect real changes in case mix) have resulted in or will result in changes in aggregate payments under the IRF classification system, we do not believe that we should defer implementing the additional adjustment for FY 2007.

Comment: Several commenters expressed concerns that the calendar year 2002 data that RAND used to analyze changes in coding and case mix may have been based on HealthSouth cost report data that, for reasons detailed in the FY 2006 IRF PPS final rule, were not complete.

Response: As we discussed in detail in the FY 2006 IRF PPS final rule (70 FR 47880, 47884), RAND's analysis included 98 IRF providers affiliated with HealthSouth that

omitted home office cost data from the 2002 and 2003 cost reports filed with CMS. However, we detailed in the FY 2006 final rule how RAND and CMS accounted for this data in the analyses for that final rule. In that final rule, we also stated that the omission of the home office cost data would have no effect on the 1.9 percent coding adjustment for FY 2006, because the only data affected by the omission of the home office costs were the cost report data and these data were not used in the analysis that supported the 1.9 percent coding adjustment. The same RAND analysis is used to support the additional coding adjustment for FY 2007, so the home office cost omission similarly has no effect on the FY 2007 coding adjustment.

Comment: Several commenters questioned CMS' legal authority to make the FY 2007 coding adjustment, claiming that the statute does not include review of Medicare margins as a reason for a coding adjustment.

Response: We disagree with the commenters' interpretation of our authority under the statute. We interpret section 1886(j)(2)(C)(ii) of the Act as requiring the Secretary to apply a coding adjustment to the payment rate when the evidence shows that such an adjustment is necessary to ensure that changes in aggregate payments are the result of real changes in case mix and do not reflect

changes in coding that are unrelated to real changes in case mix. As noted previously, we have based our assessment of the amount that changes in aggregate payments in the first year of the implementation of the IRF PPS were a result of real case mix changes and the amount that they were a result of coding changes that do not reflect real changes in case mix on RAND's analysis, not on an analysis of IRF margins. However, we have used MedPAC's analysis of IRF margins to inform our understanding of growth in IRF costs over time, which we believe has direct bearing on our understanding of trends in IRFs' real case mix. We believe that actual increases in IRF case mix in the early years of the IRF PPS would have been accompanied by larger increases in the costs associated with treating higher acuity patients.

Comment: Some commenters questioned the CMS analyses of changes in coding practices, believing that providers were being penalized for reacting to changes in the IRF PPS coding structure.

Response: The coding adjustments for FY 2006 and FY 2007 are not intended to penalize providers for reacting to changes in the IRF PPS coding structure. We encourage providers to improve the accuracy with which they are recording patient's clinical information. However, we are

required by statute to adjust payments if we determine that changes in payments are a result of changes in coding that do not reflect real changes in case mix. Further, we believe it is appropriate to consider provider responses to changes in IRF coding as part of our efforts to evaluate the need for payment adjustments because a rapid change in provider coding practices could reflect changes in IRF payment policies rather than a change in patient severity.

Comment: One commenter asked whether the data presented in Table 6 on page 28124 of the proposed rule was based on calendar year or fiscal year data.

Response: We used calendar year IRF-PAI data in the analysis for Table 6 on page 28124 of the proposed rule.

Comment: One commenter noted that the ICD-9 code 278.02 (overweight) was not recommended by the ICD-9-CM Committee and approved by the National Center for Health Care Statistics for use until October 2005, and therefore it was not surprising that this code was used fewer than 10 times before that date.

Response: We do not find the fact that the code was new as of October 2005 to have any bearing on our conclusion that the dramatic increase in its use likely reflected changes in the IRF payment structure rather than in patient severity levels. Indeed, the fact that the code

was new in October 2005 and its level of use rose immediately upon its introduction, indicates to us that providers are able to adapt their coding practices quickly to reflect coding changes. Thus, the increase in the code's use, in our view, continues to suggest that providers respond more rapidly to coding changes than we initially believed.

Final Decision: After carefully considering all of the comments that we received on the proposed reduction to the standard payment amount to account for coding changes that do not reflect real changes in case mix, we have decided to decrease the amount of the reduction to 2.6 percent, rather than the 2.9 percent that we had proposed. As we indicated in the proposed rule, we considered both 2.9 percent and 2.3 percent as possible reductions to the standard payment amount for FY 2007. However, in view of the industry's rapid adaptation to coding changes, we chose to propose a 2.9 percent reduction to the standard payment amount instead of the 2.3 percent reduction we had considered. The additional analyses the commenters offered in response to the proposed rule did not express a preference for either 2.9 percent or 2.3 percent, but were designed to show that we should not implement any additional reduction to the standard payment amount for FY

2007. In fact, some commenters presented analyses to show that CMS should provide a net increase to the standard payment amount for FY 2007 to compensate for the 2.2 percent reduction they contend occurred because of the FY 2006 refinements to the classification system (as discussed above). Further, commenters said that they did not believe that either the lower 2.3 percent reduction or the proposed 2.9 percent reduction were appropriate. Instead, commenters generally rejected any reduction to the standard payment amount. As explained previously, no reduction to the standard payment amount was not a reasonable option in light of RAND's analysis and the additional data we evaluated (as described above). Consequently, because we continue to believe a 2.3 percent reduction is too low, and in view of the significant concerns raised by commenters about the proposed 2.9 percent reduction, we have decided to implement a 2.6 percent reduction. The 2.6 percent reduction represents the midpoint between the 2.9 percent we had proposed and the 2.3 percent reduction we also had considered proposing, which would have fallen at approximately the middle of RAND's range of estimates.

In view of the significant concerns that commenters raised, and in continuing recognition of the significant changes in IRFs' patient populations that may be occurring

as a result of the current phase in of the 75 percent rule compliance percentage, we have decided that the best approach at this time is to continue to exercise caution by adopting a slightly more conservative approach to further reducing the standard payment amount. In this way, we provide IRFs more flexibility in adapting their admission practices and cost structures to the recent regulatory changes.

However, as the commenters suggested, we intend to continue analyzing changes in coding and case mix closely using the most current available data, as part of our ongoing monitoring of the IRF PPS. If, based on updated analysis, we determine that additional adjustments are needed to ensure that changes in aggregate payments are the result of real changes in case mix and not merely the result of changes in coding that do not reflect real changes in case mix, we intend to propose additional payment refinements.

For FY 2007, therefore, we are continuing our incremental approach to adjusting payments for coding changes that occurred when we first began implementing the IRF PPS in 2002. Together with the 1.9 percent reduction that we implemented for FY 2006, the 2.6 percent reduction for FY 2007 will result in a total adjustment of 4.5

percent ($1.9 + 2.6 = 4.5$). Because 4.5 percent is still well within the range of RAND's estimates of the effects of coding changes that do not reflect real changes in case mix on IRF PPS payments that occurred between 1999 and 2002, we continue to believe that we are still providing flexibility to account for the possibility that some of the observed changes may be attributable to factors other than coding changes.

We will use the same methodology that we used in the FY 2006 IRF PPS final rule (70 FR 47880, 47908) to reduce the standard payment amount to adjust for coding changes that affect payment. To reduce the standard payment amount by 2.6 percent for FY 2007, we will multiply the standard payment amount by 0.974 (obtained by subtracting 0.026 from 1.000).

In section V.D of this final rule, we further describe how we will adjust the standard payment amount by the budget neutrality factors for the wage index, the second year of the hold harmless policy, and the revisions to the CMG relative weights and tier comorbidities to produce the final FY 2007 standard payment conversion factor. In Table 6 of this final rule, we provide a step-by-step calculation that results in the FY 2007 standard payment conversion factor.

B. FY 2007 IRF Market Basket Increase Factor and Labor-Related Share

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. Accordingly, in updating the FY 2007 payment rates set forth in this final rule, we apply an appropriate increase factor to the FY 2006 IRF PPS payment rates that is based on the rehabilitation, psychiatric, and long-term care hospital (RPL) market basket. In constructing the RPL market basket, we used the methodology set forth in the FY 2006 IRF PPS final rule (70 FR 47880, 47908 through 47915) and described in the FY 2007 proposed rule.

Most of the comments that we received on the market basket and labor-related share support the update to the market basket increase and labor-related share based on more recent data as discussed in the FY 2007 proposed rule. We did not receive any comments on the continued use of the Bureau of Labor Statistics (BLS) Employment Cost Indexes (ECI) data in light of the BLS change in system usage to the North American Industrial Classification Systems based ECI.

Final Decision: For this final rule, the FY 2007 IRF market basket increase factor is 3.3 percent. This is based on the Global Insight, Inc. (GII) forecast for the second quarter of 2006 (2006q2) with historical data through the first quarter of 2006 (2006q1). The 3.3 percent market basket increase factor is 0.1 percentage point lower than the increase that we published in the proposed rule, which was based on GII's forecast for the first quarter of 2006 (2006q1).

In addition, we used the methodology described in the FY 2006 IRF PPS final rule to update the labor-related share for FY 2007. As shown in Table 5, the final FY 2007 IRF labor-related share (which is based on GII's forecast for the second quarter of 2006) is 75.612 percent in this final rule. This is approximately 0.1 percentage point lower than the labor-related share that we published in the proposed rule, which reflected GII's forecast for the first quarter of 2006 (2006q1).

Comment: One commenter believes that Global Insight, Inc.'s (GII's) market basket projection for FY 2007 underestimates the inflation pressure that hospitals face in serving Medicare beneficiaries. The commenter indicates that GII's latest forecast of the RPL market basket for FY 2006 is 3.8 percent compared to the final IRF PPS FY 2006

update of 3.6 percent.

Response: The FY 2007 IRF update of 3.3 percent is based on GII's most recent forecast, which includes the latest available historical data through 2006q1. This forecast reflects the expected inflation pressures that hospitals will face in FY 2007. The GII figure will not be final until the release of GII's 2006q4 forecast, which will include historical data through 2006q3. We continue to work closely with GII to ensure the most accurate projections possible.

Table 5: FY 2007 IRF Labor-Related Share Relative Importance

Cost Category	FY 2007 IRF Labor-Related Relative Importance
Wages and salaries	52.406
Employee Benefits	14.084
Professional fees	2.898
All other labor intensive services	2.142
SUBTOTAL:	71.530
Labor-related share of capital costs	4.082
TOTAL:	75.612

Source: Global Insight, Inc. 2ndQtr 2006, @USMACRO/CONTROL0606 @CISSIM/TL0506.SIM

C. Area Wage Adjustment

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs attributable to wages and wage-related costs by a factor

(established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustments or updates made under section 1886(j)(6) of the Act for a FY are made in a budget neutral manner.

In the FY 2007 proposed rule, we proposed to maintain the methodology and policies described in the FY 2006 IRF PPS final rule to determine the wage index, labor market area definitions, areas with missing hospital data, and hold harmless policy consistent with the rationales outlined in that final rule (70 FR 47880, 47917 through 47933).

In our review of Table 1 in the Addendum of the proposed rule, we found that the wage index published for Hinesville, Georgia (CBSA 25980) is incorrect. The corrected wage index for this area can be found in Table 1 of the Addendum in this final rule.

We received only a few comments on maintaining the methodology described in the FY 2006 final rule (70 FR 47880) for FY 2007. The comments and our responses are summarized below.

Comment: We received comments supporting our transition to the full CBSA-based labor market area definitions. However, we received several comments that recommended extending the blended wage index for another year to protect certain IRFs that would otherwise experience wage index reductions of 8 percent or more.

Response: In the FY 2006 proposed rule, we had not proposed a transition to the CBSA-based labor market area designations. However, after a review of the comments, we provided a budget neutral transition to the CBSAs, which will expire for discharges occurring on or after October 1, 2006. We agreed with commenters that it is appropriate to assist providers in adapting to the changes from MSA to CBSA in a manner that provides the most benefit to the largest number of providers. Therefore, our FY 2006 final rule adopted a transition policy that provided measurable relief to the greatest number of adversely affected IRFs with the least impact to the rest of the facilities. In the FY 2006 final rule, we discuss other transition policies recommended by the public in order to transition from the MSA to CBSA-based designations. A full discussion of the alternative transition policies that we considered and our decision to adopt the 1-year blended wage index

appears in the FY 2006 final rule (70 FR 47880, 47922 through 47923)

We also adopted a hold harmless policy specifically for rural IRFs whose labor market designations changed from rural to urban under the CBSA-based labor market area designations. This policy specifically applied to IRFs that had previously been designated rural and which, effective October 1, 2005, would otherwise have become ineligible for the 19.14 percent rural adjustment. For FY 2007, the second year of the 3-year phase out of the budget-neutral hold harmless policy, the adjustment will be up to 6.38 percent for IRFs that meet the criteria described in the FY 2006 final rule (70 FR 47880, 47923 through 47926).

As stated in our FY 2006 final rule, we did not extend the hold harmless policy to encompass facilities that remain in an urban area, because we believe that the transition wage index mitigated the impact of the change from MSAs to CBSAs. We note that periodic updating of the wage data routinely produces a certain degree of fluctuation in wage index values, which would occur even in the absence of a conversion to the CBSA-based structure.

In reviewing the data, we found that updating the wage data by itself produced similar levels of fluctuation in

wage index values under either the MSA or CBSA designations. In general, we found that approximately 1 percent of IRFs would experience a decrease of 8 percent or more in the wage index under either the MSA or CBSA designations. However, under the CBSA designations, 57 percent either remained the same or had an increase in the wage index. We also examined the impact of the wage index if we had remained under the MSA-based designations. Under this scenario, we find that only 48 percent of IRFs would have remained the same or would have had an increase in the wage index. Thus, we find that more providers would expect to have no change or an increase in the wage index under the CBSA designations. We also note that the decrease or increase in the wage index fluctuates from year to year based on the updated wage data. Therefore, we are not revising our current wage index policy at this time.

Comment: A few commenters requested that we adopt wage index policies like those under the acute inpatient prospective payment systems (IPPS). The IPPS wage index policies would allow IRFs to benefit from the IPPS reclassification and/or rural floor policies. (A discussion of the IPPS reclassification and rural floor policies may be found on our Web site at

http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.

)

In addition, we were also urged to use the most recent hospital cost report wage data available for FY 2007 instead of the most recent final hospital cost report wage data available. Several commenters recommended that we engage in wage index discussions with the industry, but recognized that legislative action may be necessary to accomplish some or all of the changes that they recommended.

Response: For FY 2007, we did not propose changes in the IRF PPS methodology relating to the wage index, either to use more recent hospital wage data or to adopt the reclassification or rural floor provisions used in IPPS. Therefore, we are not revising the IRF methodology described in the FY 2006 IRF PPS final rule. The rationale for our current wage index policies may be found in the FY 2006 final rule (70 FR 47880, 47927 through 47928). However, we agree that we should engage in further discussions with the industry to evaluate possible wage index alternatives.

Final Decision: The FY 2007 wage index will be based solely on the CBSA-based labor market area definitions and the corresponding wage index (rather than on a blended wage

index). We will use the most recent final pre-reclassified and pre-floor hospital wage data available (FY 2002 hospital wage data) based on the CBSA labor market area definitions consistent with the rationale outlined in the FY 2006 IRF PPS final rule.

D. Description of the Standard Payment Conversion Factor and the Payment Rates for FY 2007

In the FY 2006 final rule (70 FR 47880, 47937 through 47398), we revised the IRF regulations text by adding §412.624(d)(4) to indicate that we apply a factor when revisions are made to the tier comorbidities and the IRF classification system, the rural adjustment, the LIP adjustment, the teaching status adjustment, the hold harmless adjustment, or other budget-neutral policies. To clarify, we did not propose changes to the rural adjustment of 21.3 percent, the LIP exponential factor of 0.6229, or the teaching status adjustment exponential factor of 0.9012. They remain as described in the FY 2006 IRF PPS final rule. As discussed in greater detail in the FY 2007 proposed rule, because we are not changing these policies, we do not need to calculate budget neutrality factors for these policies because they are assumed in the FY 2006 standard payment conversion factor.

As described in the FY 2007 proposed rule, we will apply factors to the standard payment amount for the changes that we proposed for FY 2007, to ensure that estimated aggregate payments in FY 2007 are not greater or less than those that would have been made in the year without the updates to the wage index and labor-related share, the second year of the hold harmless policy, and the revisions to the tier comorbidities and relative weights. A description of the methodology used to derive the budget neutrality factors for these changes is included in our FY 2007 proposed rule. These same steps are used to determine the budget neutrality factors that reflect the final policies for FY 2007, as discussed in this section below.

Final Decision: We did not receive any comments regarding the methodology used to derive the budget neutrality factors. Therefore, we will apply the wage index and labor-related share budget neutrality factor of 1.0016 and the budget neutrality factor for the combined hold harmless, tier comorbidity, and relative weight changes of 1.0093. Please see Table 9 in this final rule to see how these changes are estimated to affect payments among different types of facilities. These budget neutrality factors are slightly different from the FY 2007 proposed rule because the market basket and labor-related

share are based on updated data as described in section V.B of this final rule.

The standard payment conversion factor of \$12,981 and the payment rates in Table 6 and Table 7 (respectively) will be used for FY 2007. The standard payment conversion factor in this final rule is greater than the standard payment conversion factor in the proposed rule because we used updated data for the market basket and labor-related share and will implement a 2.6 percent reduction instead of a 2.9 percent reduction to the standard payment amount (as discussed in sections V.A and B of this final rule).

Thus, consistent with §412.624(d)(4), we apply these factors to the standard payment amount in order to make the changes described in this final rule in a budget neutral manner for FY 2007. We used the methodology described in sections V.A and B of this final rule. We use the FY 2006 standard payment conversion factor (\$12,762) and apply the market basket (3.3 percent), which equals \$13,183. Then, we apply a reduction to the standard payment amount of 2.6 percent as discussed in section V.A of this final rule, which equals \$12,840. We then apply the budget-neutral wage adjustment of 1.0016 to \$12,840, which results in a standard payment amount of \$12,861.

Next, we combine the factors for the tier comorbidity and CMG relative weight changes (1.0080) and for the second year of the hold harmless policy (1.0013) by multiplying the two factors to establish a single budget neutrality factor for the two changes (1.0013 * 1.0080 = 1.0093). We apply this overall budget neutrality factor to the standard payment amount of \$12,861, resulting in the standard payment conversion factor of \$12,981 for FY 2007 (Table 6).

Table 6: Calculations to Determine the FY 2007 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations
FY 2006 Standard Payment Conversion Factor	\$12,762
FY 2007 Market Basket Increase Factor	X 1.033
Subtotal	= \$13,183
One-Time 2.6% Reduction for Coding Changes	X 0.974
Subtotal	= \$12,840
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x 1.0016
Subtotal	= \$12,861
Budget Neutrality Factor for the Hold Harmless Provision and Revisions to the Tier Comorbidities and the CMG Relative Weights	X 1.0093
FY 2007 Standard Payment Conversion Factor	= \$12,981

The FY 2007 standard payment conversion factor is applied to each of the CMG relative weights shown in Table 4, "FY 2007 IRF PPS Relative Weights and Average Lengths of Stay for Case-Mix Groups," to compute the unadjusted IRF prospective payment rates for FY 2007 shown in Table 7. To clarify further, the budget neutrality factors described

above would be applied only for FY 2007. However, if necessary, we will apply budget neutrality factors in applicable years hereafter to the extent that further adjustments are made to the IRF PPS consistent with §412.624(d) (4). Otherwise, the general methodology to determine the Federal prospective payment rate is described in §412.624(c) (3) (ii).

The resulting unadjusted IRF prospective payment rates for FY 2007 are shown below in Table 7, "FY 2007 Payment Rates."

Table 7: FY 2007 Payment Rates				
CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	\$10,004.46	\$9,480.02	\$8,531.11	\$8,239.04
0102	\$12,322.86	\$11,676.41	\$10,508.12	\$10,148.55
0103	\$14,528.34	\$13,766.35	\$12,389.07	\$11,965.89
0104	\$15,427.92	\$14,616.61	\$13,154.95	\$12,704.50
0105	\$18,512.20	\$17,539.93	\$15,786.19	\$15,246.18
0106	\$21,540.67	\$20,408.73	\$18,368.12	\$17,739.83
0107	\$24,858.62	\$23,554.02	\$21,197.97	\$20,472.34
0108	\$28,765.90	\$27,256.21	\$24,530.20	\$23,690.33
0109	\$28,555.60	\$27,056.30	\$24,349.76	\$23,516.38
0110	\$34,123.15	\$32,331.78	\$29,098.21	\$28,102.57
0201	\$10,570.43	\$8,834.87	\$7,892.45	\$7,330.37
0202	\$13,578.13	\$11,349.29	\$10,138.16	\$9,416.42
0203	\$16,230.14	\$13,565.15	\$12,117.76	\$11,255.83
0204	\$17,381.56	\$14,528.34	\$12,978.40	\$12,055.45
0205	\$21,304.42	\$17,807.34	\$15,906.92	\$14,774.97
0206	\$27,837.75	\$23,267.14	\$20,783.88	\$19,306.64
0207	\$35,910.64	\$30,014.67	\$26,812.26	\$24,904.05

Table 7: FY 2007 Payment Rates				
CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0301	\$14,790.55	\$12,374.79	\$11,101.35	\$10,088.83
0302	\$19,309.24	\$16,156.15	\$14,491.99	\$13,171.82
0303	\$22,977.67	\$19,224.86	\$17,245.26	\$15,673.26
0304	\$31,667.15	\$26,494.22	\$23,766.91	\$21,600.38
0401	\$12,444.88	\$10,976.73	\$10,023.93	\$8,902.37
0402	\$17,207.61	\$15,176.09	\$13,858.52	\$12,308.58
0403	\$29,945.87	\$26,412.44	\$24,118.70	\$21,421.25
0404	\$53,925.67	\$47,561.09	\$43,431.83	\$38,575.64
0405	\$40,722.70	\$35,915.83	\$32,797.79	\$29,130.66
0501	\$9,927.87	\$8,379.24	\$7,382.29	\$6,582.67
0502	\$13,321.10	\$11,242.84	\$9,904.50	\$8,832.27
0503	\$17,648.97	\$14,897.00	\$13,122.49	\$11,701.07
0504	\$22,046.93	\$18,608.26	\$16,392.41	\$14,616.61
0505	\$26,183.98	\$22,100.15	\$19,467.61	\$17,359.49
0506	\$35,570.54	\$30,022.46	\$26,447.49	\$23,582.58
0601	\$11,671.22	\$9,515.07	\$9,111.36	\$8,466.21
0602	\$15,535.66	\$12,665.56	\$12,126.85	\$11,270.10
0603	\$19,894.68	\$16,219.76	\$15,531.77	\$14,432.28
0604	\$25,432.38	\$20,734.55	\$19,854.44	\$18,449.90
0701	\$11,719.25	\$10,017.44	\$9,525.46	\$8,589.53
0702	\$15,234.50	\$13,023.84	\$12,382.58	\$11,166.26
0703	\$18,989.90	\$16,234.04	\$15,434.41	\$13,918.23
0704	\$23,325.56	\$19,940.11	\$18,958.75	\$17,095.98
0801	\$8,485.68	\$7,144.74	\$6,660.55	\$5,980.35
0802	\$11,088.37	\$9,337.23	\$8,702.46	\$7,814.56
0803	\$16,494.96	\$13,889.67	\$12,947.25	\$11,625.78
0804	\$14,331.02	\$12,067.14	\$11,248.04	\$10,100.52
0805	\$18,078.64	\$15,222.82	\$14,189.53	\$12,742.15
0806	\$21,708.13	\$18,279.84	\$17,038.86	\$15,300.70
0901	\$10,936.49	\$9,918.78	\$8,915.35	\$7,944.37
0902	\$14,393.33	\$13,054.99	\$11,733.53	\$10,457.49
0903	\$19,001.59	\$17,234.87	\$15,491.53	\$13,805.29
0904	\$23,808.45	\$21,595.19	\$19,409.19	\$17,297.18
1001	\$12,494.21	\$11,525.83	\$10,328.98	\$9,555.31

Table 7: FY 2007 Payment Rates				
CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1002	\$16,497.55	\$15,218.92	\$13,639.14	\$12,616.23
1003	\$23,204.84	\$21,406.97	\$19,184.62	\$17,746.33
1101	\$16,296.35	\$13,606.68	\$11,974.97	\$11,028.66
1102	\$24,435.43	\$20,402.24	\$17,955.32	\$16,536.50
1201	\$13,210.76	\$11,403.81	\$10,621.05	\$9,612.43
1202	\$17,093.38	\$14,755.50	\$13,741.69	\$12,437.10
1203	\$21,082.44	\$18,199.36	\$16,949.29	\$15,339.65
1301	\$13,440.53	\$12,508.49	\$11,048.13	\$9,643.58
1302	\$18,590.09	\$17,299.78	\$15,281.23	\$13,337.98
1303	\$23,690.33	\$22,046.93	\$19,474.10	\$16,997.32
1401	\$10,592.50	\$9,542.33	\$8,481.79	\$7,608.16
1402	\$14,328.43	\$12,908.31	\$11,473.91	\$10,291.34
1403	\$17,790.46	\$16,027.64	\$14,246.65	\$12,778.50
1404	\$22,548.00	\$20,313.97	\$18,056.57	\$16,196.39
1501	\$12,962.83	\$11,514.15	\$10,116.09	\$9,604.64
1502	\$16,435.24	\$14,598.43	\$12,825.23	\$12,177.48
1503	\$20,064.73	\$17,822.91	\$15,657.68	\$14,867.14
1504	\$26,242.39	\$23,309.98	\$20,477.53	\$19,444.24
1601	\$13,071.87	\$11,098.76	\$10,091.43	\$9,030.88
1602	\$17,947.53	\$15,238.40	\$13,854.62	\$12,399.45
1603	\$22,100.15	\$18,764.04	\$17,060.93	\$15,268.25
1701	\$12,744.75	\$12,514.98	\$11,006.59	\$9,564.40
1702	\$16,772.75	\$16,470.29	\$14,484.20	\$12,586.38
1703	\$19,933.62	\$19,575.35	\$17,215.40	\$14,959.30
1704	\$24,983.23	\$24,532.79	\$21,574.42	\$18,748.46
1801	\$15,473.35	\$12,807.05	\$10,700.24	\$9,530.65
1802	\$24,739.19	\$20,476.23	\$17,107.66	\$15,237.10
1803	\$44,527.43	\$36,854.36	\$30,792.23	\$27,424.96
1901	\$16,095.14	\$14,260.93	\$14,233.67	\$12,137.24
1902	\$30,108.13	\$26,678.55	\$26,626.63	\$22,705.07
1903	\$43,439.62	\$38,489.96	\$38,414.67	\$32,757.55
2001	\$11,337.61	\$9,581.28	\$8,742.70	\$7,897.64
2002	\$14,859.35	\$12,557.82	\$11,458.33	\$10,352.35
2003	\$19,182.02	\$16,210.67	\$14,791.85	\$13,362.64

Table 7: FY 2007 Payment Rates				
CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
2004	\$25,593.34	\$21,628.94	\$19,736.31	\$17,829.40
2101	\$28,353.10	\$28,353.10	\$21,556.25	\$18,935.38
5001	\$0.00	\$0.00	\$0.00	\$2,857.12
5101	\$0.00	\$0.00	\$0.00	\$8,244.23
5102	\$0.00	\$0.00	\$0.00	\$20,750.13
5103	\$0.00	\$0.00	\$0.00	\$9,350.21
5104	\$0.00	\$0.00	\$0.00	\$24,383.51

E. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

As described in the FY 2007 proposed rule and in this final rule, Table 8 illustrates the methodology for adjusting the Federal prospective payments. The examples below are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) can be found in Table 7 above.

One beneficiary is in Facility A, a hypothetical IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, a hypothetical IRF located in urban Harrison County, Indiana. Facility A, a non-teaching hospital, has a disproportionate share hospital (DSH) percentage of 5 percent (which results in a LIP adjustment

of 1.0309), a wage index of 0.8624, and an applicable rural adjustment of 21.3 percent. Facility B, a teaching hospital, has a DSH percentage of 15 percent (which results in a LIP adjustment of 1.0910), a wage index of 0.9251, and an applicable teaching status adjustment of 0.109.

To calculate each IRF's labor and non-labor portion of the Federal prospective payment, we begin by taking the unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) from Table 7 above. Then, we multiply the estimated labor-related share (75.612) described in section V.B by the unadjusted Federal prospective payment rate. To determine the non-labor portion of the Federal prospective payment rate, we subtract the labor portion of the Federal payment from the unadjusted Federal prospective payment.

To compute the wage-adjusted Federal prospective payment, we multiply the result of the labor portion of the Federal payment by the appropriate wage index found in the Addendum in Tables 1 and 2, which will result in the wage-adjusted amount. Next, we compute the wage-adjusted Federal payment by adding the wage-adjusted amount to the non-labor portion.

To adjust the Federal prospective payment by the facility-level adjustments, there are several steps.

First, we take the wage-adjusted Federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Then, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.109, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted Federal prospective payment rate. Table 8 illustrates the components of the adjusted payment calculation.

Table 8: Example of Computing an IRF's FY 2007 Federal Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment	\$28,102.57	\$28,102.57
2	Labor Share	X 0.75612	X 0.75612
3	Labor Portion of Federal Payment	= \$21,248.92	= \$21,248.92
4	CBSA Based Wage Index (shown in the Addendum , Tables 1 and 2)	X 0.8624	X 0.9251
5	Wage-Adjusted Amount	= \$18,325.06	= \$19,657.37
6	Nonlabor Amount	+ \$6,853.65	+ \$6,853.65
7	Wage-Adjusted Federal Payment	= \$25,178.72	= \$26,511.03
8	Rural Adjustment	X 1.213	X 1.000
9	Wage- and Rural- Adjusted Federal Payment	= \$30,541.79	= \$26,511.03
10	LIP Adjustment	X 1.0309	X 1.0910
11	FY2007 Wage-, Rural- and LIP- Adjusted Federal Prospective Payment Rate	= \$31,485.53	= \$28,923.53

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
12	FY 2007 Wage- and Rural-Adjusted Federal Prospective Payment	\$30,541.79	\$26,511.03
13	Teaching Status Adjustment	X 0.000	X 0.109
14	Teaching Status Adjustment Amount	= \$0.00	= \$2,889.70
15	FY2007 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+ \$31,485.53	+ \$28,923.53
16	Total FY 2007 Adjusted Federal Prospective Payment	= \$31,485.53	= \$31,813.23

Thus, the adjusted payment for Facility A would be \$31,485.53, and the adjusted payment for Facility B would be \$31,813.23.

VI. Update to Payments for High-Cost Outliers Under the IRF

PPS

A. Update to the Outlier Threshold Amount for FY 2007

A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold, in which case we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold. In the August 7, 2001 final rule, we discussed our decision to set the outlier threshold amount so that estimated outlier payments would equal 3 percent of total estimated payments. In the FY 2007 proposed rule (71 FR 28106), we proposed to update the outlier threshold amount to \$5,609 in accordance with this policy. However, the appropriate outlier threshold

amount for FY 2007 depends on the other policies, especially the coding adjustment, contained in this final rule.

We received several comments on the proposed update to the outlier threshold amount for FY 2007, which are summarized below.

Comment: Two commenters expressed concerns about the accuracy of the FY 2007 estimated outlier payments that we reported in the IRF rate setting file posted in conjunction with the FY 2007 proposed rule. They stated that in some cases, the information was not consistent with the actual outlier payments that they received in FYs 2004 and 2005. The commenters asked CMS to re-examine and verify our outlier payment calculations and to delay implementing an adjustment to the outlier threshold amount for FY 2007 until we can be sure the information is correct.

Response: We have re-examined our estimated outlier payment calculations, and we cannot find any inconsistencies in these calculations or with the IRF rate setting data file that we posted on the IRF PPS website. We did obtain some specific examples from the industry, but we did not find that the differences between their calculations and ours indicated any inaccuracies in our

database. We believe two factors might contribute to a particular facility's receiving different outlier payments for FYs 2004 and 2005 than the outlier payments that we estimate for FY 2007. First, the actual outlier payments that providers received in FYs 2004 and 2005 were calculated based on the outlier threshold amount at that time, which was \$11,211. The estimated outlier payments for FY 2007 in the proposed rule rate setting file are based on the proposed FY 2007 outlier threshold amount of \$5,609. Second, we used the most current available data on IRFs' cost-to-charge ratios (CCRs) to calculate the estimated FY 2007 outlier payments. The CCRs for a particular provider can vary widely over time, in part because of the ceiling that we impose on them. Thus, a provider's current CCR used in the analysis for the FY 2007 proposed and final rules could have changed substantially from the CCR used to compute the actual outlier payments for FYs 2004 and 2005.

We note that the information in the IRF rate setting file posted on the IRF PPS website is not used to determine payments to providers. The fiscal intermediaries determine IRF payments using their own data files, including the appropriate CCRs.

We welcome any specific provider concerns regarding the information contained in the IRF rate setting files, and we will work with providers to investigate any potential discrepancies in the information that we use in our analysis. However, we have not been able to find any discrepancies, and we believe that our analysis continues to demonstrate the need to update the outlier threshold amount for FY 2007 to ensure that estimated outlier payments continue to equal 3 percent of total estimated payments.

Comment: A few commenters expressed concerns about the methodology that CMS uses to estimate cost and charge growth for the purposes of calculating the outlier threshold amount. Two commenters referred to alternative methodologies developed by MedPAC and others that had been recommended for the IPPS to estimate declining CCRs. The commenters encouraged CMS to review our calculations of the outlier threshold amount carefully, use more recent data, and consider applying the suggested methodological changes to the IRF PPS to ensure that the full 3 percent of outlier funds is used.

Response: We have reviewed the comments submitted for consideration in the IPPS, and we appreciate the alternative methodologies suggested and have considered

them carefully. The CCR applied to charges provides Medicare with the most accurate measure of a provider's per-case cost for the purpose of paying for high-cost outlier cases at the point that we process the initial claim. The CCR is based on the providers' own cost and charge information as reported by the providers. For the purposes of this final rule, we have used the same methodology for projecting cost and charge growth that is used in the IPPS and in other Medicare payment systems, and we believe that this methodology is appropriate for IRFs for the same reasons that it is appropriate for IPPS hospitals. This methodology ensures that we pay the appropriate amounts over and above the standard PPS payment amount for unusually high-cost cases. We intend to consult with IPPS and MedPAC staff on a regular basis regarding outlier issues, and will investigate options for using more current data to update the outlier threshold amount in future years.

Final Decision: Based on a careful review of the comments that we received on the proposed update to the outlier threshold amount for FY 2007, we are finalizing our decision to update the outlier threshold amount for FY 2007 to \$5,534. This outlier threshold amount is slightly lower than the \$5,609 that we proposed, due to the reduction of

the coding adjustment from the 2.9 percent adjustment that we had proposed to the 2.6 percent coding adjustment that we are finalizing in this final rule. Because the coding adjustment affects the estimated amount of aggregate payments for FY 2007, it also affects our estimate of the outlier threshold amount that we estimate will maintain estimated outlier payments at 3 percent of total estimated payments.

B. Update to the IRF Cost-to-Charge Ratio Ceilings and Clarification to the Regulation Text for FY 2007

As specified in §412.624(e) (5), we apply a ceiling to IRFs' cost-to-charge ratios (CCRs). In the FY 2007 IRF PPS proposed rule, we proposed to update the national average urban and rural CCRs and to revise §412.624(e) (5) to emphasize that we calculate a single overall cost-to-charge ratio (combined operating and capital) for IRFs because IRF PPS payments are based on a prospective payment per discharge for both inpatient operating and capital-related costs. We proposed to update the national urban and rural CCRs for IRFs to 0.488 and 0.613, respectively. However, we noted that these estimates were subject to change in this final rule based on updated analysis and data. We did not receive any comments on the proposed update to the IRF cost-to-charge ratio ceilings or clarification to

the regulation text for FY 2007. However, we updated our analysis using the most recent available data. For the proposed rule, we used the FY 2004 cost report data compiled by CMS as of December 2005, at which point the FY 2004 cost reports were about 85 percent complete. For this final rule, we have used the FY 2004 cost report data compiled as of March 2006, at which point we had about 97 percent of the FY 2004 cost report information. Thus, based on the more recent cost report data, we are finalizing the national average urban CCR at 0.484 and the national average rural CCR at 0.600, as well as our estimate of 3 standard deviations above the corresponding national geometric mean, which we are finalizing at 1.56 for FY 2007.

VII. Revisions to the Classification Criteria Percentage for IRFs

In order to be excluded from the acute care inpatient hospital PPS specified in §412.1(a)(1) and instead be paid under the IRF PPS, a hospital or rehabilitation unit of an acute care hospital must meet the requirements for classification as an IRF contained in subpart B of part 412. Section 412.23(b)(2) specifies that an IRF's cost reporting period will determine the percentage of the IRF's total inpatient population that required intensive

rehabilitation services for treatment of at least one of the 13 medical conditions listed in the regulation. The compliance percentage requirement is commonly known as the "75 percent rule," and is one of the criteria that Medicare uses for classifying a hospital or a rehabilitation unit of an acute care hospital as an IRF.

On May 7, 2004, we published a final rule (69 FR 25752) that specified the compliance percentage requirements that a hospital or rehabilitation unit of an acute care hospital must meet during a particular cost reporting period in order to be classified as an IRF. However, section 5005 of the DRA of 2005 revised the compliance percentage requirements in §412.23(b)(2) that must be met for certain cost reporting periods in order for a hospital or rehabilitation unit of an acute care hospital to be classified as an IRF. Therefore, in order to conform the regulations to the DRA, we proposed modifying the compliance percentages in §412.23(b)(2)(i) and (ii) as follows:

- Reducing the compliance threshold that must be met from 65 to 60 percent for cost reporting periods beginning on or after July 1, 2006, and before July 1, 2007.

- Reducing the compliance threshold that must be met from 75 to 65 percent for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2008.
- Stipulating that an IRF with a cost reporting period beginning on or after July 1, 2008, must meet a compliance threshold of 75 percent.

In addition to specifying a compliance threshold, §412.23(b)(2)(i) currently permits a patient's comorbidity that meets certain qualifying criteria as outlined in the regulations to count toward satisfying the classification criteria percentage. However, §412.23(b)(2)(ii) currently provides that a patient's comorbidities will not be used to determine compliance once the transition to the 75 percent compliance level has been completed. Since the transition to the 75 percent compliance threshold has been extended one year, we also proposed a 1-year extension of the current policy of using a patient's comorbidities to the extent they met the conditions outlined in our regulations to determine compliance with the classification criteria in §412.23(b)(2)(i). Thus, under our proposal, an IRF with a cost reporting period beginning before July 1, 2008 would be able to use comorbidities to count toward the required applicable percentage requirements outlined in the

regulations. This proposed approach maintains consistency with our current approach with respect to the counting of comorbidities before the 75 percent threshold applies. We received many comments as summarized below on the proposed revisions to the classification criteria.

Comment: Commenters supported the proposed revisions to the compliance thresholds that IRFs must meet for certain cost reporting periods. However, most of the commenters requested that we not terminate the use of comorbidities to determine the compliance percentage once the extended transition period has expired.

Response: In the May 7, 2004 final rule (69 FR 25752, 25762), we stated that we planned to use the phase-in period to the 75 percent compliance threshold to evaluate the use of comorbidities for determining compliance with the classification percentage criteria. We believed that many IRFs probably would have to make adjustments not only to their case-mix but to their operating procedures in order to respond to changes in the regulations, the methodology for determining compliance, and the local coverage policies FIs had or were planning to implement.

We believed that such adjustments might take some IRFs a considerable amount of time. Therefore, we wanted to use the phase-in period to the 75 percent compliance threshold

to provide administrative flexibility so that a case with a comorbidity that met the qualifying conditions specified above would be included as part of the IRF population used to calculate the compliance percentage.

As we stated in the May 7, 2004 final rule (69 FR 25752, 25762), we will use the phase-in period to the 75 percent compliance threshold to evaluate whether the regulations should be revised. As part of that evaluation process, we will consider if we should propose to extend the time period that comorbidities meeting the qualifying conditions outlined in the regulations are included as part of the process that determines the compliance percentage. We have not completed our analysis on this issue and, thus, because our review is incomplete we believe that it is premature to extend beyond the transition period the use of a patient's comorbidities in determining if an IRF met the compliance threshold.

Final Decision: Consistent with the proposed rule and the rationale discussed above, we are finalizing our proposed policy as set forth in this paragraph. In accordance with section 5005 of the DRA, we are extending the transition period to the 75 percent compliance threshold, as follows: For cost reporting periods starting on or after July 1, 2006, and before July 1, 2007, the

compliance threshold is 60 percent. For cost reporting periods starting on or after July 1, 2007, and before July 1, 2008, the compliance threshold is 65 percent. For cost reporting periods starting on or after July 1, 2008, the compliance threshold is 75 percent. Under the authority of section 1886(d)(1)(B) of the Act, we are continuing until the end of the extended transition period to permit the use of comorbidities that meet the qualifying criteria in §412.23(b)(2)(i)(A) through §412.23(b)(2)(i)(C) to count toward satisfying the required applicable percentages in §412.23(b)(2)(i). However, for cost reporting periods starting on or after July 1, 2008, comorbidities may not be used when calculating the compliance percentage attained by an IRF.

VIII. IRF PPS: Other Issues

A. Integrated Post Acute Care Payment

In the FY 2007 IRF proposed rule, we described our plans to explore refinements to the existing provider-oriented "silos" to create a more seamless system for payment and delivery of post-acute care (PAC) under Medicare. This new model will be characterized by more consistent payments for the same type of care across different sites of service, quality driven pay-for-performance incentives, and

collection of uniform clinical assessment information to support quality and discharge planning functions. We also noted that section 5008 of the DRA provides for a demonstration on uniform assessment and data collection across different sites of service. We are in the early stages of developing a standard, comprehensive assessment instrument to be completed at hospital discharge and ultimately integrated with PAC assessments, and the demonstration will enable us to test the usefulness of this instrument, and to analyze cost and outcomes across different PAC sites.

Comment: We received several comments from providers and their representatives or associations on the post-acute care reform demonstration discussion of the May 15, 2006 proposed rule. Most of the commenters expressed support for the objective of aligning Medicare payment more closely with the clinical characteristics of post-acute patients. A number of commenters recommended that developing a common patient assessment instrument should be developed collaboratively with post acute care providers. Many offered to provide insight on the demonstration design and the

development of the instrument. The commenters noted that the instrument must be capable of taking into account the medical and resource needs of individual patients, such as functional ability and medical status. One commenter recommended use of the IRF-PAI.

Response: Currently, we are in the early stages of designing the instrument and the demonstration. Although it is too early in the process to communicate specific details about either the instrument or the demonstration design, CMS is committed to including industry representatives in various stages of both efforts. We intend to convene technical advisory panels with industry representatives at several points in the project, including a panel to review the proposed assessment instrument once developed, and a panel to assist in recruiting providers for the demonstration. We will provide status information on the progress of the instrument design as well as demonstration progress via CMS public Web sites, open door forums, and stakeholder meetings. Further, in accordance with section 5008(c) of the DRA, We plan to publish a Report to the Congress upon completion of the

demonstration and the associated analysis.

Comment: One commenter requested that CMS provide the rehabilitation industry with access to the University of Colorado study on uniform patient assessment.

Response: We have made this report publicly available via our quality initiatives general information Web site, at <http://www.cms.hhs.gov/QualityInitiativesGenInfo/>.

B. Transparency and Health Information Technology Initiatives

The FY 2007 Inpatient Prospective Payment Systems (IPPS) proposed rule (71 FR 23996, April 25, 2006) discussed in detail the Health Care Information Transparency Initiative and our efforts to promote effective use of health information technology (HIT) as a means of promoting health care quality and greater efficiency. The IPPS proposed rule also discussed several potential options for making pricing and quality information more readily available to the public (71 FR 24120 through 24121). It solicited comments on ways to encourage transparency in health care quality and pricing, whether through voluntary incentives or through

regulatory requirements, and sought comments on the Department's statutory authority to impose these requirements. In addition, it discussed the potential for HIT to facilitate improvements in the quality and efficiency of health care services (71 FR 24100 through 24101), and the appropriate role of HIT in potential value-based purchasing programs. The IPPS proposed rule also invited comments on the promotion of the use of HIT through Medicare conditions of participation.

Subsequently, in the FY 2007 IRF PPS proposed rule (71 FR 28134 through 28135, May 15, 2006), we invited comments on the specific implications of these initiatives for the IRF PPS. We received a small number of comments in response to the FY 2007 IRF PPS proposed rule's transparency and HIT discussions. However, as they are all generalized comments that are not specific to the IRF setting, we are inviting the commenters to refer to the FY 2007 IPPS final rule for full responses to comments received on the FY 2007 IPPS proposed rule's comprehensive discussions of transparency and HIT.

IX. Miscellaneous IRF PPS Public Comments

Comment: We received numerous comments

requesting that CMS make additional IRF data files and software available to the public. The commenters specifically requested wage index data, cost report data, IRF-PAI data, MEDPAR data, data on facility adjustments, data files such as those produced for IPPS hospitals, other data files that CMS uses in the analyses that support the proposed and final rules, and the software program or software algorithm used by the fiscal intermediaries to determine the 75 percent rule presumptive compliance percentage.

Response: The data files mentioned by the commenters are generally available (and were generally available during the comment period for this final rule) to the public through CMS' standard data distribution systems. More information on CMS's data distribution policies is available on CMS's Web site at <http://www.cms.hhs.gov/researchers/statsdata.asp>.

Regarding the specific files that the commenters mentioned, we post the wage index files for the proposed and final rules each year on the IRF PPS Web site, along with the rate setting file. The cost report data are publicly available on the CMS Web site. The IRF-PAI and the MEDPAR data are generally available through CMS' standard data distribution systems for patient-level data. We

include the data that we use in our analysis regarding other facility-level adjustments in the IRF rate setting file that is posted on the IRF PPS Web site in conjunction with each proposed and final rule. Data on IRF facility-level adjustments are also available for download from the CMS Web site in a file called the provider-specific file. We also encourage IRFs to contact their fiscal intermediaries regarding the data used to compute payments for their particular facilities.

We are in the process of developing user-friendly specifications for the software program used to determine presumptive compliance with the 75 percent rule. In the near future, we will post the data specifications for the software program on the IRF PPS Web site.

In addition, we will consult with the IPPS staff and examine the data files that are publicly distributed in conjunction with the IPPS proposed and final rules. Where feasible, we will make every effort to provide additional IRF data files that would be helpful to industry representatives and researchers.

Comment: A few commenters requested that we provide clarification on the teaching status and full-time equivalent (FTE) resident cap of a

facility that converts from a long-term care hospital (LTCH), or another type of inpatient facility, to an IRF.

Response: We did not propose any changes to the IRF teaching status adjustment in the FY 2007 proposed rule. Thus, this comment is outside the scope of this final rule. However, we intend to issue future guidance on the teaching status of facilities that convert to IRFs in our standard contractor communication documents. We also intend to publish a provider education article on the CMS Medicare Learning Network (MLN), and post a clarification of this issue on the IRF PPS Web site.

Comment: We also received other comments that are outside the scope of this final rule, such as support for the revisions to the rural and LIP adjustments that we implemented in the FY 2006 IRF PPS final rule. We also received a comment reiterating a number of concerns with the IRF classification revisions that were implemented in the FY 2006 IRF PPS final rule, particularly the weighted motor score methodology and the revised CMG definitions.

Response: Although we did not propose any changes to the rural and LIP adjustments for FY 2007, we appreciate the commenters' support for the

changes that we implemented for FY 2006. Regarding the commenter's concerns about the weighted motor score methodology and the revisions to the CMG definitions implemented for FY 2006, we will carefully consider the issues raised by the commenter in our future analyses of the IRF classification system.

Comment: We received a number of general comments on the 75 percent rule that are outside the scope of this final rule. For example, commenters urged CMS to conduct research to revise the conditions contained in the 75 percent rule that are currently considered appropriate for treatment in an IRF, saying that these conditions are out of date and do not reflect current treatment practices. Commenters also urged CMS to conduct research to develop a new method for classifying a facility as an IRF. Until such research is completed and the 75 percent rule is updated, they requested that CMS stop enforcement of the current compliance criteria. The commenters generally stated that patients are denied access to care because of the 75 percent rule, and that patients receive better rehabilitation care in an IRF due to better medical management. The commenters urged CMS to develop or fund research studies in conjunction with NIH, independent

researcher, or industry consortiums. In addition to direct funding assistance, they recommended ways in which we could support these research efforts by either waiving enforcement of the 75 percent rule or of local coverage determinations (LCDs) for facilities participating in research projects.

Response: Because the 75 percent rule provisions in the proposed rule were limited to the compliance thresholds that IRFs must meet for certain cost reporting periods and the extension of the use of comorbidities in determining compliance for an additional cost reporting period (until the full 75 percent compliance percentage becomes effective), these general comments on the 75 percent rule are outside of the scope of this final rule. We note that we responded to these and other similar comments in the May 7, 2004 (69 FR 25752) final rule. However, we continue to be concerned with ensuring that patients have access to treatment in the most appropriate settings. Therefore, we will continue to monitor patients' access to care carefully and will, as warranted, propose additional refinements to our policies in the future to ensure that patients continue to have appropriate access to care.

In addition, we are committed to supporting the research effort through the development of a series of

collaborative relationships. For example, we have collaborated with the National Center for Medical Rehabilitation Research (NCMRR) of the National Institute of Child Health and Human Development at the National Institutes of Health (NIH) in convening a panel of rehabilitation experts that reviewed the medical literature in order to provide guidance regarding the optimal approaches to research. This review found a paucity of relevant studies, and confirmed the need for additional work to identify the benefits of IRF care for different types of patients and to collect comparative outcome data across care settings. Since that time, both CMS and NIH staff have worked with researchers in an informal advisory capacity to support industry efforts to design and run clinical studies. In fact, we recently met with the director of the NCMRR to discuss how NCMRR and CMS could collaborate in encouraging and sponsoring research, and are in the process of developing a set of appropriate research questions that can be used to establish a common focus for discussion and design of new studies. We were also pleased to learn that industry representatives are themselves providing financial support to new research efforts. We believe that by working together, we can foster clinical studies that meet NIH criteria, and that the results of

these studies can be used to support a comprehensive review of CMS' methods for classifying facilities as IRFs.

Further, as discussed in section VIII of this final rule, CMS is exploring refinements to the existing provider-oriented "silos" to create a more seamless delivery system for payment and delivery of post-acute care (PAC) under Medicare. The new model will be characterized by more consistent payments for the same type of care across different sites of service. We expect that the knowledge gained through this initiative will also help us to understand the similarities and differences among post-acute care settings.

X. DMEPOS Competitive Bidding Implementation Provisions and Accreditation for DMEPOS Suppliers

A. Implementation Contractor

1. Legislative Provisions

Section 1847(b)(9) of the Act provides that the Secretary may contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program. Section 1847(a)(1)(C) of the Act also authorizes the Secretary to waive such provisions of the Federal Acquisition Regulation (FAR) as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and

such other provisions as the Secretary determines appropriate.

2. Provisions of the May 1, 2006 Proposed Rule

In the May 1, 2006 proposed rule (71 FR 25661), we proposed to designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program (proposed §414.406(a)). In addition, we specified that the Secretary is exercising his authority under section 1847(a)(1)(C) of the Act to waive all requirements of the FAR, other than provisions dealing with confidentiality, because of the need for expeditious implementation of a program of this significance and magnitude. However, we stated that the Secretary's exercise of discretion on this issue would not preclude us from voluntarily using or adapting certain provisions of the FAR for purposes of the Medicare DMEPOS Competitive Bidding Program.

We stated in the proposed rule that we envision that the Medicare DMEPOS Competitive Bidding Program will have six primary functions, including overall oversight, operation design functions (including the design of both bidding and outreach material templates, as well as program processes), bidding and evaluation, access and quality

monitoring, outreach and education, and claims processing. We also stated that we considered the organizational structure and requirements necessary to conduct these functions, and chose to exercise our contracting authority under section 1847(b) (9) of the Act and contract with one or more CBICs to assist us with many of these functions.

In the proposed rule, we described several options that we considered in designing the most appropriate framework for implementing the Medicare DMEPOS Competitive Bidding Program. As the implementation of competitive bidding involves many functions that are time limited and require specialized skills (for example, setting up bidding areas, reviewing bids, and setting single payment amounts), we believe that it would be prudent initially to implement most aspects of the Medicare DMEPOS Competitive Bidding Program through one or more CBICs. Processing of Medicare claims for most DMEPOS is currently done by two DME regional carriers (DMERCS) and two DME Medicare Administrative Contractors (DME MACs). We note that we are currently in the process of transitioning from DMERCs to DME MACs. For purposes of consistency, from this point forward, we will be referencing the DME regional carriers as DME MACs. Under our proposal, the DME MACs would process claims for DMEPOS items subject to competitive

bidding. We also stated that we had evaluated the anticipated feasibility and cost of using one or more implementation contractors to assist us with implementing the Medicare DMEPOS Competitive Bidding Program, concentrating on the potential for capturing economies of scale and scope, program consistency, existing resources and infrastructure, and the viability of implementation under the timeframe mandated by section 1847(a)(1)(B) of the Act.

We proposed to contract with one or more CBICs to conduct some program functions at a national level and interact with the DME MAC contractors. Specifically, we envisioned that the CBIC(s) would conduct certain functions related to competitive bidding, such as preparing the request for bids (RFB), performing bid evaluations, selecting qualified suppliers, and setting single payment amounts for all competitive bidding areas. In addition, the CBIC(s) would be charged with educating the DME MACs on the bidding process and procedures. The CBIC(s) would also assist CMS and the DME MACs in monitoring program effectiveness, access, and quality. The DME MACs would continue to provide outreach and education to beneficiaries and suppliers in their regions, process claims, apply the single payment amounts set by the CBIC(s) for each

competitive bidding area, and continue to be responsible for complaints related to claims processing. We would continue to be responsible for overall oversight as well as policy-related outreach and education to the CBIC(s), DME MACs, suppliers, and beneficiaries.

We stated that in our view, this approach would achieve economies of scale, since the responsibility for producing program materials and evaluating bids would rest with the CBIC(s). As a result, we believed that this approach would both lower costs and ensure regional consistency in that the responsibility would not be divided between various entities.

We also discussed two other alternatives that we had considered for implementation of the Medicare DMEPOS Competitive Bidding Program. The first was to have each DME MAC conduct competitive bidding in its respective area and be responsible for all activities related to competitive bidding. The second alternative was to have the CMS Consortium Contractor Management Officer (CCMO)/Regional Offices (RO) and DME MACs implement the program. However, we stated that we believed that by using one or more specialized CBICs, we could successfully implement and effectively manage this program.

3. Public Comments Received and Our Responses

Comment: Two commenters support our decision to use competitive bidding implementation contractor(s) to implement the program. Another commenter stated that selecting and announcing implementation contractors are essential tasks for starting the Medicare DMEPOS Competitive Bidding Program.

Response: We agree. We expect to award one or more contracts to appropriate entities in order to assist us in implementing this program.

Comment: Several commenters expressed concern that we proposed to use our authority under section 1847(a)(1)(C) of the Act to waive all of the provisions of the Federal Acquisition Act (FAR), except those dealing with confidentiality of information. The commenters suggested that this waiver would lead to bidders using dishonest tactics and would result in inferior DMEPOS items and services being furnished to beneficiaries.

Response: After considering these comments and the best interest of the program, we have decided to apply the FAR to the CBIC for this instance. In this final rule, we are only responding to comments as they relate to the procurement of CBIC services. Section 1847 (a)(1)(C) of the Act allows the Secretary to waive such provisions of the FAR as are necessary for the efficient implementation

of the Medicare DMEPOS Competitive Bidding Program. We have determined that it is currently unnecessary for the efficient implementation of this program to waive the FAR to procure the CBIC(s) services.

Comment: One commenter asserted that we should strictly limit the use of CBICs to ensure responsiveness to small businesses. The commenter expressed concern that there could be situations in which neither we nor the CBICs would be clearly responsible for making important decisions. Such situations could be particularly problematic for small businesses with limited resources. This commenter further stated that there must be appropriate oversight and accountability if we choose to proceed with the use of one or more CBICs.

Response: We continue to believe that it is necessary and appropriate for us to use one or more CBIC(s) to assist in implementing the Medicare DMEPOS Competitive Bidding Program. We agree that it is important to establish clear lines of responsibility and accountability for the CBIC(s). As we indicated in the proposed rule, we will be responsible for overall oversight of the CBIC(s). We expect that the CBIC(s) will conduct certain functions, such as developing and implementing an ombudsman program to provide education and assistance to stakeholders involved

in the program, and developing and implementing a monitoring process to ensure that complaints will be addressed and resolved in a timely manner. The CBIC duties will be fully detailed in the final CBIC contract(s).

Comment: One commenter was unclear as to how the CBIC(s) and DMERCs will interact in terms of development of policy. The commenter noted that the contractors must work together, and with us, to ensure that beneficiaries have access to all of the recertification/retesting requirements that may be implemented as a result of competitive bidding.

Response: We will require the CBIC(s) to develop and maintain strong relationships with all appropriate Medicare contractors to ensure that all interested parties have the necessary education and access to the requirements and guidelines set forth for the Medicare DMEPOS Competitive Bidding Program. We also intend to work closely with the CBIC(s) and to engage in our own efforts to educate suppliers on the specifics of this program. In terms of the interaction between the CBIC(s) and the DME MACS, we have previously stated that the CBIC(s) will be responsible for certain functions related to competitive bidding, such as preparing the request for bids, performing bid evaluations, and setting single payment amounts for items furnished under the program, and the DME MACs will be

responsible for claims processing. Although the CBIC(s) and the DME MACs will be interacting on a number of functions, such as educating the public about the program and conducting monitoring activities, we would be responsible for overall oversight and policy development under the program. To the extent that the commenter referenced recertification/retesting requirements, we believe that the commenter is referring to the need for physicians and treating practitioners to, on some occasions, provide new documentation and certification to a supplier that a DMEPOS item furnished to a beneficiary remains medically necessary. We would like to clarify that we are not developing recertification or retesting requirements for the Medicare DMEPOS Competitive Bidding Program, and that the implementation of the program would not change or alter any existing certification requirements.

Comment: One commenter noted that the CBIC is a vital part of the entire process and that suppliers need to know more about the credentialing process for the CBIC and what type of authoritative power it will possess.

Response: As noted above, we will follow FAR requirements and engage in a full and open competition to procure the CBIC services in this instance. We will also

provide the CBIC(s) with guidelines and roles for implementing the competitive bidding program. Also, as we noted above, we will monitor and review all CBIC functions on a consistent basis to ensure that the CBIC(s) is performing its intended functions. In addition, we will be providing an intensive education program for suppliers to inform them about the Medicare DMEPOS Competitive Bidding Program. This educational program will inform suppliers in the competitive bidding areas about the Medicare DMEPOS Competitive Bidding Program as well as functions of the CBIC(s).

Comment: One commenter noted that we should utilize multiple CBICs to ensure that correct and effective implementation of the competitive bidding program is guaranteed and that cost savings to the Medicare program is a priority.

Response: We appreciate the comment and will take it into consideration as we evaluate the most cost-efficient and productive way to procure CBIC services.

Comment: One commenter requested that we define the quantitative, objective measures and evaluation tools that the CBIC(s) will use in evaluating the bids submitted by suppliers.

Response: Bid evaluation methodology will be

addressed in a future rulemaking. We will ensure that the CBIC uses appropriate methodologies and tools to evaluate bids.

Comment: One commenter recommended that we eliminate regional inconsistencies and that the CBIC should be established, structured, and managed to ensure national consistency.

Response: We agree. When we implement the competitive bidding program, it is our goal to implement it consistently in each competitive bidding area. We will accomplish this by requiring the CBIC(s) to apply the same methodologies and policies that are adopted for the Medicare DMEPOS Competitive Bidding Program in each competitive bidding area.

Comment: Several commenters recommended that we ensure that any CBIC entity avoids any potential conflict of interest. Several commenters gave the same example of a conflict of interest as the CBIC also being a private payor that negotiates directly with DME suppliers in a managed care context.

Response: We agree that we should take steps in procuring CBIC services to ensure that the CBIC(s) do not have any potential conflicts of interest that could interfere with their ability to fulfill their contract

obligations. For example, we plan to specify in the CBIC contract that the CBIC contractor shall not, throughout the duration of the contract, use information received as a result of the Medicare DMEPOS Competitive Bidding Program for any purpose other than for purposes of fulfilling its contract obligations, unless that information is otherwise publicly available. We believe it is in the best interest of the public as well as the Federal government that there are no conflicts of interest between the CBIC(s) and other entities.

Additionally, we note that the FAR, in Subpart 9.5, Organizational and Consultant Conflicts of Interest (OCI) requires the contracting officer to identify, evaluate, neutralize, or mitigate any potential OCIs prior to award. The FAR Subpart seeks to avoid any conflict of interest that, among other considerations, will bias a contractor's judgment.

Comment: Several commenters asked a variety of questions related to the CBIC selection process and performance evaluation. Specifically, one commenter asked what criteria will be used to select the CBIC. Another commenter asked how CMS would audit the CBIC's performance. Another commenter asked what the service expectations were of the CBIC relative to educating the DMERCs and suppliers.

Response: As noted in our response to a previous comment, we are currently following the requirements of the FAR in procuring and monitoring the CBIC(s). Some examples of the CBIC functions and service expectations were discussed above and will be addressed in the final CBIC contract(s). We will evaluate the CBIC performance in accordance with the FAR and agency procedures annually and at the time the work under the contract(s) is completed.

Final Decision: After consideration of the public comments received, we are finalizing at this time two paragraphs of proposed §414.406. First, we are finalizing proposed §414.406(a), which allows us to designate one or more CBICs for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program. Second, we are finalizing proposed §414.406(e), which codifies our proposal to have the regional carrier (now referred to as a DME MAC) that would otherwise be processing claims for a particular geographic region also process claims for items furnished under a competitive bidding program in the same geographic region. We will respond to any comments that we receive on our proposals related to proposed §§414.406(b)-(d), as well as comments that relate to other issues related to implementing the Medicare DMEPOS Competitive Bidding Program in a future rulemaking.

B. Education and Outreach

1. Supplier Education

In the May 1, 2006 proposed rule (71 FR 25683 through 25684), we provided a discussion of our plans to undertake a proactive education campaign to provide all suppliers with information about the Medicare DMEPOS Competitive Bidding Program, bidding timelines, and bidding and program requirements. We stated that the goal of this campaign is to make it as easy as possible for suppliers to submit bids.

To ensure that suppliers have timely access to accurate information on competitive bidding, we stated that we planned to instruct the CBIC and the DME MACs to provide early education and resources to suppliers, referral agents, beneficiaries, and other providers who service a competitive bidding area. Customer service support, ombudsman networks, and the claims processing system would all be used to notify and educate all parties regarding competitive bidding. The CBIC(s) would be instructed to utilize data analysis in tailoring outreach to those that will be directly affected by competitive bidding.

We also indicated that, after the release of bidding instructions, we would hold bidders conferences that would

provide an open forum to educate suppliers and allow us to disseminate additional information. We stated that more information on the bidders conferences and other competitive bidding activities would be available on our Web site at <http://www.cms.hhs.gov/center/dme.asp>. We note that this is an updated Web site address that is different from the one that was listed in the proposed rule.

We additionally indicated that each DME MAC would include discussions and updates on competitive bidding as part of its existing outreach mechanisms. We stated that the fundamental goal of our supplier educational outreach is to ensure that those who supply DMEPOS products to Medicare beneficiaries receive the information they need in a timely manner so that they have an understanding of the program and our expectations.

Comment: One commenter agreed with our overall plan to use the CBIC, regional carriers, customer service support, and the claims processing system to notify and educate all parties regarding competitive bidding.

Response: We appreciate this comment. We continue to expect to use these resources as part of our education and outreach efforts.

Comment: One commenter suggested that we conduct extensive outreach to the supplier community so that

suppliers can understand what is required of them in submitting bids. Other commenters expressed concern about our ability to communicate with suppliers within the initial ten MSAs and with suppliers that may have small operations within an MSA but may be part of a larger organization located outside of that MSA.

Response: We plan to conduct an extensive education and outreach campaign to educate suppliers about the Medicare DMEPOS Competitive Bidding Program and to facilitate understanding of competitive bidding implementation efforts. We are committed to educating suppliers about this program as part of our ongoing educational efforts. Bidders conferences will be part of the educational process for those suppliers that are interested in bidding. At these conferences, we expect to provide information about the Medicare DMEPOS Competitive Bidding Program, such as technical details about the bidding forms and the process for submitting bids. These conferences will be open to all suppliers interested in learning the bid submission process, regardless of whether they are located in one of the ten initial areas that we designate as competitive bidding areas. In addition, we plan to utilize other educational tools, which may include a Medicare Learning Network Webpage dedicated to DMEPOS

competitive bidding, contractor bulletins, etc., to disseminate information about the program as widely as possible. Further, we plan to work closely with the CIBC(s) that we designate, as well as the DME MACs, so that they are properly equipped to both educate suppliers about the program and to respond to questions.

Comment: One commenter urged us to include specific educational requirements that address each of the components that will be included in the composite bid that will create the single payment amount for each item. The commenter noted that such components would include, for example, the cost of equipment, training, supplies, transportation of the device, and beneficiary education on safe use of the equipment, etc. The commenter was concerned that if suppliers are not educated regarding what to include in their bids, then they might not submit bids that actually reflect all of the components that make up the safe operation of a piece of durable medical equipment in a beneficiary's home.

Response: We agree that all suppliers must be educated on what is to be included in their bid prices for competitively bid products. As part of our education and outreach campaign, we will inform suppliers of the items and services that they should include in their bids, such

as training, supplies, transportation of the device, beneficiary education on safe use of the equipment, etc.

Comment: One commenter agreed that bidders conferences should be held to provide an open forum for suppliers to exchange information with us. One commenter requested information on the logistics for the bidders conferences. A commenter suggested that it might be helpful to allow suppliers who will be introduced to competitive bidding in 2009 to speak with those suppliers who were introduced in 2007.

Response: We will provide logistical information about bidders conferences as soon as it becomes available. We expect to make this information available on the CMS website and elsewhere, as appropriate. The purpose of the bidders conferences is to provide information about the Medicare DMEPOS Competitive Bidding Program, such as technical details about the bidding forms and the process for submitting bids. However, we encourage suppliers that participate in competitive bidding in 2007 to share their experiences with suppliers that plan to participate in future competitive bidding rounds.

Comment: One commenter suggested that the CMS Web site be revamped to make it more user-friendly, in order for beneficiaries to easily access publications.

Response: We recognize the importance of having a high-quality, helpful Web site. We plan to make our Web site as user-friendly as possible.

Comment: A commenter recommended that the PAOC review any educational materials that relate to the DMEPOS Competitive Bidding Program to ensure that appropriate communications are sent to suppliers.

Response: The Program Advisory and Oversight Committee (PAOC) meets periodically to review policy considerations and issues that we are considering with respect to the Medicare DMEPOS Competitive Bidding Program. The PAOC will continue to be available to provide us with advice until the end of 2009. We are using the PAOC for advice on implementation of the program and intend to take PAOC advice we have received into consideration when developing educational materials. Additional information about the PAOC can be found at 71 FR 25658.

Comment: Several commenters suggested that competitive bidding education must be provided to suppliers' referral sources, such as home health agencies, health insurance companies, HMOs, hospitals, physical and occupational therapists, and others. The commenters also believed that we should hold educational sessions for suppliers to ensure consistency in the way beneficiaries

are educated and in the information they are provided. They suggested that we provide materials that can be used by suppliers to educate beneficiaries effectively about the Medicare DMEPOS Competitive Bidding Program. Additionally, they indicated that we should not depend solely on either suppliers or our website to educate beneficiaries and that we should hold town hall meetings in each competitive bidding area (CBA) to ensure that beneficiaries and referral sources are knowledgeable about the competitive bidding program. One commenter requested that we collaborate with industry groups to develop appropriate communications to be sent to suppliers to minimize confusion in the supplier community. One commenter suggested that we make a concerted effort to educate non-contract suppliers in an MSA and suppliers in non-competitively bid areas.

Response: We plan to conduct an extensive education and outreach campaign to educate beneficiaries, suppliers, and referral agents about the Medicare DMEPOS Competitive Bidding Program. Our outreach strategy will be designed to ensure that information is consistent, readily available, and disseminated through a variety of information sources. We discuss our plans for beneficiary education in section X.B.2 of this final rule.

2. Beneficiary Education

As we stated in the May 1, 2006 proposed rule (71 FR 25684), the Medicare DMEPOS Competitive Bidding Program will have an impact on the beneficiaries who receive DMEPOS items in a competitive bidding area (CBA). Competitive bidding represents a new way for Medicare beneficiaries to receive their DMEPOS products and for setting payment for DMEPOS items; therefore, we believe that education is important to the success of the program.

We outlined our plans to educate beneficiaries utilizing numerous approaches. For example, we stated that our press office might consider creating press releases and fact sheets for each CBA. In addition, notices could provide summaries of competitive bidding, background information, and objectives of the competitive bidding program. Publications might also be available on the CMS Web sites, and from local contractors and the DME MACs.

We stated that we believe it is important for beneficiaries to learn about the benefits of the Medicare DMEPOS Competitive Bidding Program, such as lower out-of-pocket expenses and increased quality of products, from suppliers that have completed the detailed selection process that CMS will require under the program. We also expect that the implementation of quality standards and

accreditation requirements for DMEPOS suppliers will result in higher quality items and services being furnished to beneficiaries.

Comment: A few commenters stated that they appreciate our commitment in providing a proactive education approach. One commenter indicated that beneficiary education will be critical to the success of the program.

Response: We agree with the commenters and recognize the importance of an extensive education and outreach campaign to educate beneficiaries, suppliers, and referral agents about the DMEPOS Medicare Competitive Bidding Program.

Comment: One commenter encouraged us to provide beneficiary education and outreach for beneficiaries with diabetes. The commenter noted that ensuring that beneficiaries have access to their diabetic supplies and remain compliant with their diabetes self-management programs, as well as ensuring that beneficiaries understand the proper procedures for obtaining supplies while away from home, are two areas where aggressive education and outreach efforts are needed.

Response: We agree that a comprehensive education program is necessary to ensure the success of the Medicare DMEPOS Competitive Bidding Program. We plan to conduct an

aggressive education and outreach campaign for all beneficiaries, including those who have diabetes, to ensure that they understand competitive bidding and have sufficient access to contract suppliers that can furnish the items they need.

Comment: A commenter indicated that many Medicare beneficiaries temporarily change their residences during the course of a year, and thus may find themselves outside of a specified competitive bidding area for several months at a time. The commenter urged us to establish a system to ensure that all beneficiaries will continue to have access to their suppliers even while residing outside of their permanent domiciles.

The commenter suggested that this plan should require that suppliers aggressively educate beneficiaries on the proper procedures for obtaining their supplies while away from home, and should allow beneficiaries to purchase extra supplies for extended vacations or temporary changes of residence. Further, the commenter noted that this plan should allow beneficiaries to purchase their supplies from non-contract suppliers in the event of an emergency.

Response: We expect that our educational program will address the issue of beneficiaries who temporarily change their residence during the course of the year. We will

address in a future final rule the portions of this comment pertaining to emergency situations and the proposed policy for ensuring that beneficiaries who maintain a permanent residence in a competitive bidding area but travel outside the area have sufficient access to items while traveling.

Comment: One commenter stated that CMS should clearly specify in the final rule, or require CBICs to identify, the necessary telephone and internet resources that beneficiaries may use to raise questions and concerns related to the competitive bidding program.

Response: We agree that beneficiaries need to have access to appropriate resources on the Medicare DMEPOS Competitive Bidding Program. We note that we are in the process of developing our education and outreach campaign. We expect to identify appropriate telephone and internet resources for beneficiaries to use, which may include 1-800-MEDICARE and www.medicare.gov. Future guidance on this will be forthcoming as we move into the education and outreach phase of competitive bidding.

Comment: Some commenters recommended that a comprehensive education process be organized and put in place before implementation of the Medicare DMEPOS Competitive Bidding Program. A commenter stated that competitive bidding will drastically alter the way

beneficiaries receive needed medical products and supplies.

Response: We plan to conduct an educational campaign for suppliers, beneficiaries, and referral agents before we begin the Medicare DMEPOS Competitive Bidding Program. We agree that this program may change the way beneficiaries receive needed DMEPOS items and the payment amount for these items, but note that beneficiaries will continue to have sufficient access to needed DMEPOS items and services under the program.

Comment: A few commenters stated concerns about the enormity of communicating to all referral sources and our ability to communicate effectively with beneficiaries, particularly when they are traveling. A commenter believed that beneficiaries will not understand the DMEPOS Competitive Bidding Program. The commenter requested that we define and publish plans for communicating information about implementing the program.

Response: Our outreach strategy will have a consistent message that is readily available and disseminated using a variety of tools, techniques, and informational sources. We also expect to use appropriate educational resources to educate beneficiaries on the specifics of the program. These resources might include 1-800-MEDICARE and www.medicare.gov. In addition, we are

exploring the possibility of working with beneficiary organizations and local groups to conduct beneficiary outreach and develop beneficiary-focused communications. We also plan on coordinating a proactive outreach campaign at the national, regional and state levels in which we expect to provide accurate, reliable, relevant, and understandable information about the Medicare DMEPOS Competitive Bidding Program. Through these activities, we anticipate being able to sufficiently educate beneficiaries on what they need to know in order to obtain DMEPOS items and services under the program.

Comment: One commenter indicated that special attention should be given to inner city, minority, and low income populations who may be more difficult to contact than the population at large.

Response: We understand that Medicare beneficiaries are an extremely diverse population with different educational needs. We will consider this diversity in developing and implementing our education and outreach program.

Comment: One commenter recommended that we publish supplier customer satisfaction survey results and/or statistics on quality measures to assist beneficiaries in making informed decisions regarding contract supplier

selection. The commenter also stated that we should not mislead beneficiaries by stating that one focus of our education efforts toward beneficiaries will be the increased quality of products that beneficiaries will be receiving as a result of competitive bidding.

Response: We will be monitoring beneficiary satisfaction under the Medicare DMEPOS Competitive Bidding Program and are in the process of determining how best to measure it. We expect that implementing DMEPOS quality standards and accreditation will lead to increased quality of items and services throughout the DMEPOS industry. Therefore, we believe it is accurate to indicate in our education campaign that beneficiaries will receive improved quality DMEPOS items and services under the Medicare DMEPOS Competitive Bidding Program. We also note that we expect to see this improved quality not just in the DMEPOS items and services that are furnished by contract suppliers under the Medicare DMEPOS Competitive Bidding Program, but in the items and services furnished by all accredited DMEPOS suppliers.

Comment: A commenter suggested that we should target direct mail or disseminate information through high-Medicare-volume physician offices rather than through expensive direct-to-consumer television or media

advertising. A commenter suggested that we rely on the homecare supplier community to educate beneficiaries.

Response: We are in the process of finalizing our education and outreach plan. We will consider the suggestion to engage physicians and the homecare supplier community in our efforts to disseminate information through physicians as we move forward with this plan. However, we note that the education and outreach strategy will have a consistent message that is readily available and disseminated through a variety of tools, techniques, and information sources.

Comment: One commenter suggested that we use webinars (interactive Web-based seminars) and teleconferences to provide education on the competitive bidding program. The commenter suggested that the education and outreach program start sooner rather than later.

Response: We are in the process of finalizing our education and outreach campaign and will consider using webinars and teleconferences as part of our overall approach to disseminate information as widely as possible. We expect to disseminate our message timely through a variety of tools, techniques, and informational sources.

Comment: A commenter expressed concern that beneficiaries would not know about the implications of the

DMEPOS Competitive Bidding Program until such time as they attempt to obtain a particular item. Since many beneficiaries are not able to go to a pharmacy, the commenter observed that we have a significant challenge in educating beneficiaries and their caregivers about the program. The commenter also asserted that beneficiaries should know that the type and quality of DMEPOS items and services they receive under the program might be different from the ones they are currently using. The commenter added that beneficiary education materials should provide information on these important facts, and not just on the benefits of competitive bidding.

Response: Our objective will be to inform beneficiaries timely about all of the changes that will affect them as a result of the Medicare DMEPOS Competitive Bidding Program. We are aware of the challenges we face in ensuring that beneficiaries understand the program prior to attempting to obtain items. As we have noted above, our outreach strategy is to create a consistent message that is disseminated through a variety of tools, techniques and information sources. We also expect that as a result of implementing quality standards and accreditation requirements for all DMEPOS suppliers, including suppliers that participate in competitive bidding, beneficiaries will

be able to obtain high quality DMEPOS items and services under the program.

C. Quality Standards for Suppliers of DMEPOS

Section 302(a)(1) of the MMA added section 1834(a)(20) to the Act, which requires the Secretary to establish and implement DMEPOS quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item, for which payment is made under Part B, and to receive and retain a supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these DMEPOS quality standards to suppliers of the following items for which we deem the DMEPOS quality standards to be appropriate:

- Covered items, as defined in section 1834(a)(13) of the Act, for which payment may be made under section 1834(a);
- Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4) of the Act; and
- Items described in section 1842(s)(2) of the Act,

which include medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrients, equipment, and supplies; electromyogram devices; salivation devices; blood products; and transfusion medicine.

Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the DMEPOS quality standards by program instruction or otherwise after consultation with representatives of relevant parties. After consulting with a wide range of stakeholders, we determined that it was in the best interest of the industry and beneficiaries to publish the DMEPOS quality standards through program instructions and select the accreditation organizations in order to ensure that suppliers that want to participate in competitive bidding will know what DMEPOS quality standards they must meet in order to be awarded a contract.

After consultation with a wide range of stakeholders, we published the draft DMEPOS quality standards on the CMS Web site at <http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/> and provided for a 60-day public comment period. We received more than 5,600 public comments on the draft quality standards. After careful consideration of all comments, these quality standards will be published shortly

on the CMS web site. They will be available at <http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>. The DMEPOS quality standards will become effective for use as part of the accreditation selection process when posted on the website. The quality standards will be applied by the accreditation organizations, and all suppliers of DMEPOS and other items to which section 1834(a)(20) of the Act applies will be required to meet them as part of the accreditation process.

As is authorized under section 1834(a)(20)(E) of the Act, we will be establishing the DMEPOS quality standards through program instruction and will publish them on our Web site. Although we previously stated that we would propose to address DMEPOS supplier requirements for enrollment and enforcement procedures in a future rule, we do not plan on issuing another rule concerning these issues at this time.

Comment: Several commenters expressed concern that the quality standards had not yet been issued in final form. One commenter stated that issuing final quality standards and selecting accreditation organizations are essential tasks for starting the competitive bidding program. A commenter requested that we extend the comment period on the May 1, 2006 proposed rule for 120 days so

that the commenter could develop detailed responses to a number of issues raised in the proposed rule, including the finalization of quality standards and the impact of the proposed rule on coordination of care. Other commenters suggested that we should provide additional time for suppliers to analyze the quality standards in conjunction with our proposed rule on competitive bidding and to identify criteria we will use to identify accrediting bodies.

Response: We agree that the quality standards are a key factor in ensuring the success of the Medicare DMEPOS Competitive Bidding Program. We have provided for extensive opportunity for public input on the quality standards. In addition to seeking the advice of the Program Advisory and Oversight Committee (PAOC), discussed in more detail in the May 1, 2006 proposed rule at 71 FR 25658, we posted the draft quality standards on our Web site on September 26, 2005 for a public comment period that ended November 28, 2005. After careful consideration of all comments, these quality standards will be published on the CMS web site at <http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>. The DMEPOS quality standards will become effective for use as part of the accreditation selection process when posted on

the website. We believe that this public process provided sufficient opportunity for stakeholders to comment on the draft quality standards and do not believe that granting an extension of the comment period on the May 1, 2006 proposed rule or additional time to comment on the draft quality standards themselves is necessary.

Comment: Several commenters suggested that we not implement competitive bidding until we issue quality standards and select accreditation organizations. Commenters also specifically suggested that we should not select the 10 MSAs for the first phase of competitive bidding until we issue quality standards and select accreditation organizations.

Response: As noted earlier, we expect to issue the quality standards in the near future. We expect to identify the 10 competitive bidding areas in which competitive bidding will take place after we publish a future final rule on the Medicare DMEPOS Competitive Bidding Program. Our proposals for selecting accreditation organizations are discussed in section X.D of this final rule.

Comment: A commenter recommended that we base our quality standards on the existing standards used by the Accreditation Commission for Health Care (ACHC), Community

Health Accreditation Program (CHAPS), and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). One commenter encouraged us to include diabetes management experts in the development of the DMEPOS quality standards.

Response: These comments appear to concern the substantive nature of the draft quality standards that were developed and published on our website on September 26, 2005. We expect to respond to all the comments that we received on the draft DMEPOS quality standards in an accompanying document that will be published shortly on the CMS web site at

<http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>. The DMEPOS quality standards will become effective for use as part of the accreditation selection process when posted on the website.

Comment: Seven commenters supported the implementation of quality standards, while others opposed the implementation of additional quality standards and accreditation requirements. Another commenter suggested that quality standards should be appropriate, realistic, and clearly defined.

Response: We appreciate the comments that expressed support for the establishment and implementation of DMEPOS quality standards, which is mandated by section 1834(a)(20)

of the Act. We have worked collaboratively with a wide range of stakeholders to ensure that the quality standards are reflective of best industry practices for business and beneficiary services.

Comment: One commenter recommended that CMS provide its proposed revisions to the draft quality standards to the Program Advisory and Oversight Committee (PAOC) for review and comment before adopting these standards in final form. The commenter also recommended that CMS use these final standards to identify appropriate accreditation organizations for DMEPOS suppliers.

Response: These comments appear to concern the substantive nature of the draft quality standards that were developed and published on our website on September 26, 2005. We expect to respond to all the comments that we received on the draft DMEPOS quality standards in an accompanying document that will be published shortly on the CMS web site at

<http://www.cms.hhs.gov/competitiveAcqforDMEPOS/>.

D. Accreditation for Suppliers of DMEPOS and Other Items

Section 1834(a)(20)(B) of the Act requires the Secretary, notwithstanding section 1865(b) of the Act, to designate and approve one or more independent accreditation organizations to apply the DMEPOS quality standards to

suppliers of DMEPOS and other items. Section 1865(b) of the Act sets forth the general procedures for CMS to designate national accreditation organizations that can deem suppliers to meet Medicare conditions of participation or coverage if they are accredited by a national accreditation organization approved by CMS. Certain limited types of suppliers have a choice between having the State agency or the CMS-approved accreditation organization survey them pursuant to our regulation at §488.6. If such suppliers select the CMS-approved accreditation organization and meet the accreditation organization's standards, we deem them to have met the Medicare conditions of participation or coverage. We are responsible for the oversight and monitoring of the State agencies and the approved accreditation organizations. The procedures, implemented by the Secretary, for designating non-DMEPOS accreditation organizations and the Federal review process for accreditation organizations are located at parts 422 (for Medicare Advantage organizations) and 488 (for most providers and certain suppliers).

To accommodate DMEPOS suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, we will phase-in the accreditation process and give preference to accreditation organizations to

prioritize their surveys to accredit suppliers in the selected competitive bidding areas. We will specify the approval submission procedures for accreditation organizations to accredit DMEPOS suppliers after this rule is finalized.

Section 1847(b)(2)(A)(i) of the Act specifies that a contract may not be awarded to any entity unless the entity meets applicable DMEPOS quality standards specified by the Secretary under section 1834(a)(20) of the Act. Any DMEPOS supplier seeking to participate in the Medicare DMEPOS Competitive Bidding Program will need to satisfy the DMEPOS quality standards issued under section 1834(a)(20) of the Act. In addition, section 1834(a)(20) of the Act gives us the authority to establish through program instructions or otherwise DMEPOS quality standards for all suppliers of DMEPOS and other items, including those who do not participate in competitive bidding, and to designate one or more independent accreditation organizations to implement the DMEPOS quality standards.

In the May 1, 2006 proposed rule (71 FR 25684), to ensure the integrity of suppliers' businesses and products, we proposed to revise §424.57 of our existing regulations and add a new §424.58.

E. Special Payment Rules for Items Furnished by DMEPOS

Suppliers and Issuance of DMEPOS Supplier Billing Privileges (§424.57)

In accordance with sections 1834(a)(20) and 1834(j)(1)(B)(ii)(IV) of the Act, in the May 1, 2006 proposed rule (71 FR 25685), we proposed to revise §424.57 to specify in a proposed new paragraph (c)(22) that all suppliers of DMEPOS and other items be accredited by a CMS-approved accreditation organization to receive and retain a supplier billing number. We proposed the following definitions under §424.57(a): "CMS-approved accreditation organization" would mean a recognized independent accreditation organization approved by CMS under §424.58; an "Accredited DMEPOS supplier" would mean a supplier that has been accredited by a recognized independent accreditation organization meeting the requirements of and approved by CMS in accordance with §424.58; and an "Independent accreditation organization" would mean an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

Comment: Four commenters supported our proposed requirement at §424.57(c)(22) that all DMEPOS suppliers be accredited by a CMS-approved accreditation organization in

order to receive a supplier number. One commenter expressed concern that some accreditation organizations might be unsuitable to accredit DMEPOS suppliers because these organizations have a hospital and home health nursing orientation and lack an understanding of how suppliers function, while another commenter noted that currently, the standards of accreditation organizations vary greatly. Another commenter stated that they were uncertain as to how CMS planned to proceed with its accreditation process for the retail pharmacy industry and to conform to standards not yet developed for a retail pharmacy or mail order pharmacy. Another commenter asked whether we had selected accreditation organizations.

Response: We will take into consideration the uniqueness of the DMEPOS environment by considering proposals from those accreditation organizations that can demonstrate their skills, knowledge, and ability, to survey the DMEPOS supplier industry. We hope to receive proposals from those accreditation organizations that have experience with specialized supplies (such as orthotics and prosthetics) or supplier types (such as pharmacies and physicians' offices).

Comment: Several commenters noted that the costs of meeting quality standards and accreditation requirements

will cause suppliers to furnish inexpensive equipment and that some suppliers of purchased equipment will not provide service that beneficiaries are not trained to perform.

Response: We believe that the DMEPOS quality standards represent basic good business practices and that meeting the DMEPOS quality standards will result in improved quality of items and services furnished to Medicare beneficiaries. Approving accreditation organizations that only accredit one supplier type gives a small business owner the opportunity to reduce its accreditation cost. In the impact analysis, we have assumed costs to be on the average of \$3,000 over a 3-year period.

Comment: One commenter recommended that we require all suppliers to receive accreditation. Another commenter stated that currently an accrediting body would consider a new location of an accredited supplier to be accredited without conducting an on-site visit. The commenter recommended that CMS make an allowance for this situation and consider any new location associated with an already-accredited supplier to qualify for the immediate issuance of a Medicare supplier number, followed up by a subsequent accreditation survey.

Response: We agree and will require enrolled,

accredited DMEPOS suppliers to notify their accreditation organizations when a new location is opened. The accrediting organization of the enrolled DMEPOS supplier may accredit the new supplier location for three months after it is operational without a site visit.

Comment: Commenters suggested that a supplier should not be required to be reaccredited each time that it elects to add a new product line.

Response: We disagree and are requiring that a DMEPOS supplier disclose upon enrollment all products and services for which they are seeking accreditation. Thus, if a new product line is added after enrollment, the supplier must notify the accrediting body of the new product or service so that the supplier can be re-surveyed and accredited for these new products or services.

After consideration of the public comments received, we are finalizing our proposal with modifications. We have modified §424.57(c)(22), to clarify that all suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

We added a new provision at §424.57(c)(23), requiring that DMEPOS suppliers must notify their accreditation organizations when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without visiting the new site visit.

We added a new provision at §424.57(c)(24), which requires that all DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier can be denied enrollment or their enrollment could be revoked, if we determined that they were not in compliance with the DMEPOS quality standards.

We have added a new provision at §424.57(c)(25), requiring that all DMEPOS suppliers must disclose upon enrollment all products and services, for which they are seeking accreditation. If a new product line or service is added after enrollment, the supplier will be responsible for notifying the accrediting body of the new product so that the supplier can be re-surveyed and accredited for these new products.

F. Accreditation (§424.58)

In accordance with section 1834(a)(20) of the Act, in

the May 1, 2006 proposed rule (71 FR 25685 and 25702), we proposed to add a new §424.58(a) and (b) to set requirements for CMS-approved accreditation organizations in the application of the quality standards to suppliers of DMEPOS and other items.

To promote consistency in accrediting suppliers throughout the Medicare program, we proposed to use existing criteria (with modifications) for the application, reapplication, selection, and oversight of accreditation organizations detailed at 42 CFR Part 488 and apply them to organizations accrediting suppliers of DMEPOS and other items. We proposed to require an independent accreditation organization applying for approval or reapproval of deeming authority to-

- Identify the types of DMEPOS supplies and services for which the organization is requesting approval.
- Provide CMS with a detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare DMEPOS quality standards (for example, a crosswalk);
- Provide a detailed description of the organization's survey processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and

instructions to surveyors, and quality review processes for deficiencies identified with accreditation requirements;

- Describe the decision-making processes and describe procedures used to notify suppliers of compliance or noncompliance with the accreditation requirements;

- Describe procedures used to monitor the correction of deficiencies found during the survey; and

- Describe procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products that the supplier provides.

In the proposed rule, we indicated that we would request detailed information about the professional background of the individuals who perform surveys for the accreditation organization, including: the size and composition of accreditation survey teams for each type of supplier accredited; the education and experience requirements that surveyors must meet; the content and frequency of the continuing education training provided to survey personnel; the evaluation systems used to monitor the performance of individual surveyors and survey teams; and policies and procedures for a surveyor or institutional affiliate of an accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which this individual or institution is

professionally or financially affiliated.

We also indicated that we would request a description of the organization's data management, analysis, and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. We would require a description of the organization's procedures for responding to and investigating complaints against accredited facilities including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, National Supplier Clearinghouse, and with CMS; a description of the organization's policies and procedures for notifying CMS of facilities that fail to meet the requirements of the accrediting organization; a description of all types, categories, and duration of accreditation decisions offered by the organization; a list of all currently accredited suppliers; a list of the types and categories of accreditation currently held by each supplier; a list of the expiration date of each supplier's current accreditation; and a list of the next survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

We proposed that we would require the accreditation

organization to submit the following supporting documentation:

- A written presentation that would demonstrate the organization's ability to furnish CMS with electronic data in ASCII-comparable code.
- A resource analysis that would demonstrate that the organization's staffing, funding, and other resources are sufficient to perform the required surveys and related activities.
- An acknowledgement that the organization would permit its surveyors to serve as witnesses if CMS took an adverse action against the DMEPOS supplier based on the accreditation organization's findings.

We proposed to survey accredited suppliers from time to time to validate the survey process of a DMEPOS accreditation organization (validation survey). These surveys would be conducted on a representative sample basis or in response to allegations of supplier noncompliance with DMEPOS quality standards. When conducted on a representative sample basis, we proposed that the survey would be comprehensive and address all Medicare DMEPOS quality standards or would focus on a specific standard. When conducted in response to an allegation, we proposed that the CMS survey team would survey for any standard that

we determined was related to the allegations. If the CMS survey team substantiated a deficiency and determined that the supplier was out of compliance with the DMEPOS quality standards, we proposed to revoke the supplier billing number and reevaluate the accreditation organization's approved status. We proposed to require a supplier selected for a validation survey to authorize the validation survey to occur and to authorize the CMS survey team to monitor the correction of any deficiencies found through the validation survey. We proposed that if a supplier selected for a validation survey failed to comply with the requirements at §424.58(b)(4), it would no longer be deemed to meet the DMEPOS quality standards and its supplier billing number would be revoked.

Comment: Commenters stated that it would be difficult for accreditation organizations to survey timely the large number of suppliers, with commenters noting that the accreditation process can take six to 12 months. A commenter noted that it was unclear whether any of the accrediting bodies would be willing or able to meet our requirements to be a CMS-approved accreditation organization. A commenter stated that it would be difficult for suppliers to become accredited before the bidding process began. Commenters requested that CMS

provide sufficient time after it identifies accreditation organizations for suppliers to become accredited.

Response: Our DMEPOS quality standards for use by accreditation organizations are streamlined and require less resources to implement than are currently used by some accreditation organizations. We believe that the quality standards that have been developed are appropriate, realistic, and clearly defined.

Comment: Several commenters suggested that we "grandfather" suppliers already accredited by organizations that we select as accreditation organizations, while another commenter opposed such "grandfathering," stating that only suppliers that receive accreditations which address our revised quality standards should be allowed to contract under the bidding program. Some commenters suggested that CMS should grandfather any organization that meets minimal accreditation standards, even if that organization is not ultimately selected as an accrediting organization or if the standards used are not totally consistent with the standards required by CMS.

Response: We recognize the need to provide an alternative mechanism to accommodate currently accredited suppliers. As stated in the proposed rule we will provide further guidance on a process to accredit DMEPOS suppliers

that currently maintain an accreditation with an accreditation organization.

Comment: One commenter argued that the role of the Medicare National Supplier Clearinghouse (NSC) should be limited to reviewing complaints regarding non-compliance, conducting spot checks for compliance with the accreditation standards, and issuing supplier numbers based on accreditation verification.

Response: We appreciate this comment; however, this rule does not address the role of the NSC.

Comment: One commenter observed that most enteral patients are in long-term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long-term care market. The commenter believed that the proposed rule would require enteral nutrition suppliers to be accredited for compliance with the Part B standards, even though those standards do not apply to the patients they serve. The commenter stated that the provision of enteral nutrition to patients who qualify for the home health benefit would not be subject to the new Part B standards. Another commenter stated that manufacturers of customized ocular prosthetics are excluded from the accreditation requirements that we proposed at §424.58 because these items are not included in proposed

§414.402. Several commenters stated that CMS should deem pharmacies, occupational therapists, physical therapists and ophthalmologists as accredited because of the licensure and education requirements that they already fulfill and because their role as a supplier is inextricably linked to their professional service. Another commenter stated that skilled nursing homes should be excluded from the implementation of this rule.

Response: The Secretary may implement standards for such items and services listed at 1834(a)(20)(D) as he deems appropriate. The Secretary has decided to implement quality standards for all such items and services.

Comment: Several commenters noted that the accreditation process is costly, with estimates ranging from two thousand to 20 thousand dollars. They noted that accreditation was expensive and burdensome to many DMEPOS suppliers, including small suppliers, rural suppliers, pharmacies, non-mail order suppliers with small numbers of employees, suppliers that furnish supplies to a high percentage of beneficiaries that live nearby, suppliers with a small volume of Medicare business, or a limited line of supplies (such as diabetic supplies). Several of these commenters suggested exempting suppliers with these characteristics from the accreditation requirement or

creating a two-tier system with less expensive and burdensome alternatives to current accreditation fees. One commenter suggested that hospitals and other health care suppliers with certified DME programs should not be required to acquire new certification until the current certification expires. One commenter suggested making accreditation mandatory to keep the quality standards consistent.

Response: We do not have the statutory authority to exempt any categories of suppliers under section 1834(a)(20) of the Act except insofar as the Secretary exempts specific DMEPOS items and services under (20)(D). Suppliers must meet our DMEPOS quality standards as applied by approved accreditation organizations pursuant to section 1834(a)(20)(B) of the Act. We hope that approving many DMEPOS accreditation organizations will induce competition and decrease cost.

Comment: One commenter questioned why CMS could not deem between one and three already-existing accrediting organizations to meet its expectations and then require any supplier that wishes to participate in competitive acquisition to become accredited by one of those three organizations. One commenter suggested modifying §424.58(b) by adding special categories for orthotics and

prosthetics and pedorthics accrediting organizations.

Response: We do want to receive applications from existing organizations. However, in order to accommodate the large number of DMEPOS suppliers that need to be accredited in order to bid, we must allow a variety of organizations to become accreditation organizations. We believe §424.58 (b) does include categories such as orthotics and prosthetics and pedorthics. Therefore in order to accommodate small and specialty suppliers, we hope to receive applications from small or specialty accrediting firms that will be able to accredit these specialty suppliers at a reduced cost.

Comment: One commenter indicated that CMS should require accrediting bodies to submit their conflict of interest disclosure policies, since some surveyors also have consulting businesses that may conflict with certain clients.

Response: We agree and have added this requirement.

Comment: Two commenters stated that the process for the validation survey of suppliers should be outlined in greater detail in the regulation's preamble to include the survey frequency, who will perform the surveys, and the methodology used to determine the validation sample.

Response: We plan to issue further guidance regarding

the validation survey process through program instructions.

Comment: One commenter stated that proposed 42 CFR 424.58(b)(3) is redundant and confusing to specify "If CMS discovers a deficiency and determines that the DMEPOS supplier is out of compliance with Medicare quality standards,...".

Response: We agree and we have revised the language appropriately.

Comment: One commenter stated that it is unclear what is meant by the use of the term "subsequent full accreditation survey" and that there is no statutory authority that would permit CMS to specify that the accreditation organization perform a survey at its own expense.

Response: "Subsequent full accreditation survey" is a type of survey that may be performed by the accreditation organization if CMS determines that the DMEPOS supplier is out of compliance with the Medicare DMEPOS quality standards. The statutory authority for this requirement is found in Section 1834(a)(20)(B), which permits the Secretary to utilize his discretion in deciding the terms under which accreditation organizations will be approved to accredit DMEPOS suppliers.

Comment: One commenter suggested that the CMS

oversight provision should be clarified to describe: who is eligible to be "a designated survey team;" the methodology for selecting suppliers for the CMS survey; and detailed information on how the disparity rate will be calculated. The commenter also suggested that we clarify what is meant by "disparity between findings that constitute immediate jeopardy to patient health and safety" and "widespread or systemic problems in an organization's process."

Response: In order to accommodate the dynamics of the survey process and the ever-changing needs of the DMEPOS suppliers, we plan to issue the specifics of our oversight strategies in program instructions.

Comment: Two commenters stated that accrediting bodies do not currently notify ombudsman programs or NSC of unfavorable accreditation decisions. The commenter stated that any such notice process should be preceded by or include an appropriate appeal and cure process for suppliers to access prior to any punitive action being taken (Although the commenter didn't specify the exact organization that he believed would take such punitive action). A mediation process must be included in the overall plan so that an accreditation organization would have a channel for appealing CMS's validation survey findings.

Response: We agree and we have added the requirement that the accreditation organizations provide a copy of their dispute resolution policies and or appeals policies/procedures to CMS. Additionally, we plan to provide a venue for accreditation organizations and suppliers to resolve conflicts about deficiency findings. We will issue further guidance on this process through program instructions.

Comment: One commenter submitted detailed information on the nature of the commenter's organization and the specific accreditation costs that it incurs, and argued that unless a supplier has already undergone an accreditation process, it cannot properly estimate its costs associated with seeking and maintaining accreditation and, therefore, it cannot submit an accurate bid to CMS.

Response: We appreciate this information. We have utilized this information in our analysis of the rule's financial impact on DMEPOS suppliers.

Comment: One commenter suggested that CMS should have a supplier's accrediting organizations conduct follow-up visits with the supplier on any allegation of supplier noncompliance with quality standards. The commenter asserted that the Program Integrity Unit's (PIU's) current plan of auditing only high-volume, claims-generating DMEPOS

suppliers creates a situation where those suppliers are audited over and over again, with largely successful outcomes, while smaller suppliers that may not be following Medicare guidelines go unaudited for many years. They noted that audits represent a large administrative burden for suppliers, and those that pass successfully should be moved on to some kind of representative sampling methodology to ensure ongoing compliance. The commenter suggested that if the PIU continues its current sampling methodology, it will continue to overlook those suppliers that are more likely to be violating rules and regulations than the ones that have high volume and pass audits successfully time after time.

Response: We appreciate the comment regarding activities of the Program Integrity Units (PIUs). (Although the commenter didn't specify the exact organization to which he was referring, we assume the commenter means CMS's Program Integrity Unit, which is a branch of CMS's Office of Financial Management). However, the PIU's role is to ensure that claims submitted for Medicare reimbursement are covered, correctly coded and are reasonable and necessary based on the clinical condition of the patient. PIUs are not responsible for ensuring compliance with DMEPOS quality standards.

Comment: One commenter asked whether CMS would set ethical conduct standards for an accreditation organization's dispute-resolution process when suppliers challenged such organization's adverse findings. This commenter suggested that the hearing process for the accreditation organizations needs to be formal and involve a more independent, objective mediator than one that is appointed by the CMS Administrator. The commenter indicated that the hearing process should allow for testimony and other evidence to be accepted and admissible under the usual rules of court procedures.

Response: We understand the commenter's concerns about the fair and objective process when there is a dispute over the accreditation findings. We will be asking accreditation organizations to address their practices for dispute resolution in their CMS approval application.

Comment: A commenter indicated that the accreditation process should include reasonable mechanisms that the accrediting organization must use to identify those suppliers which are not in compliance with minimum competency requirements. The commenter recommended adding a description of the organization's method for determining the process that surveyors would utilize to assess compliance with each accreditation standard, including a

description of how the organization would translate surveyor observations into a score for each accreditation standard; how that score would aggregate into an overall score; and how that score would identify competent suppliers.

Response: We agree with the commenter's suggestion but believe it is best implemented through guidance. We plan to utilize many of these processes as well as those that are consistent with existing accreditation procedures identified in Part 488.

Comment: Commenters recommended that each accrediting organization should be compelled to demonstrate that it has the knowledge and experience necessary to properly classify suppliers and measure their organizational performance in the specific product and service types.

Response: We agree and we will address eligibility criteria through future program instructions.

Comment: Commenters argued that the two-calendar day requirement for reporting non-compliance to CMS under §424.58(c)(4) is an unreasonable standard because it failed to recognize holidays and weekends as periods when complying with this requirement would be problematic. They suggested that it is more reasonable for CMS to require this critical notification via any format within five

business days. They further requested CMS to identify those specific standards with which noncompliance would rise to the level of posing immediate jeopardy to a beneficiary or to the general public.

Response: We disagree with the first part of the comment as we believe that two calendar days is a reasonable standard and is consistent with our current survey requirements. "Immediate jeopardy to a beneficiary or to the public" is determined by criteria set by the accreditation organization. We will review these criteria at the time of the application process.

Comment: Some commenters noted that it takes 6 months to prepare for an initial survey and 4 months for an ongoing survey. They added that a supplier going through accreditation for the first time will need 10 to 12 months to complete that process. The commenters observed that CMS should expect it to take a minimum of one year for some suppliers to complete the accreditation process and become officially accredited.

Response: Our DMEPOS quality standards for use by accreditation organizations are streamlined and require less resources to implement than are currently used by some accreditation organizations. We believe that the quality standards that have been developed are appropriate,

realistic, and clearly defined. We are requiring that accreditation organizations perform unannounced surveys. This will assist in reducing the survey process timeframe and cost.

Comment: Commenters requested us to clarify the relationship between accreditation organizations and CMS complaint investigation more broadly. In particular, when a supplier organization is deemed to be in full compliance with the quality standards and the 21 supplier standards by an approved accreditation organization, the commenters asked whether CMS will be permitted to separately revoke or suspend a supplier's participation status if CMS determines that the supplier was not in compliance with these requirements.

Response: We will be providing further guidance on the relationship between accreditation organizations and CMS complaint investigations in program instructions. However, if a complaint or validation survey discovered serious deficiencies CMS could revoke the supplier's billing number in accordance with §424.58 (b) (3).

Comment: Commenters observed that the regulation requiring applicants to submit a lengthy history of companies that it has accredited would not allow new companies to enter the market in a timely manner.

Response: We understand the commenter's concern. This history will not give an existing organization an advantage over a new organization. We will be considering all new and established accrediting organizations equally during the review process.

Comment: Some commenters asserted that requiring full disclosure of an accreditation report for each accredited supplier constitutes an invasion of privacy regarding the supplier and would be a breach of proprietary information. They asked under what authority CMS could require full disclosure about customers of a private business.

Response: We disagree with this comment. We are not requiring accreditation organizations to provide information about suppliers not participating in Medicare, and enrollment for a supplier number is strictly voluntary. However, in order to ensure that accreditation organizations are correctly implementing CMS quality standards, we believe that having access to supplier-specific information will be necessary.

After consideration of the public comments received, we are adopting as final with modifications the provisions under the proposed new §424.58 (a) and (b), containing the application and reapplication procedures for CMS-approved accreditation organizations in the application of the

DMEPOS quality standards to suppliers of DMEPOS and other items.

As part of their application process, accreditation organizations must provide CMS with a detailed description of their dispute resolution process to allow DMEPOS suppliers the opportunity to appeal negative survey findings or decisions. We have added a new provision at §424.58(b)(1)(iii) to require accreditation organizations to have a policy and procedure in place to allow DMEPOS suppliers to dispute a negative accreditation survey or survey findings. This process is consistent with existing processes under part 422.

In response to public comments we have revised the provision at §424.58 (b) (3) to state that if CMS discovers a supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

We have also revised §424.58 (b) (6) to indicate that if a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number

revoked.

G. Ongoing Responsibilities of CMS-Approved Accreditation Organizations

In this final rule, we require that DMEPOS independent accreditation organizations approved by CMS undertake the following activities on an ongoing basis:

- Provide to CMS in written form and on a monthly basis all of the following:

- ++ Copies of all accreditation surveys along with any survey-related information that CMS may require (including corrective action plans and summaries of CMS requirements that are not met).

- ++ Notice of all accreditation decisions.

- ++ Notice of all complaints related to suppliers of DMEPOS and other items.

- ++ Information about any supplier of DMEPOS and other items for which the accreditation organization has denied the supplier's accreditation request.

- ++ Notice of any proposed changes in its accreditation standard, requirements, or survey processes. If the accreditation organization implemented the changes before or without CMS approval, CMS has the authority to withdraw its approval of the accreditation organization.

- Submit to CMS (within 30 days of a change in CMS

quality standard requirements):

++ An acknowledgment of CMS's notification of the change;

++ A revised crosswalk reflecting the new DMEPOS quality standard requirements; and

++ An explanation of how the accreditation organization would alter its standards to conform to CMS's new requirements, within the time frames specified by CMS in the notification.

- Permit its surveyors to serve as witnesses if CMS takes an adverse action against a supplier based on accreditation findings.

- Provide CMS with written notice of any deficiencies and adverse actions implemented by the independent accreditation organization against an accredited DMEPOS supplier within 2 calendar days of identifying these deficiencies, if these deficiencies pose immediate jeopardy to a beneficiary and/or the general public.

- Provide CMS with written policies and procedures to ensure that DMEPOS suppliers are accredited every 3 years.

- Provide written notice of CMS's withdrawal of the accreditation organization's approval to all accredited suppliers within 10 calendar days of receipt of CMS's withdrawal notice.

- Provide, on an annual basis, summary data specified by CMS that related to the past year's accreditation activities and trends.

Comment: One commenter suggested that the guidelines proposed in §424.58(c) were unreasonable.

Response: We disagree. Section 424.58(c) addresses the ongoing responsibilities of a CMS-approved accreditation organization. This section provides requirements with which the accreditation organization must comply on an ongoing basis in the application of the DMEPOS quality standards to suppliers of DMEPOS and other items.

Comment: Three commenters indicated that requiring notice of all complaints related to suppliers of DMEPOS and other items and services is overly broad and burdensome, and that section 424.58(c)(1)(iii) is redundant with §424.58(c)(1)(iv) and should be eliminated.

Response: These provisions are not redundant. Section 424.58(c)(1)(iii) requires that accreditation organizations provide a notice or listing of all complaints received. Section 424.58(c)(1)(iv) requires that an accreditation organization provides information on the outcomes of the remedial and adverse actions that it takes against the suppliers that it accredits.

Comment: One commenter indicated that requiring

approved accreditation organizations to provide copies of all written surveys, corrective action plans, and summaries represent a significant paperwork burden to the accrediting organization and CMS.

Response: We disagree, and note that in order for us to ensure the integrity of the DMEPOS accreditation program these requirements are necessary and are consistent with existing accreditation requirements for providers and suppliers under Part 488.

Comment: One commenter indicated that scoring methodologies differ amongst the three accrediting organizations and slightly different standards and requirements may be assessed. Without an executive summary written by either the accrediting organization or the supplier itself, CMS might find itself unable to interpret the results of the survey accurately.

Response: We agree and we are requiring the accreditation organizations to describe their decision making process to reduce misinterpretation of survey findings. We also note that the accreditation organizations must submit a crosswalk to their own standards as part of the application process.

Comment: One commenter requested that CMS provide a reasonable timeframe for itself in which to review an

accreditation organization's request for change under §424.58(c)(1)(v). The commenter recommended that CMS commit to respond to any proposed change within 60 days of submission by the approved accrediting organization.

Response: We plan to provide a reasonable timeframe in which we will review an accrediting organization's request for change and will outline this timeframe through program instructions.

Comment: Two commenters indicated that though they thought it was reasonable for CMS to expect the accrediting organizations to inform the agency of changes in standards, it was unreasonable to penalize the organization by withdrawing its approval if it implemented the changes before or without CMS' approval.

Response: We disagree and believe that this requirement is essential to ensure that appropriate DMEPOS standards are being utilized by accreditation organizations.

Comment: A commenter requested clarification on what constitutes "written format" in §424.58(c)(1).

Response: We will clarify in the regulation text that written format means either hard copy or electronic format.

Comment: One commenter suggested amending §424.58(c)(5) by inserting the word "business" between "10"

and "days" and that notice should be required only after CMS has issued a final determination that approval is to be withdrawn.

Response: We agree that this requirement should be clarified but that notice should be more prompt than 10 business days. Therefore, we will revise the regulation to add the word "calendar" between the words "10" and "days".

After consideration of the public comments received, we are adopting as final with modifications the following:

We have modified §424.58(c)(1) to clarify that written format means either hard copy or electronic format.

We have revised §424.58(c)(2) and (5) to add the word "calendar" before the word "days".

H. Continuing Federal Oversight of Approved Accreditation Organizations

Section 424.58(d) establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

1. Equivalency Review

We will compare the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS quality standard requirements and processes when: CMS imposes new requirements or changes its survey process; an

accreditation organization proposes to adopt new quality standards or changes in its survey process; or the term of an accreditation organization's approval expires.

2. Validation Survey

A CMS survey team will conduct a survey of the accreditation organization, examine the results of the accreditation organization's own survey procedure onsite, or observe the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, we will identify any accreditation programs for which validation survey results indicate:

- A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS on standards that do not constitute immediate jeopardy to patient health and safety if not met;
- Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if not met; or
- Widespread or systemic problems in the organization's accreditation processes such that the accreditation of the DMEPOS supplier no longer provides assurance that the supplier meets or exceeds the Medicare

requirements, irrespective of the rate of disparity.

3. Notice of Intent to Withdraw Approval for Deeming Authority.

If an equivalency review, validation review, onsite observation, or our concerns with the ethical conduct of the accreditation organization suggest that the accreditation organization is not meeting the requirements of §424.58, we will provide the accreditation organization with written notice of our intent to withdraw approval of the accreditation organization's deeming authority. We will collaborate with the DMEPOS accreditation organization in order to transition those DMEPOS suppliers to a new accreditation organization.

4. Withdrawal of Approval for Deeming Authority

We will withdraw approval of an accreditation organization at any time if we determine that: accreditation by the organization no longer guarantees that the suppliers of DMEPOS and other items met the DMEPOS quality standards and that the failure to meet those standards poses or may potentially pose an immediate jeopardy to the health or safety of Medicare beneficiaries or constitutes a significant hazard to public health; or the accreditation organization fails to meet its obligations for application and reapplication procedures.

Comment: One commenter suggested that the term "guarantees" should be replaced by "adequate assurance" since the latter term more appropriately represents the process of accreditation in that accreditation can provide such assurance that the quality standards are met, but cannot "guarantee" such an assertion.

Response: We will clarify this in the regulation text.

After consideration of public comments received, we are adopting as final with modifications the following:

We have modified §424.58(d)(4)(i) to utilize the term "adequately assures" that rather than "guarantees". The modified provision now states "Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other items and services are meeting the DMEPOS quality standards, and that failure to meet those standards could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health."

I. Reconsideration

If an accreditation organization is dissatisfied with a CMS determination that its accreditation requirements do not provide or no longer provide reasonable assurance that the entities accredited by such organization meet the

applicable DMEPOS supplier quality standards, such organization would be entitled to reconsideration of that determination. We will reconsider any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration through its authorized officials or through its legal representative.

The request must be filed within 30 days of the receipt of CMS notice of an adverse determination or non-renewal. The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement. A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination. In response to a request for reconsideration, we will provide the accreditation organization the opportunity for an informal hearing that will be conducted by a hearing officer appointed by the Administrator of CMS. The hearing will provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw (or not renew) deeming authority.

We will provide written notice of the time and place of the informal hearing at least 10 calendar days before the scheduled date. The informal reconsideration hearing will be open to CMS and the organization requesting the reconsideration, including authorized representatives, technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts), and legal counsel. The hearing will be conducted by the hearing officer, who will receive testimony and documents related to the proposed action. The hearing officer may accept testimony and other evidence that would be inadmissible under the usual rules of court procedures. The hearing officer will not have the authority to compel by subpoena the production of witnesses, papers, or other evidence. Within 45 calendar days of the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration. The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision will be final.

After consideration of the public comments received, we are adopting as final without substantive modification the provisions of the new proposed §424.58(d) governing

continuing Federal oversight of approved accreditation organizations relating to equivalency reviews, validation reviews, notice of intent to withdraw approval for deeming authority, withdrawal of approval for deeming authority, and reconsiderations. We have revised §424.58(e)(6) and (8) to add the word "calendar" before the word "days".

XI. Provisions of the Final Regulations

A. IRF PPS

The provisions of this final rule restate the provisions of the FY 2007 IRF PPS proposed rule (71 FR 28106) except as noted elsewhere in the preamble. Following is a highlight of the policies that we are finalizing in this final rule:

- We are revising the relative weight and average length of stay tables based on re-analysis of the data by CMS and our contractor, the RAND Corporation, as discussed in section IV of this final rule.
- We are reducing the standard payment amount by 2.6 percent to account for coding changes that do not reflect real changes in case mix, as discussed in section V.A of this final rule.
- We are updating the FY 2007 IRF PPS payment rates by the market basket (3.3 percent), as discussed

in section V.B of this final rule.

- We are updating the FY 2007 IRF PPS payment rates by the labor related share (75.612 percent), the wage indexes, and the second year of the hold harmless policy in a budget neutral manner, as discussed in sections V.C and D of this final rule.
- We are updating the outlier threshold amount for FY 2007 to \$5,534, as discussed in section VI.A of this final rule.
- We are updating the urban and rural national cost-to-charge ratio ceilings for purposes of determining outlier payments under the IRF PPS and are clarifying the methodology described in the regulation text, as discussed in section VI.B of this final rule.
- We are revising the regulation text at §412.23(b)(2)(i) and §412.23(b)(2)(ii) to reflect the compliance percentages specified in section 5005 of the DRA, as discussed in section VII of this final rule. In addition, we are revising §412.23(b)(2)(i) to permit comorbidities meeting the qualifying criteria outlined in §412.23(b)(2)(i)(A) and (B) and (C) to count

toward satisfying the compliance percentages specified in §412.23(b)(2)(i).

- We are making a technical correction to amend the cross-reference to several portions of §412.624(e) that currently appear in the regulation text in §412.624(f)(2)(v), by re-inserting a cross-reference to paragraph (e)(1). We inadvertently deleted this reference in the FY 2006 final rule.

B. Quality Standards and Accreditation for DMEPOS Suppliers

The provisions of this final rule restate the provisions of the May 1, 2006 proposed rule, except as follows:

- We have modified §404.406(e) to make a technical change to clarify that the Durable Medical Equipment Medicare Administrative Contractors will be taking over for the DMERCs/regional carriers for processing DMEPOS claims.
- We have modified §424.57(c)(22), to clarify that all suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services for which the supplier

- is accredited in order for the supplier to receive payment for those specific products and services.
- We have added a new provision at §424.57(c)(23), requiring that all DMEPOS suppliers must notify their accreditation organizations when a new location is opened. The accrediting organization of the enrolled DMEPOS supplier may accredit the new supplier location for three months after it is operational without a new site visit.
 - We have added a new provision at §424.57(c)(24), which requires that each supplier location, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or its enrollment may be revoked, if CMS determines that it was not in compliance with the DMEPOS quality standards.
 - We have added a new provision at §424.57(c)(25), which requires that all DMEPOS suppliers must disclose upon enrollment all products and services for which they are seeking accreditation. If a new product line is added after enrollment, the supplier will be responsible for notifying the accrediting body of the new product or service so that the supplier can be re-

surveyed and accredited for these new products or services.

- We are adding a provision at §424.58(b)(1)(iii) that accreditation organizations must provide CMS with a detailed description of their dispute resolution process and policies which would allow DMEPOS suppliers the opportunity to appeal negative survey findings or decisions.
- We are revising the provision at §424.58(b)(3) to state that if CMS discovers a supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.
- We are revising the provision at §424.58(b)(6) to indicate that if a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.
- We have modified §424.58(c)(1) to clarify that written format means either hard copy or electronic format.

- We have revised §424.58(c)(2) and (5) and §424.58(e)(6) and (8) to add the word "calendar" before the word "days."
- We have modified §424.58(d)(4)(i) to utilize the term "adequately assures" that rather than "guarantees." The modified provision now states "Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other items and services are meeting the supplier quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health."

XII. Waiver of Delayed Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and

the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

The Secretary finds that good cause exists to implement the regulatory changes to part 414 of 42 CFR, other than § 414.406(e), related to Competitive Bidding Implementation Contractors (CBICs) for the Medicare DMEPOS Competitive Bidding Program on [**OFR: Insert date 30 days after display**]. We note that we are not waiving the APA requirements since we are giving 30 days notice. We are, however, waiving the 60-day delayed effective date for major rules. Section 1847(b)(9) of the Act explicitly allows the Secretary to contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program. The Secretary has determined that it is administratively necessary to use one or more CBICs to assist in implementing the Medicare DMEPOS Competitive Bidding Program. This final rule codifies this statutory provision in regulations.

Under section 1847(a)(1)(B) of the Act, the Medicare DMEPOS Competitive Bidding Program must be phased in so that the competition under the programs occurs in 10 of the largest metropolitan statistical areas (MSAs) in 2007. To comply with that statutory mandate, it will be necessary for us to designate one or more CBICs, as well as finalize

contracts with those entities, prior to October 1, 2006 (the beginning of Federal Fiscal Year (FY) 2007)) so that the CBIC(s) have sufficient time to prepare for the bidding process and to educate thousands of DMEPOS suppliers and referral agents, as well as millions of Medicare beneficiaries prior to the beginning of the bidding process. If one or more CBIC(s) are not designated before October 1, 2006, there will be insufficient time for those entities to conduct the large-scale preparations necessary to ensure the success of the program consistent with our statutory mandate. Additionally, if we are unable to designate one or more CBIC(s) prior to the end of FY 2006 then our ability to meet the implementation timetable set forth in section 1847(a)(1)(B) of the Act would be further jeopardized. Therefore, the Secretary has determined that it would be impracticable and contrary to the public interest to delay the effective date of the regulatory changes to part 414 of 42 CFR, other than § 414.406(e). An effective date of **[OFR: Insert date 30 days after display]**, for the regulatory changes to part 414 of 42 CFR, other than § 414.406(e), will ensure that the procurement of CBIC services can proceed and will afford the selected CBIC(s) needed time to prepare for the bidding process and education of beneficiaries, suppliers, and referral agents

on the Medicare DMEPOS Competitive Bidding Program.

For all these reasons, we believe that a 60-day delay in the effective date of the provisions that apply to the CBIC(s) would be impracticable and contrary to the public interest. We therefore find good cause for waiving the 60-day delay in the effective date for the regulatory changes to part 414 of 42 CFR, other than § 414.406(e).

XIII. Collection of Information Requirements

The sections of this document pertaining to the IRF PPS and to the DMEPOS do not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

XIV. Regulatory Impact Analysis for the IRF PPS

A. Overall IRF PPS Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA, September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties)

directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule is a major rule, as defined in Title 5, United States Code, section 804(2), because we estimate the impact to the Medicare program, and the annual effects to the overall economy, will be more than \$100 million. We estimate that the total impact of these changes for estimated FY 2007 payments compared to estimated FY 2006 payments will be an increase of approximately \$50 million (this reflects a \$220 million increase from the update to the payment rates and a \$10 million increase due to updating the outlier threshold amount to increase estimated outlier payments from 2.9 percent in FY 2006 to 3.0 percent in FY 2007, offset by a \$180 million estimated decrease from the reduction to the standard payment amount to account for changes in coding that do not reflect real changes in case mix).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the

RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most IRFs and most other providers and suppliers are considered small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432, November 17, 2000.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs. Therefore, we assume that all IRFs (an approximate total of 1,200 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. Because the net effect of this final rule on almost all facilities will only be about 1 percent or less of revenues, and will be positive, we have concluded that this final rule will not have a significant effect on a substantial number of small entities. Medicare fiscal intermediaries and carriers are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

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. As discussed in detail below, the rates and policies set forth in this final rule will not have an adverse impact on rural hospitals based on the data of the 181 rural units and 20 rural hospitals in our database of 1,202 IRFs for which data were available.

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. That threshold level is currently approximately \$120 million. The IRF PPS portions of this final rule will not mandate any requirements for State, local, or tribal governments, nor will they affect private sector costs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State

and local governments, preempts State law, or otherwise has Federalism implications. As stated above, this final rule will not have a substantial effect on State and local governments.

B. Anticipated Effects of the IRF PPS Final Rule

We discuss below the impacts of this final rule on the budget and on IRFs.

1. Basis and Methodology of Estimates

This final rule sets forth updates of the IRF PPS rates contained in the FY 2006 final rule and establishes a 2.6 percent decrease to the standard payment amount to account for the increase in estimated aggregate payments as a result of changes in coding that do not reflect real changes in case mix. In addition, we are updating the comorbidity tiers and the CMG relative weights, and the outlier threshold amount.

Based on the above, we estimate that the FY 2007 impact will be a net increase of \$50 million in payments to IRF providers (this reflects a \$220 million estimated increase from the update to the payment rates and a \$10 million estimated increase due to updating the outlier threshold amount to increase estimated outlier payments from 2.9 percent in FY 2006 to 3.0 percent in FY 2007, offset by a \$180 million estimated decrease from the

reduction to the standard payment amount to account for the increase in estimated aggregate payments as a result of changes in coding that do not reflect real changes in case mix). The impact analysis in Table 9 of this final rule represents the projected effects of the policy changes in the IRF PPS for FY 2007 compared with estimated IRF PPS payments in FY 2006 without the policy changes. We estimate the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. In addition, changes to the Medicare program may continue to be made as a result of the BBA, the BBRA, the BIPA, the MMA, the DRA, or new statutory provisions. Although these changes may not be specific to

the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2007, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used to adjust the Federal rates). These revisions will increase payments to IRFs by approximately \$220 million.

The aggregate change in payments associated with this final rule is estimated to be an increase in payments to IRFs of \$50 million for FY 2007. The market basket increase of \$220 million and the \$10 million increase due to updating the outlier threshold amount to increase estimated outlier payments from 2.9 percent in FY 2006 to 3.0 percent in FY 2007, combined with the estimated decrease of \$180 million due to the reduction to the standard payment amount to account for coding changes (not related to real changes in case mix), results in a net change in estimated payments from FY 2006 to FY 2007 of \$50 million.

The impacts are shown in Table 9. The following changes are discussed separately below:

- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the expiration of the one-year budget-neutral transition policy for adopting the new CBSA-based geographic area definitions announced by OMB in June 2003.
- The effects of the update to the outlier threshold amount to increase total estimated outlier payments from 2.9 to 3 percent of total estimated payments for FY 2007, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the RPL market basket) to IRF PPS payment rates, as required by sections 1886(j)(3)(A)(i) and 1886(j)(3)(C) of the Act.
- The effects of the decrease to the standard payment amount to account for the increase in estimated aggregate payments as a result of changes in coding that do not reflect real changes in case mix, as required under section 1886(j)(2)(C)(ii) of the Act.

- The effects of the second year of the 3-year budget-neutral hold-harmless policy for IRFs that were rural under \$412.602 during FY 2005, but are urban under \$412.602 during FY 2006 and FY 2007 and lose the rural adjustment, resulting in a loss of estimated IRF PPS payments if not for the hold harmless policy.
- The effect of the budget-neutral revisions to the comorbidity tiers and the CMG relative weights, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2007 policies relative to estimated FY 2006 payments without the policies.

2. Description of Table 9

The table below categorizes IRFs by geographic location, including urban or rural location and location with respect to CMS's nine census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities by ownership (otherwise called for-profit,

non-profit, and government), and by teaching status. The top row of the table shows the overall impact on the 1,202 IRFs included in the analysis.

The next 12 rows of Table 9 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership: all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 1,001 IRFs located in urban areas included in our analysis. Among these, there are 807 IRF units of hospitals located in urban areas and 194 freestanding IRF hospitals located in urban areas. There are 201 IRFs located in rural areas included in our analysis. Among these, there are 181 IRF units of hospitals located in rural areas and 20 freestanding IRF hospitals located in rural areas. There are 398 for-profit IRFs. Among these, there are 326 IRFs in urban areas and 72 IRFs in rural areas. There are 743 non-profit IRFs. Among these, there are 630 urban IRFs and 113 rural IRFs. There are 61 government-owned IRFs. Among these, there are 45 urban IRFs and 16 rural IRFs.

The remaining three parts of Table 9 show IRFs grouped by their geographic location within a region, and the last part groups IRFs by teaching status. First, IRFs located in urban areas are categorized with respect to their location within a particular one of the nine CMS geographic regions. Second, IRFs located in rural areas are categorized with respect to their location within a particular one of the nine CMS geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. Finally, IRFs are grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent.

The estimated impact of each change to the facility categories listed above is shown in the columns of Table 9. The description of each column is as follows:

Column (1) shows the facility classification categories described above.

Column (2) shows the number of IRFs in each category.

Column (3) shows the number of cases in each category.

Column (4) shows the estimated effect of adjusting the outlier threshold amount so that estimated outlier payments increase from 2.9 percent in FY 2006 to 3 percent of total estimated payments for FY 2007.

Column (5) shows the estimated effect of the market basket update to the IRF PPS payment rates.

Column (6) shows the estimated effect of the update to the IRF labor-related share, wage index, and hold harmless policy.

Column (7) shows the estimated effects of the budget-neutral revisions to the comorbidity tiers and the CMG relative weights.

Column (8) shows the estimated effects of the decrease in the standard payment amount to account for the increase in aggregate payments as a result of changes in coding that do not reflect real changes in case mix, as discussed in section V.A of this final rule. Section 1886(j)(2)(C)(ii) of the Act requires us to adjust the per discharge PPS payment rate to eliminate the effect of coding or classification changes that do not reflect real changes in case mix if we determine that these changes result in a change in aggregate payments under the classification system.

Column (9) compares our estimates of the payments per

discharge, incorporating all changes reflected in this final rule for FY 2007, to our estimates of payments per discharge in FY 2006 (without these changes). The average estimated increase for all IRFs is approximately 0.8 percent. This estimated increase includes the effects of the 3.3 percent market basket update. It also includes the 0.1 percent overall estimated increase to IRF payments from the update to the outlier threshold amount, and the estimated impact of the 2.6 percent reduction to the standard payment amount to account for changes in coding that increased payments to IRFs. Because we will make the remainder of the changes outlined in this final rule in a budget-neutral manner, they will not affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will affect the estimated distribution of payments among providers.

Table 9: Projected Impact on the IRF PPS for FY 2007

Facility Classification (1)	No. of IRFs (2)	No. of cases (3)	Outlier (4)	Market Basket (5)	FY07 Wage Index, Labor-share, and Hold Harmless (6)	Comorbid. Tier and relative weight Revisions (7)	2.6% reduct (8)	Est. Total Change (9)
Total	1,202	487,281	0.1%	3.3%	0.0%	0.0%	-2.6%	0.8%
Urban unit	807	272,017	0.2%	3.3%	-0.1%	0.0%	-2.6%	0.7%
Rural unit	181	38,880	0.1%	3.3%	0.0%	0.1%	-2.6%	0.8%
Urban hospital	194	168,880	0.1%	3.3%	0.2%	0.0%	-2.6%	0.9%
Rural hospital	20	7,504	0.1%	3.3%	0.3%	0.0%	-2.6%	1.0%
Urban For-Profit	326	167,631	0.1%	3.3%	0.1%	0.1%	-2.6%	0.9%

Facility Classification (1)	No. of IRFs (2)	No. of cases (3)	Outlier (4)	Market Basket (5)	FY07 Wage Index, Labor-share, and Hold Harmless (6)	Comorbid. Tier and relative weight Revisions (7)	2.6% reduct (8)	Est. Total Change (9)
Rural For-Profit	72	16,106	0.1%	3.3%	-0.2%	0.1%	-2.6%	0.6%
Urban Non-Profit	630	258,037	0.1%	3.3%	0.0%	0.0%	-2.6%	0.7%
Rural Non-Profit	113	26,950	0.1%	3.3%	0.2%	0.1%	-2.6%	1.1%
Urban Government	45	15,229	0.2%	3.3%	0.1%	0.1%	-2.6%	1.1%
Rural Government	16	3,328	0.2%	3.3%	-0.4%	0.2%	-2.6%	0.5%
Urban	1,001	440,897	0.1%	3.3%	0.0%	0.0%	-2.6%	0.8%
Rural	201	46,384	0.1%	3.3%	0.0%	0.1%	-2.6%	0.9%
Urban by region								
New England	36	21,739	0.1%	3.3%	-0.2%	0.0%	-2.6%	0.6%
Middle Atlantic	159	80,502	0.1%	3.3%	0.6%	0.1%	-2.6%	1.4%
South Atlantic	127	78,495	0.1%	3.3%	-0.3%	0.1%	-2.6%	0.5%
East North Central	192	70,435	0.1%	3.3%	-0.3%	-0.3%	-2.6%	0.1%
East South Central	50	29,203	0.1%	3.3%	0.2%	0.0%	-2.6%	0.9%
West North Central	70	23,874	0.2%	3.3%	-0.6%	-0.1%	-2.6%	0.0%
West South Central	183	81,394	0.1%	3.3%	0.0%	0.1%	-2.6%	0.9%
Mountain	74	27,231	0.1%	3.3%	0.0%	0.1%	-2.6%	0.9%
Pacific	110	28,024	0.2%	3.3%	0.8%	-0.2%	-2.6%	1.5%
Rural by region								
New England	4	1,010	0.2%	3.3%	2.1%	-0.1%	-2.6%	2.9%
Middle Atlantic	19	6,074	0.1%	3.3%	0.5%	0.3%	-2.6%	1.4%
South Atlantic	25	6,692	0.1%	3.3%	-0.8%	0.2%	-2.6%	0.1%
East North Central	29	6,255	0.1%	3.3%	0.4%	0.0%	-2.6%	1.2%
East South Central	22	5,629	0.1%	3.3%	0.3%	0.1%	-2.6%	1.1%
West North Central	34	6,471	0.2%	3.3%	0.0%	0.0%	-2.6%	0.8%
West South Central	55	12,650	0.2%	3.3%	-0.3%	0.1%	-2.6%	0.6%
Mountain	9	1,041	0.3%	3.3%	-1.9%	0.1%	-2.6%	-1.0%
Pacific	4	562	0.2%	3.3%	2.8%	0.1%	-2.6%	3.7%
Teaching Status								
Non-teaching	1,090	433,028	0.1%	3.3%	0.0%	0.1%	-2.6%	0.8%
Resident to ADC less than 10%	61	35,227	0.1%	3.3%	0.3%	-0.3%	-2.6%	0.8%

Facility Classification (1)	No. of IRFs (2)	No. of cases (3)	Outlier (4)	Market Basket (5)	FY07 Wage Index, Labor-share, and Hold Harmless (6)	Comorbid. Tier and relative weight Revisions (7)	2.6% reduct (8)	Est. Total Change (9)
Resident to ADC 10%-19%	32	15,011	0.1%	3.3%	-0.3%	-0.4%	-2.6%	0.1%
Resident to ADC greater than 19%	19	4,015	0.1%	3.3%	-0.1%	-0.1%	-2.6%	0.6%

3. Impact of the Update to the Outlier Threshold Amount
(Column 4, Table 9)

In the FY 2006 IRF PPS final rule (70 FR 30188), we used FY 2003 patient-level claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2006 so that estimated outlier payments will equal 3 percent of total estimated payments for FY 2006. For this final rule, we have updated our analysis using FY 2004 data. Between FYs 2003 and 2004, we observed that IRFs' cost-to-charge ratios continued to fall, a trend that has occurred each year since we first implemented the IRF PPS. We are still investigating the reasons for this. However, this decrease in cost-to-charge ratios affected our estimate of outlier payments as a percentage of total estimated payments for FY 2006, which declined from 3 percent using the FY 2003 data to 2.9 percent using the updated FY 2004 data. Thus, we will adjust the outlier threshold amount for FY 2007 to \$5,534

in order to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2007 (see section VI.A of this final rule for a detailed discussion of the factors that influence how we arrive at the outlier threshold amount). The estimated change in total payments between FY 2006 and FY 2007, therefore, includes a 0.1 percent overall estimated increase in payments because the outlier portion of total payments is estimated to increase from 2.9 percent to 3 percent.

The impact of this update (as shown in column 4 of Table 9) is to increase estimated overall payments to IRFs by 0.1 percent. We estimate the largest increase in payments to be a 0.3 percent increase in payments to rural IRFs in the Mountain region. We do not estimate that any group of IRFs will experience a decrease in payments from this update.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates (Column 5, Table 9)

In column 5 of Table 9, we present the estimated effects of the market basket update to the IRF PPS payment rates. In the aggregate, and across all hospital groups, the update will result in a 3.3 percent increase in overall payments to IRFs.

5. Impact of the Full CBSA Wage Index, Labor-Related

Share, and the Hold Harmless Policy for FY 2007 (Column 6, Table 9)

In column 6 of Table 9, we present the effects of the budget neutral wage index, labor-related share, and the hold harmless policy. In FY 2006, we provided a 1-year blended wage index and a 3-year phase out of the rural adjustment for IRFs that changed designation because of the change from MSAs to CBSAs (referenced as the hold harmless policy). We applied the blended wage index to all IRFs and the hold harmless policy to those IRFs that qualify, as described in §412.624(e)(7), in order to mitigate the impact of the change from the MSA-based labor area definitions to the CBSA-based labor area definitions for IRFs.

As discussed in this final rule, the blended wage index expires in FY 2007 and will not be applied for discharges occurring on or after October 1, 2006. Because we are in the second year of the hold harmless policy, we are not changing this policy and will continue to apply it as described in the FY 2006 final rule in a budget neutral manner.

As discussed in this final rule, we are updating the wage index based on the CBSA-based labor market area definitions in a budget neutral manner. We will also apply

the second year of the hold harmless policy in a budget neutral manner. Thus, in the aggregate, the estimated impact of the wage index and the labor-related share is zero percent.

In the aggregate for all urban and all rural IRFs, we do not estimate that these changes will affect overall estimated payments to IRFs. However, we estimate these changes to have small distributional effects. We estimate the largest increase in payments to be a 2.8 percent increase for rural IRFs in the Pacific region and the largest decrease in payments to be a 1.9 percent decrease among rural IRFs in the Mountain region.

6. Impact of the Changes to the Comorbidity Tiers and the CMG Relative Weights (Column 7, Table 9)

In column 7 of Table 9, we present the effects of the changes to the comorbidity tiers and the CMG relative weights. Since we are implementing these changes in a budget neutral manner, we estimate that they will have no overall effect on payments to IRFs. Similarly, we estimate no overall effect of these changes on payments to urban IRFs. However, we estimate a 0.1 percent increase in payments to rural IRFs. We estimate the largest increase in payments to be a 0.3 percent increase among rural IRFs located in the Middle Atlantic region. We estimate the

largest decrease to be a 0.4 percent decrease among teaching IRFs with intern and resident to average daily census ratios in the 10 percent to 19 percent category.

7. Impact of the 2.6 Percent Decrease to the Standard Payment Amount to Account for Coding Changes (Column 8, Table 9)

In column 8 of Table 9, we present the effects of the decrease in the standard payment amount to account for the increase in estimated aggregate payments as a result of changes in coding that do not reflect real changes in case mix.

In the aggregate, and across all hospital groups, we estimate that the policy will result in a 2.6 percent decrease in overall payments to IRFs. Thus, we estimate that the 2.6 percent reduction in the standard payment amount will result in a cost savings to the Medicare program of approximately \$180 million.

C. IRF PPS Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 10 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the increase in Medicare

payments under the IRF PPS as a result of the changes presented in this final rule based on the data for 1,202 IRFs in our database. All estimated expenditures are classified as transfers to Medicare providers (that is, IRFs).

Table 10: Accounting Statement: Classification of Estimated Expenditures, from the 2006 IRF PPS Rate Year to the 2007 IRF PPS Rate Year (in Millions)

Category	Transfers
Annualized Monetized Transfers	\$50 million
From Whom To Whom?	Federal Government to IRF Medicare Providers

D. IRF PPS Alternatives Considered

Because we have determined that this final rule will have a significant economic impact on IRFs, we will discuss the alternative changes to the IRF PPS that we considered.

We considered a reduction to the standard payment amount by an amount of up to 3.9 percent (5.8 percent minus the 1.9 percent adjustment to the standard payment amount for FY 2006), because one of RAND’s methodologies for determining the amount of real change in case mix and the amount of coding change that occurred between 1999 and 2002 suggested that coding change could have been responsible for up to 5.8 percent of the observed increase in IRFs’ case mix. This suggests that we could have implemented a reduction greater than 2.6 percent and as high as 3.9

percent. We also considered the possibility of making a somewhat lower adjustment of 2.3 percent, which would fall at approximately the middle of RAND's range of estimates. However, for the reasons discussed in section V.A of this final rule, we have instead decided to implement a 2.6 percent reduction to the standard payment amount. Further, in light of recent changes to the IRF PPS that affect IRF utilization trends, including the revised phase-in schedule of the IRF 75 percent rule compliance percentage, we believe it is appropriate to take an incremental approach in adjusting for coding changes. In this way, we maintain the flexibility to assess the impact of these changes and propose additional changes, if appropriate, in the future.

We considered not updating the comorbidity tiers and the CMG relative weights for FY 2007. However, as described in section IV of this final rule, re-analysis of the data indicates that some minor technical revisions are appropriate to align the distribution of payments as closely as possible with the costs of IRF care.

We also considered not updating the outlier threshold amount for FY 2007. However, analysis of updated FY 2004 data indicates that estimated outlier payments would not equal 3 percent of estimated total payment for FY 2007 unless we update the outlier threshold amount.

E. IRF PPS Conclusion (column 9, Table 9)

Overall, estimated payments per discharge for IRFs in FY 2007 are projected to increase by 0.8 percent, compared with those in FY 2006, as reflected in column 9 of Table 9. We estimate that IRFs in rural areas will experience a 0.9 percent increase in estimated payments per discharge compared with FY 2006. We estimate that IRFs in urban areas will experience a 0.8 percent increase in estimated payments per discharge compared with FY 2006. We estimate that rehabilitation units in urban areas will experience a 0.7 percent increase in estimated payments per discharge, while freestanding rehabilitation hospitals in urban areas will experience a 0.9 percent increase in estimated payments per discharge. We estimate that rehabilitation units in rural areas will experience a 0.8 percent increase in estimated payments per discharge, while freestanding rehabilitation hospitals in rural areas will experience a 1.0 percent increase in estimated payments per discharge.

Overall, we estimate that the largest payment increase will be 3.7 percent among rural IRFs in the Pacific region. We estimate that the only overall decrease in estimated payments will be a 1.0 percent decrease for rural IRFs in the Mountain region.

In accordance with the provisions of Executive Order

12866, this regulation was reviewed by the Office of Management and Budget.

XV. Regulatory Impact Analysis for DMEPOS Suppliers

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that accreditation expenses for DMEPOS suppliers may exceed this threshold.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the

RFA, section 604, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 90 percent of DMEPOS suppliers are considered small businesses according to the Small Business Administration's size standards, with total revenues of \$6 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. This final rule will have a significant impact on small businesses.

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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this rule will not have a significant effect on small rural hospitals. We expect that small rural hospitals primarily furnish inpatient and outpatient hospital services, rather than services that would require compliance with the DMEPOS quality standards and accreditation.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs

and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. We estimate the total undiscounted annualized accreditation costs for DMEPOS suppliers between CY 2007 and CY 2011 to be approximately \$93.1 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. We have determined that this final rule will not have substantial direct effects on the rights, roles, and responsibilities of States.

B. Anticipated Effects for DMEPOS Suppliers

Under the proposed rule, DMEPOS suppliers will have to be accredited by an approved accreditation organization in order to obtain a supplier number and to receive Medicare reimbursement for DMEPOS items and services furnished to beneficiaries. This section of the rule will have an impact on DMEPOS suppliers and organizations that accredit DMEPOS suppliers. DMEPOS suppliers will incur costs for becoming accredited. Accreditation organizations will

incur costs to accredit suppliers; we assume that these costs are approximately equal to the accreditation fees paid by suppliers.

To estimate the impact on suppliers, we calculate the total cost of accreditation as the sum of accreditation fees and other accreditation costs, and we multiply this cost by the number of suppliers requiring accreditation. Our calculation incorporates other relevant factors, including the number of suppliers that are already accredited, the number of suppliers that probably will not seek accreditation because they currently are not receiving Medicare reimbursement, and the possible phase-in timing for accreditation. These factors are described in more detail below. Costs are calculated over a period of 5 years, beginning in 2007.

Factors Affecting the Cost Impact

The National Supplier Clearinghouse (NSC) issues 10-digit NSC supplier numbers to suppliers that bill Medicare for DMEPOS items and services. Some DMEPOS suppliers operate multiple locations while others operate at a single location. Suppliers that are part of a single firm share the first 6 digits of the 10-digit NSC supplier number, with the last 4 digits set equal to 0001, 0002, and so on

to denote individual locations. In the following discussion, we will refer to the first 6 digits as the "6-digit NSC supplier number" to represent individual suppliers, while the 10-digit number represents individual supplier locations.

The distinction is important for the impact analysis because accreditation organizations generally charge one fee for a supplier's first location, and a lower fee for subsequent locations. Some of the accreditation organizations also offer lower accreditation fees to small suppliers, which typically have few locations.

There are currently 118,406 unique 10-digit NSC numbers and 65,549 unique 6-digit NSC numbers. This total includes suppliers as well as providers and physicians that furnish items under Medicare Part B as suppliers. The distribution of locations by supplier is very uneven across the industry. Over 90 percent of suppliers operate a single location, while some drug chains, grocery stores, optometry companies, and a few medical equipment companies have over a hundred locations.

Suppliers with NSC numbers are diverse. Physicians and other professionals who bill Medicare Part B carriers account for 14 percent of 10-digit NSC numbers; durable medical equipment companies account for 17 percent; drug

stores, grocery stores, and optician/optometry companies account for 53 percent; and orthotic/prosthetic makers account for 11 percent.

Number of Suppliers Currently Accredited

Currently, there is no single registry that tracks the number of DMEPOS suppliers and locations that are accredited. Media reports and data from DMEPOS accreditation organizations suggest that about 2,500 suppliers and 7,500 locations are currently accredited.

Suppliers that Probably Will Not Seek Accreditation

Many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and/or do not specialize in DMEPOS. In 2004, about 7,154 suppliers received \$0 in allowed charges, and 29,155 received between \$1 and \$10,000; the corresponding numbers in 2005 were 6,679 and 30,121 suppliers. These suppliers will have to make a business decision on whether to seek accreditation. In our base impact analysis, we assume that the approximately 6,900 suppliers that currently receive \$0 in allowed charges will not seek accreditation. This accounts for about 11.7 percent of single-location suppliers that are not currently accredited.

Accreditation Fees

Fees vary between accreditation organizations and, in general, currently cover all or some of the following items: application fee, manuals, initial accreditation fee (which can cover 1 to 3 years), annual renewal fees (when the accreditation fee only covers the first year), onsite surveys (generally once every 3 years), and travel for survey personnel. At least one accreditation organization includes consultations within its base fee. Accreditation costs also vary by the size of the supplier seeking accreditation, its number of locations, and the number of services that it provides. Because of these factors, it is sometimes difficult to compare fees across accreditation organizations. We obtained information on total accreditation fees from four accreditation organizations that currently accredit DME suppliers and a fifth organization that recently formed to perform accreditations. In addition, we obtained information on total accreditation fees for two organizations that accredit orthotic and prosthetic suppliers; these costs were generally lower than accreditation fees for other DME suppliers. Although the information obtained from the accrediting organizations is helpful in determining the overall impact, we believe that the fees under the DMEPOS

accreditation process will be close to or below the lower fee estimates because we will be requiring a more streamlined accreditation process. Because the details of the accreditation process are not currently known to potential DMEPOS accrediting organizations, it is difficult to make definitive projections for fees under the DMEPOS accreditation program with certainty.

In addition to information that we received from accrediting organizations on fees under the current process, we received public comments on accreditation fees. We also have data, which were presented to the PAOC, which estimate lower fees. Based on all information that we obtained, we estimate accreditation fees will be approximately \$3,000 for a DME supplier. Because accreditation is for a 3-year period, the estimated average cost per year would be approximately \$1,000. We expect that accreditation fees for an orthotics and prosthetics supplier would be approximately \$2,000; the average cost per year would then be approximately \$670.

We recognize that becoming accredited imposes a burden on DMEPOS suppliers, especially small suppliers. We have attempted to minimize that burden. In compliance with section 604 of the RFA, we have responded to public comments in section X.D of this final rule, and we have

implemented the following options to minimize the burden of accreditation on suppliers, including small businesses:

- Multiple accreditation organizations: We expect that many accrediting organizations will apply to become and be selected as DMEPOS accrediting organizations. We believe that selection of more than one accreditation organization and specialty organizations will introduce competition resulting in reductions in accreditation costs.

- Required plan for small businesses. During the application process, we will ask accreditation organizations to include a plan that details their methodology to reduce accreditation fees and burden for small or specialty DMEPOS suppliers and DMEPOS suppliers that have multiple locations.

- Strict application of quality standards: Currently, accreditation organizations use a survey process in which they expand on published conditions of participation or other standards, which often requires a lengthy onsite evaluation. This results in greater travel expenditures incurred by the accreditation organization and results in higher accreditation survey fees. We believe that the DMEPOS quality standards (developed in collaboration with accreditation, DME, and small business industry experts) will be sufficiently streamlined in order to ensure an

effective and efficient survey process. We strongly believe that accreditation organizations will not need to expand on these standards in order to deter fraudulent practices and ensure quality DMEPOS services.

- Streamlined process: Currently, accreditation organizations require activities such as consultation services and purchasing manuals. We have clarified in this final rule that the role of the accreditation organization is to ensure compliance with the quality standards and that accreditation should not be contingent on using consultation services or purchasing manuals. Therefore, we believe that the cost of performing DMEPOS surveys that do not include these additional accreditation organization activities will be significantly less. Some accrediting organizations may require a 6-month survey preparation process that includes self-assessment. Under accreditation for DMEPOS suppliers, all surveys will be unscheduled; therefore, there may not be a 6-month survey preparation time and additional costs associated with preparation time.

- Reasonable quality standards: We plan to issue quality standards that represent basic good business practices. Many DMEPOS suppliers should already be complying with the standards and have incorporated these practices into their daily operations. Therefore, there

would be no "ramp up costs" and DMEPOS suppliers would not need to devote significant time to be compliant with many of these standards. Additionally, it is our belief that compliance with the quality standards will result in more efficient and effective business practices and will assist DMEPOS suppliers in reducing overall costs.

- All Part B suppliers will need to meet these accreditation requirements. We hope to minimize burden and duplication of effort for suppliers that have already been accredited, Medicare-certified, and/or licensed under state law, by taking into consideration any previous accreditation, certification, and/or licensure findings that indicate that DMEPOS quality standards are being met at the time the accreditation organization surveys the supplier.

Other Accreditation Costs

It is difficult to estimate precisely the costs of preparing for accreditation. However, we note that we will be instituting a streamlined process under which the accrediting organization will be using unannounced surveys. Nevertheless, we recognize that there is a cost to the supplier to come into compliance initially, and thus prepare for the accreditation survey, this process should result in minimal preparation and cost.

Table 11. Total Accreditation Costs (\$ Millions)								
	2007	2008	2009	2010	2011	5-year Total Costs (Undiscounted)	5-year Total Costs (Discounted @ 3%)	5-year Total Costs (Discounted @7%)
Total Accreditation Fees	\$37.99	\$58.58	\$79.17	\$67.37	\$67.37	\$310.48	\$290.99	\$268.28
Total Other Accreditation Costs	\$18.99	\$29.29	\$39.59	\$33.68	\$33.68	\$155.24	\$145.50	\$134.14
TOTAL COSTS	\$56.98	\$87.87	\$118.76	\$101.05	\$101.05	\$465.72	\$436.50	\$402.41

Uncertainty

There are at least three important sources of uncertainty in estimating the impact of accreditation on DMEPOS suppliers. First, our estimates assume that all current DMEPOS suppliers with positive Medicare payments will seek accreditation. As noted previously, many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and/or do not specialize in DMEPOS. We assume that suppliers that currently receive no Medicare allowed charges will choose not to seek accreditation, and that many of the suppliers with allowed charges between \$1 and \$10,000 may decide not to incur the costs of accreditation. It is also possible that these suppliers may choose to expand their businesses in anticipation of the DMEPOS Competitive Bidding Program being implemented.

Second, it is unclear how high or low accreditation fees will be in the future. With required accreditation causing more suppliers to seek accreditation, fees may fall if the accreditation organizations can enjoy economies of scale as they expand. This would lessen the impact on DMEPOS suppliers.

Third, the timing of accreditation could differ from our assumption that one-third of suppliers will be accredited during each of the next 3 years. We cannot precisely predict the timing of accreditation surveys and how this might affect costs.

C. Alternatives Considered for DMEPOS Suppliers

Section 302 (a) (1) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added section 1834(a) (20) of the Social Security Act (the Act) and requires the Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations.

In compliance with section 604 of the RFA, we have implemented options to minimize the burden of accreditation on suppliers, which include approving multiple accreditation organizations that serve smaller suppliers, and accreditation organizations that will be responsible

for only surveying the streamlined quality standards for compliance and not providing any consultative services that may increase the time and cost of the survey process.

Also, we believe that unannounced surveys will reduce the time and cost involved in suppliers' receiving and reviewing documents prior to the survey.

D. Accounting Statement for DMEPOS Suppliers

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the table below we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the costs under section 1834(a)(20) of the Act. All expenditures are classified as costs to the suppliers from the DMEPOS accreditation organizations.

Accounting Statement: Classification of Estimated Expenditures, from CY 2007 to CY 2011 (in millions/year)			
Category	Costs	Discount Rate	From Whom To Whom
Costs-Annualized Monetized	\$80.48	7%	DMEPOS to Accreditation Organizations
Costs-Annualized Monetized	\$87.30	3%	DMEPOS to Accreditation Organizations

E. Conclusion for DMEPOS Suppliers

We estimate that DMEPOS suppliers will incur total accreditation costs from this regulation of \$465.7 million over 5 years. Discounted at 7 percent and at 3 percent, the 5-year accreditation costs to DMEPOS suppliers are approximately \$402.4 million and \$436.5 million, respectively. In CY 2007, we estimate the total accreditation costs to be approximately \$56.98 million. In CY 2008 and CY 2009, we estimate the total accreditation costs to be approximately \$87.87 million and \$118.76 million, respectively. In CY 2010 and CY 2011, we estimate the total accreditation costs to be approximately \$101.1 million annually. The DME supplier accreditation requirement has no anticipated fiscal impact on the benefit payments from the Medicare trust funds.

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 412**

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, 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 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).

Subpart P--Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units

2. Section 412.23 is amended by--

- A. Revising paragraph (b) (2) (i) introductory text.
- B. Revising paragraph (b) (2) (ii).

The revisions read as follows:

§412.23 Excluded hospitals: Classifications.

* * * * *

(b) * * *

(2) * * *

(i) For cost reporting periods beginning on or after July 1, 2004 and before July 1, 2005, the hospital has served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005 and before July 1, 2007, the hospital has served an inpatient population of whom at least 60 percent,

and for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2008, the hospital has served an inpatient population of whom at least 65 percent required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section. A patient with a comorbidity, as defined at §412.602, may be included in the inpatient population that counts toward the required applicable percentage if—

* * * * *

(ii) For cost reporting periods beginning on or after July 1, 2008, the hospital has served an inpatient population of whom at least 75 percent required intensive rehabilitative services for treatment of one or more of the conditions specified in paragraph (b)(2)(iii) of this section. A patient with a comorbidity as described in paragraph (b)(2)(i) of this section is not included in the inpatient population that counts toward the required 75 percent.

* * * * *

3. In §412.624, paragraphs (e)(5) and (f)(2)(v) are revised to read as follows:

§412.624 Methodology for calculating the Federal prospective payment rates.

* * * * *

(e) * * *

(5) Adjustment for high-cost outliers. CMS provides for an additional payment to an inpatient rehabilitation facility if its estimated costs for a patient exceed a fixed dollar amount (adjusted for area wage levels and factors to account for treating low-income patients, for rural location, and for teaching programs) as specified by CMS. The additional payment equals 80 percent of the difference between the estimated cost of the patient and the sum of the adjusted Federal prospective payment computed under this section and the adjusted fixed dollar amount. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will be subject to the adjustments at §412.84(i), except that CMS calculates a single overall (combined operating and capital) cost-to-charge ratio and national averages that will be used instead of statewide averages. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will also be subject to adjustments at §412.84(m), except that CMS calculates a single overall (combined operating and capital) cost-to-charge ratio.

* * * * *

(f) * * *

(2) * * *

(v) By applying the adjustments described in paragraphs (e) (1), (e) (2), (e) (3), (e) (4), and (e) (7) of this section to the unadjusted payment amount determined in paragraph (f) (2) (iv) of this section to equal the adjusted transfer payment amount.

* * * * *

PART 414-- PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

4. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b) (1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b) (1)).

Subpart A-General Provisions

5. Section 414.1 is amended by adding in numerical order the statutory sections to read as follows:

§414.1 Basis and scope.

* * * * *

1847(a) and (b) - Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). * * * * *

6. A new subpart F is added to read as follows:

Subpart F- Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Secs.**414.400 - 414.404 [Reserved]****414.406 Implementation of programs.****414.408 - 414.426 [Reserved]****Subpart F-Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)****§414.400 - §414.404 [Reserved]****§414.406 Implementation of programs.**

(a) Implementation contractor. CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) - (d) [Reserved]

(e) Claims processing. The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

§414.408 - §414.426 [Reserved]**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

7. The authority citation for part 424 continues to read as follows:

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

Subpart A-General Provisions

8. Section 424.1 is amended by adding in numerical order the statutory sections to read as follows:

§424.1 Basis and scope.

* * * * *

1834(a) - Payment for durable medical equipment.

1834(j) - Requirements for suppliers of medical equipment and supplies.

* * * * *

Subpart D—To Whom Payment is Ordinarily Made

9. Section 424.57 is amended by--

A. Adding the definitions "Accredited DMEPOS suppliers," "CMS approved accreditation organization" and "Independent accreditation organization" in alphabetical order in paragraph (a).

B. Adding new paragraphs (c)(22)- (c)(25).

The additions and revision read as follows:

§424.57 Special payment rules for items furnished by DMEPOS Suppliers and issuance of DMEPOS Supplier billing privileges.

(a) Definitions. * * *

Accredited DMEPOS suppliers means suppliers that have been accredited by a recognized independent accreditation organization approved by CMS in accordance with the requirements at §424.58.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under §424.58.

* * * * *

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

* * * * *

(c) Application certification standards. * *

*

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

* * * * *

10. A new §424.58 is added to read as follows:

§424.58 Accreditation.

(a) Scope and purpose. This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the DMEPOS quality standards for suppliers of DMEPOS and other items or services. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the DMEPOS quality standards under

section 1834(a)(20) of the Act before being awarded a contract.

(b) Application and reapplication procedures for accreditation organizations. (1) An independent accreditation organization applying for approval or re-approval of authority to survey suppliers for compliance with the DMEPOS quality standards is required to furnish the following to CMS:

(i) A list of the types of DMEPOS supplies, and a list of products and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements, and dispute resolution processes and policies when there is a negative survey finding or decision.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation

requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data

management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiii) A written presentation that demonstrates the

organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that the accreditation organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(2) Validation survey. CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted--

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) Discovery of a deficiency. If CMS discovers that a DMEPOS supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's

billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) Authorization. A supplier selected for a validation survey must authorize the--

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) Refusal to cooperate with survey. If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b) (4) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its supplier billing number revoked.

(6) Validation survey findings. If a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.

(c) Ongoing responsibilities of a CMS-approved accreditation organization. An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written

format (either electronic or hard copy) and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any supplier of DMEPOS and other items and services against which the CMS-approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised cross walk reflecting the new

requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS's notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all of the CMS-approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) Continuing Federal oversight of approved accreditation organizations. This paragraph establishes specific criteria and procedures for continuing oversight

and for withdrawing approval of a CMS-approved accreditation organization.

(1) Equivalency review. CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when--

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) Validation survey. CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS-approved accreditation organization's survey of a supplier, or observe a CMS-approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS-approved accreditation organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate--

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not

constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, irrespective of the rate of disparity, there are widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements.

(3) Notice of intent to withdraw approval. CMS provides the organization written notice of its intent to withdraw approval if an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(4) Withdrawal of approval. CMS may withdraw its approval of an accreditation organization at any time if CMS determines that--

(i) Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other

items and services are meeting the DMEPOS quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(e) Reconsideration. (1) An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization meet the applicable supplier quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(2) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(3) The request for reconsideration must specify the

findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(4) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(5) In response to a request for reconsideration, CMS provides the accreditation organization the opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

(6) CMS provides written notice of the time and place of the informal hearing at least 10 calendar days before the scheduled date.

(7) The informal reconsideration hearing is open to CMS and the organization requesting the reconsideration, including authorized representatives; technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and legal counsel.

(i) The hearing is conducted by the hearing officer who receives testimony and documents related to the

proposed action.

(ii) Testimony and other evidence may be accepted by the hearing officer even though it is inadmissible under the rules of court procedures.

(iii) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(9) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision is final.

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare - Hospital Insurance; and Program No. 93.774,
Medicare - Supplemental Medical Insurance Program).

Dated: _____

Mark B. McClellan,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: _____

Michael O. Leavitt,
Secretary.

BILLING CODE 4120-01-P

The following addendum will not appear in the Code of Federal Regulations.

Addendum

This addendum contains the tables referred to throughout the preamble to this final rule. The tables presented below are as follows:

Table 1 Core-Based Statistical Area Urban Wage Index effective for discharges occurring on or after October 1, 2006 and on or before September 30, 2007

Table 2 Core-Based Statistical Area Rural Wage Index effective for discharges occurring on or after October 1, 2006 and on or before September 30, 2007

The following addendum will not appear in the Code of Federal Regulations.

ADDENDUM

This addendum contains the tables referred to throughout the preamble of this final rule. The tables presented below are as follows:

Table 1.-- Inpatient Rehabilitation Facility Wage Index for Urban Areas for Discharges Occurring from October 1, 2006 through September 30, 2007

Table 2.-- Inpatient Rehabilitation Facility Wage Index for Rural Areas for Discharges Occurring from October 1, 2006 through September 30, 2007

**Table 1.— INPATIENT REHABILITATION FACILITY WAGE INDEX
FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM
OCTOBER 1, 2006 THROUGH SEPTEMBER 30, 2007¹**

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10180	Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX	0.7896
10380	Aguadilla-Isabela-San Sebastián, PR Aguada Municipio, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR	0.4738
10420	Akron, OH Portage County, OH Summit County, OH	0.8982
10500	Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA	0.8628
10580	Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY	0.8589
10740	Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM	0.9684
10780	Alexandria, LA Grant Parish, LA Rapides Parish, LA	0.8033

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10900	Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA	0.9818
11020	Altoona, PA Blair County, PA	0.8944
11100	Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX	0.9156
11180	Ames, IA Story County, IA	0.9536
11260	Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK	1.1895
11300	Anderson, IN Madison County, IN	0.8586
11340	Anderson, SC Anderson County, SC	0.8997
11460	Ann Arbor, MI Washtenaw County, MI	1.0859
11500	Anniston-Oxford, AL Calhoun County, AL	0.7682
11540	Appleton, WI Calumet County, WI Outagamie County, WI	0.9288
11700	Asheville, NC Buncombe County, NC Haywood County, NC Henderson County, NC Madison County, NC	0.9285
12020	Athens-Clarke County, GA Clarke County, GA Madison County, GA Oconee County, GA Oglethorpe County, GA	0.9855

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12060	Atlanta-Sandy Springs-Marietta, GA Barrow County, GA Bartow County, GA Butts County, GA Carroll County, GA Cherokee County, GA Clayton County, GA Cobb County, GA Coweta County, GA Dawson County, GA DeKalb County, GA Douglas County, GA Fayette County, GA Forsyth County, GA Fulton County, GA Gwinnett County, GA Haralson County, GA Heard County, GA Henry County, GA Jasper County, GA Lamar County, GA Meriwether County, GA Newton County, GA Paulding County, GA Pickens County, GA Pike County, GA Rockdale County, GA Spalding County, GA Walton County, GA	0.9793
12100	Atlantic City, NJ Atlantic County, NJ	1.1615
12220	Auburn-Opelika, AL Lee County, AL	0.8100
12260	Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC	0.9748

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12420	Austin-Round Rock, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX	0.9437
12540	Bakersfield, CA Kern County, CA	1.0470
12580	Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD	0.9897
12620	Bangor, ME Penobscot County, ME	0.9993
12700	Barnstable Town, MA Barnstable County, MA	1.2600
12940	Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA	0.8593
12980	Battle Creek, MI Calhoun County, MI	0.9508
13020	Bay City, MI Bay County, MI	0.9343
13140	Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX	0.8412
13380	Bellingham, WA Whatcom County, WA	1.1731
13460	Bend, OR Deschutes County, OR	1.0786
13644	Bethesda-Gaithersburg-Frederick, MD Frederick County, MD Montgomery County, MD	1.1483

CBSA Code	Urban Area (Constituent Counties)	Wage Index
13740	Billings, MT Carbon County, MT Yellowstone County, MT	0.8834
13780	Binghamton, NY Broome County, NY Tioga County, NY	0.8562
13820	Birmingham-Hoover, AL Bibb County, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL	0.8959
13900	Bismarck, ND Burleigh County, ND Morton County, ND	0.7574
13980	Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA	0.7954
14020	Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN	0.8447
14060	Bloomington-Normal, IL McLean County, IL	0.9075
14260	Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID	0.9052
14484	Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA	1.1558
14500	Boulder, CO Boulder County, CO	0.9734
14540	Bowling Green, KY Edmonson County, KY Warren County, KY	0.8211
14740	Bremerton-Silverdale, WA Kitsap County, WA	1.0675

CBSA Code	Urban Area (Constituent Counties)	Wage Index
14860	Bridgeport-Stamford-Norwalk, CT Fairfield County, CT	1.2592
15180	Brownsville-Harlingen, TX Cameron County, TX	0.9804
15260	Brunswick, GA Brantley County, GA Glynn County, GA McIntosh County, GA	0.9311
15380	Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY	0.9511
15500	Burlington, NC Alamance County, NC	0.8905
15540	Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT	0.9410
15764	Cambridge-Newton-Framingham, MA Middlesex County, MA	1.1172
15804	Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ	1.0517
15940	Canton-Massillon, OH Carroll County, OH Stark County, OH	0.8935
15980	Cape Coral-Fort Myers, FL Lee County, FL	0.9356
16180	Carson City, NV Carson City, NV	1.0234
16220	Casper, WY Natrona County, WY	0.9026
16300	Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA	0.8825
16580	Champaign-Urbana, IL Champaign County, IL Ford County, IL Piatt County, IL	0.9594

CBSA Code	Urban Area (Constituent Counties)	Wage Index
16620	Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV	0.8445
16700	Charleston-North Charleston, SC Berkeley County, SC Charleston County, SC Dorchester County, SC	0.9245
16740	Charlotte-Gastonia-Concord, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC	0.9750
16820	Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA	1.0187
16860	Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN	0.9088
16940	Cheyenne, WY Laramie County, WY	0.8775
16974	Chicago-Naperville-Joliet, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL	1.0790
17020	Chico, CA Butte County, CA	1.0511

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17140	Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH	0.9615
17300	Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN	0.8284
17420	Cleveland, TN Bradley County, TN Polk County, TN	0.8139
17460	Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH	0.9213
17660	Coeur d'Alene, ID Kootenai County, ID	0.9647
17780	College Station-Bryan, TX Brazos County, TX Burleson County, TX Robertson County, TX	0.8900
17820	Colorado Springs, CO El Paso County, CO Teller County, CO	0.9468
17860	Columbia, MO Boone County, MO Howard County, MO	0.8345

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17900	Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC	0.9057
17980	Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscogee County, GA	0.8560
18020	Columbus, IN Bartholomew County, IN	0.9588
18140	Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH	0.9860
18580	Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX	0.8550
18700	Corvallis, OR Benton County, OR	1.0729
19060	Cumberland, MD-WV Allegany County, MD Mineral County, WV	0.9317
19124	Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX	1.0228
19140	Dalton, GA Murray County, GA Whitfield County, GA	0.9079

CBSA Code	Urban Area (Constituent Counties)	Wage Index
19180	Danville, IL Vermilion County, IL	0.9028
19260	Danville, VA Pittsylvania County, VA Danville City, VA	0.8489
19340	Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA	0.8724
19380	Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH	0.9064
19460	Decatur, AL Lawrence County, AL Morgan County, AL	0.8469
19500	Decatur, IL Macon County, IL	0.8067
19660	Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL	0.9299
19740	Denver-Aurora, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO	1.0723
19780	Des Moines, IA Dallas County, IA Guthrie County, IA Madison County, IA Polk County, IA Warren County, IA	0.9669
19804	Detroit-Livonia-Dearborn, MI Wayne County, MI	1.0424
20020	Dothan, AL Geneva County, AL Henry County, AL Houston County, AL	0.7721

CBSA Code	Urban Area (Constituent Counties)	Wage Index
20100	Dover, DE Kent County, DE	0.9776
20220	Dubuque, IA Dubuque County, IA	0.9024
20260	Duluth, MN-WI Carlton County, MN St. Louis County, MN Douglas County, WI	1.0213
20500	Durham, NC Chatham County, NC Durham County, NC Orange County, NC Person County, NC	1.0244
20740	Eau Claire, WI Chippewa County, WI Eau Claire County, WI	0.9201
20764	Edison, NJ Middlesex County, NJ Monmouth County, NJ Ocean County, NJ Somerset County, NJ	1.1249
20940	El Centro, CA Imperial County, CA	0.8906
21060	Elizabethtown, KY Hardin County, KY Larue County, KY	0.8802
21140	Elkhart-Goshen, IN Elkhart County, IN	0.9627
21300	Elmira, NY Chemung County, NY	0.8250
21340	El Paso, TX El Paso County, TX	0.8977
21500	Erie, PA Erie County, PA	0.8737
21604	Essex County, MA Essex County, MA	1.0538
21660	Eugene-Springfield, OR Lane County, OR	1.0818
21780	Evansville, IN-KY Gibson County, IN Posey County, IN Vanderburgh County, IN Warrick County, IN Henderson County, KY Webster County, KY	0.8713

CBSA Code	Urban Area (Constituent Counties)	Wage Index
21820	Fairbanks, AK Fairbanks North Star Borough, AK	1.1408
21940	Fajardo, PR Ceiba Municipio, PR Fajardo Municipio, PR Luquillo Municipio, PR	0.4153
22020	Fargo, ND-MN Cass County, ND Clay County, MN	0.8486
22140	Farmington, NM San Juan County, NM	0.8509
22180	Fayetteville, NC Cumberland County, NC Hoke County, NC	0.9416
22220	Fayetteville-Springdale-Rogers, AR-MO Benton County, AR Madison County, AR Washington County, AR McDonald County, MO	0.8661
22380	Flagstaff, AZ Coconino County, AZ	1.2092
22420	Flint, MI Genesee County, MI	1.0655
22500	Florence, SC Darlington County, SC Florence County, SC	0.8947
22520	Florence-Muscle Shoals, AL Colbert County, AL Lauderdale County, AL	0.8272
22540	Fond du Lac, WI Fond du Lac County, WI	0.9640
22660	Fort Collins-Loveland, CO Larimer County, CO	1.0122
22744	Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL	1.0432
22900	Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Sequoyah County, OK	0.8230
23020	Fort Walton Beach-Crestview-Destin, FL Okaloosa County, FL	0.8872

CBSA Code	Urban Area (Constituent Counties)	Wage Index
23060	Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN	0.9793
23104	Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX	0.9486
23420	Fresno, CA Fresno County, CA	1.0538
23460	Gadsden, AL Etowah County, AL	0.7938
23540	Gainesville, FL Alachua County, FL Gilchrist County, FL	0.9388
23580	Gainesville, GA Hall County, GA	0.8874
23844	Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN	0.9395
24020	Glens Falls, NY Warren County, NY Washington County, NY	0.8559
24140	Goldsboro, NC Wayne County, NC	0.8775
24220	Grand Forks, ND-MN Polk County, MN Grand Forks County, ND	0.7901
24300	Grand Junction, CO Mesa County, CO	0.9550
24340	Grand Rapids-Wyoming, MI Barry County, MI Ionia County, MI Kent County, MI Newaygo County, MI	0.9390
24500	Great Falls, MT Cascade County, MT	0.9052
24540	Greeley, CO Weld County, CO	0.9570

CBSA Code	Urban Area (Constituent Counties)	Wage Index
24580	Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI	0.9483
24660	Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC	0.9104
24780	Greenville, NC Greene County, NC Pitt County, NC	0.9425
24860	Greenville, SC Greenville County, SC Laurens County, SC Pickens County, SC	1.0027
25020	Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR	0.3181
25060	Gulfport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS	0.8929
25180	Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV	0.9489
25260	Hanford-Corcoran, CA Kings County, CA	1.0036
25420	Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA	0.9313
25500	Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA	0.9088
25540	Hartford-West Hartford-East Hartford, CT Hartford County, CT Litchfield County, CT Middlesex County, CT Tolland County, CT	1.1073
25620	Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS	0.7601

CBSA Code	Urban Area (Constituent Counties)	Wage Index
25860	Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC	0.8921
25980	Hinesville-Fort Stewart, GA Liberty County, GA Long County, GA	0.9198 ¹
26100	Holland-Grand Haven, MI Ottawa County, MI	0.9055
26180	Honolulu, HI Honolulu County, HI	1.1214
26300	Hot Springs, AR Garland County, AR	0.9005
26380	Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA	0.7894
26420	Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX	0.9996
26580	Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV	0.9477
26620	Huntsville, AL Limestone County, AL Madison County, AL	0.9146
26820	Idaho Falls, ID Bonneville County, ID Jefferson County, ID	0.9420

CBSA Code	Urban Area (Constituent Counties)	Wage Index
26900	Indianapolis, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN	0.9920
26980	Iowa City, IA Johnson County, IA Washington County, IA	0.9747
27060	Ithaca, NY Tompkins County, NY	0.9793
27100	Jackson, MI Jackson County, MI	0.9304
27140	Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS	0.8311
27180	Jackson, TN Chester County, TN Madison County, TN	0.8964
27260	Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL	0.9290
27340	Jacksonville, NC Onslow County, NC	0.8236
27500	Janesville, WI Rock County, WI	0.9538
27620	Jefferson City, MO Callaway County, MO Cole County, MO Moniteau County, MO Osage County, MO	0.8387

CBSA Code	Urban Area (Constituent Counties)	Wage Index
27740	Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN	0.7937
27780	Johnstown, PA Cambria County, PA	0.8354
27860	Jonesboro, AR Craighead County, AR Poinsett County, AR	0.7911
27900	Joplin, MO Jasper County, MO Newton County, MO	0.8582
28020	Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI	1.0381
28100	Kankakee-Bradley, IL Kankakee County, IL	1.0721
28140	Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO	0.9476
28420	Kennewick-Richland-Pasco, WA Benton County, WA Franklin County, WA	1.0619
28660	Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX	0.8526

CBSA Code	Urban Area (Constituent Counties)	Wage Index
28700	Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA	0.8054
28740	Kingston, NY Ulster County, NY	0.9255
28940	Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN	0.8441
29020	Kokomo, IN Howard County, IN Tipton County, IN	0.9508
29100	La Crosse, WI-MN Houston County, MN La Crosse County, WI	0.9564
29140	Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN	0.8736
29180	Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA	0.8428
29340	Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA	0.7833
29404	Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI	1.0429
29460	Lakeland, FL Polk County, FL	0.8912
29540	Lancaster, PA Lancaster County, PA	0.9694
29620	Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI	0.9794
29700	Laredo, TX Webb County, TX	0.8068
29740	Las Cruces, NM Dona Ana County, NM	0.8467

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29820	Las Vegas-Paradise, NV Clark County, NV	1.1437
29940	Lawrence, KS Douglas County, KS	0.8537
30020	Lawton, OK Comanche County, OK	0.7872
30140	Lebanon, PA Lebanon County, PA	0.8459
30300	Lewiston, ID-WA Nez Perce County, ID Asotin County, WA	0.9886
30340	Lewiston-Auburn, ME Androscoggin County, ME	0.9331
30460	Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY	0.9075
30620	Lima, OH Allen County, OH	0.9225
30700	Lincoln, NE Lancaster County, NE Seward County, NE	1.0214
30780	Little Rock-North Little Rock, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR	0.8747
30860	Logan, UT-ID Franklin County, ID Cache County, UT	0.9164
30980	Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX	0.8730
31020	Longview, WA Cowlitz County, WA	0.9579
31084	Los Angeles-Long Beach-Glendale, CA Los Angeles County, CA	1.1783

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31140	Louisville, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Jefferson County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY	0.9251
31180	Lubbock, TX Crosby County, TX Lubbock County, TX	0.8783
31340	Lynchburg, VA Amherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA	0.8691
31420	Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA	0.9443
31460	Madera, CA Madera County, CA	0.8713
31540	Madison, WI Columbia County, WI Dane County, WI Iowa County, WI	1.0659
31700	Manchester-Nashua, NH Hillsborough County, NH Merrimack County, NH	1.0354
31900	Mansfield, OH Richland County, OH	0.9891
32420	Mayagüez, PR Hormigueros Municipio, PR Mayagüez Municipio, PR	0.4020

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32580	McAllen-Edinburg-Mission, TX Hidalgo County, TX	0.8934
32780	Medford, OR Jackson County, OR	1.0225
32820	Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN	0.9397
32900	Merced, CA Merced County, CA	1.1109
33124	Miami-Miami Beach-Kendall, FL Miami-Dade County, FL	0.9750
33140	Michigan City-La Porte, IN LaPorte County, IN	0.9399
33260	Midland, TX Midland County, TX	0.9514
33340	Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI	1.0146
33460	Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI	1.1075
33540	Missoula, MT Missoula County, MT	0.9473
33660	Mobile, AL Mobile County, AL	0.7891

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33700	Modesto, CA Stanislaus County, CA	1.1885
33740	Monroe, LA Ouachita Parish, LA Union Parish, LA	0.8031
33780	Monroe, MI Monroe County, MI	0.9468
33860	Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL	0.8618
34060	Morgantown, WV Monongalia County, WV Preston County, WV	0.8420
34100	Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN	0.7961
34580	Mount Vernon-Anacortes, WA Skagit County, WA	1.0454
34620	Muncie, IN Delaware County, IN	0.8930
34740	Muskegon-Norton Shores, MI Muskegon County, MI	0.9664
34820	Myrtle Beach-Conway-North Myrtle Beach, SC Horry County, SC	0.8934
34900	Napa, CA Napa County, CA	1.2643
34940	Naples-Marco Island, FL Collier County, FL	1.0139
34980	Nashville-Davidson--Murfreesboro, TN Cannon County, TN Cheatham County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN	0.9790

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35004	Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY	1.2719
35084	Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA	1.1883
35300	New Haven-Milford, CT New Haven County, CT	1.1887
35380	New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA	0.8995
35644	New York-White Plains-Wayne, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY	1.3188
35660	Niles-Benton Harbor, MI Berrien County, MI	0.8879
35980	Norwich-New London, CT New London County, CT	1.1345
36084	Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA	1.5346
36100	Ocala, FL Marion County, FL	0.8925
36140	Ocean City, NJ Cape May County, NJ	1.1011
36220	Odessa, TX Ector County, TX	0.9884

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36260	Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT	0.9029
36420	Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McClain County, OK Oklahoma County, OK	0.9031
36500	Olympia, WA Thurston County, WA	1.0927
36540	Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sarpy County, NE Saunders County, NE Washington County, NE	0.9560
36740	Orlando-Kissimmee, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL	0.9464
36780	Oshkosh-Neenah, WI Winnebago County, WI	0.9183
36980	Owensboro, KY Daviness County, KY Hancock County, KY McLean County, KY	0.8780
37100	Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA	1.1622
37340	Palm Bay-Melbourne-Titusville, FL Brevard County, FL	0.9839
37460	Panama City-Lynn Haven, FL Bay County, FL	0.8005
37620	Parkersburg-Marietta-Vienna, WV-OH Washington County, OH Pleasants County, WV Wirt County, WV Wood County, WV	0.8270

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37700	Pascagoula, MS George County, MS Jackson County, MS	0.8156
37860	Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL	0.8096
37900	Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL	0.8870
37964	Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA Philadelphia County, PA	1.1038
38060	Phoenix-Mesa-Scottsdale, AZ Maricopa County, AZ Pinal County, AZ	1.0127
38220	Pine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR	0.8680
38300	Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA	0.8845
38340	Pittsfield, MA Berkshire County, MA	1.0181
38540	Pocatello, ID Bannock County, ID Power County, ID	0.9351
38660	Ponce, PR Juana Díaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR	0.4939

CBSA Code	Urban Area (Constituent Counties)	Wage Index
38860	Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME	1.0382
38900	Portland-Vancouver-Beaverton, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA	1.1266
38940	Port St. Lucie-Fort Pierce, FL Martin County, FL St. Lucie County, FL	1.0123
39100	Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY	1.0891
39140	Prescott, AZ Yavapai County, AZ	0.9869
39300	Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI	1.0966
39340	Provo-Orem, UT Juab County, UT Utah County, UT	0.9500
39380	Pueblo, CO Pueblo County, CO	0.8623
39460	Punta Gorda, FL Charlotte County, FL	0.9255
39540	Racine, WI Racine County, WI	0.8997
39580	Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC	0.9691
39660	Rapid City, SD Meade County, SD Pennington County, SD	0.8987
39740	Reading, PA Berks County, PA	0.9686

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39820	Redding, CA Shasta County, CA	1.2203
39900	Reno-Sparks, NV Storey County, NV Washoe County, NV	1.0982
40060	Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Chesterfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA	0.9328
40140	Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA	1.1027
40220	Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA	0.8374
40340	Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN	1.1131

CBSA Code	Urban Area (Constituent Counties)	Wage Index
40380	Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY	0.9121
40420	Rockford, IL Boone County, IL Winnebago County, IL	0.9984
40484	Rockingham County--Strafford County, NH Rockingham County, NH Strafford County, NH	1.0374
40580	Rocky Mount, NC Edgecombe County, NC Nash County, NC	0.8915
40660	Rome, GA Floyd County, GA	0.9414
40900	Sacramento--Arden-Arcade--Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA	1.2969
40980	Saginaw--Saginaw Township North, MI Saginaw County, MI	0.9088
41060	St. Cloud, MN Benton County, MN Stearns County, MN	0.9965
41100	St. George, UT Washington County, UT	0.9392
41140	St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO	0.9519

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41180	St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO	0.8954
41420	Salem, OR Marion County, OR Polk County, OR	1.0442
41500	Salinas, CA Monterey County, CA	1.4128
41540	Salisbury, MD Somerset County, MD Wicomico County, MD	0.9064
41620	Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT	0.9421
41660	San Angelo, TX Irion County, TX Tom Green County, TX	0.8271
41700	San Antonio, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX	0.8980
41740	San Diego-Carlsbad-San Marcos, CA San Diego County, CA	1.1413

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41780	Sandusky, OH Erie County, OH	0.9019
41884	San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA	1.4994
41900	San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR	0.4650
41940	San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA	1.5099

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41980	San Juan-Caguas-Guaynabo, PR Aguas Buenas Municipio, PR Aibonito Municipio, PR Arecibo Municipio, PR Barceloneta Municipio, PR Barranquitas Municipio, PR Bayamón Municipio, PR Caguas Municipio, PR Camuy Municipio, PR Canóvanas Municipio, PR Carolina Municipio, PR Cataño Municipio, PR Cayey Municipio, PR Ciales Municipio, PR Cidra Municipio, PR Comerío Municipio, PR Corozal Municipio, PR Dorado Municipio, PR Florida Municipio, PR Guaynabo Municipio, PR Gurabo Municipio, PR Hatillo Municipio, PR Humacao Municipio, PR Juncos Municipio, PR Las Piedras Municipio, PR Loíza Municipio, PR Manatí Municipio, PR Maunabo Municipio, PR Morovis Municipio, PR Naguabo Municipio, PR Naranjito Municipio, PR Orocovis Municipio, PR Quebradillas Municipio, PR Río Grande Municipio, PR San Juan Municipio, PR San Lorenzo Municipio, PR Toa Alta Municipio, PR Toa Baja Municipio, PR Trujillo Alto Municipio, PR Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR	0.4621
42020	San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA	1.1349

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42044	Santa Ana-Anaheim-Irvine, CA Orange County, CA	1.1559
42060	Santa Barbara-Santa Maria, CA Santa Barbara County, CA	1.1694
42100	Santa Cruz-Watsonville, CA Santa Cruz County, CA	1.5166
42140	Santa Fe, NM Santa Fe County, NM	1.0920
42220	Santa Rosa-Petaluma, CA Sonoma County, CA	1.3493
42260	Sarasota-Bradenton-Venice, FL Manatee County, FL Sarasota County, FL	0.9639
42340	Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA	0.9461
42540	Scranton--Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA	0.8540
42644	Seattle-Bellevue-Everett, WA King County, WA Snohomish County, WA	1.1577
43100	Sheboygan, WI Sheboygan County, WI	0.8911
43300	Sherman-Denison, TX Grayson County, TX	0.9507
43340	Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA	0.8760
43580	Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD	0.9381
43620	Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD	0.9635
43780	South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI	0.9788

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43900	Spartanburg, SC Spartanburg County, SC	0.9172
44060	Spokane, WA Spokane County, WA	1.0905
44100	Springfield, IL Menard County, IL Sangamon County, IL	0.8792
44140	Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA	1.0248
44180	Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO	0.8237
44220	Springfield, OH Clark County, OH	0.8396
44300	State College, PA Centre County, PA	0.8356
44700	Stockton, CA San Joaquin County, CA	1.1307
44940	Sumter, SC Sumter County, SC	0.8377
45060	Syracuse, NY Madison County, NY Onondaga County, NY Oswego County, NY	0.9574
45104	Tacoma, WA Pierce County, WA	1.0742
45220	Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL Wakulla County, FL	0.8688
45300	Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL	0.9233

CBSA Code	Urban Area (Constituent Counties)	Wage Index
45460	Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN	0.8304
45500	Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX	0.8283
45780	Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH	0.9574
45820	Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS	0.8920
45940	Trenton-Ewing, NJ Mercer County, NJ	1.0834
46060	Tucson, AZ Pima County, AZ	0.9007
46140	Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK	0.8543
46220	Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL	0.8645
46340	Tyler, TX Smith County, TX	0.9168
46540	Utica-Rome, NY Herkimer County, NY Oneida County, NY	0.8358
46660	Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA	0.8866

CBSA Code	Urban Area (Constituent Counties)	Wage Index
46700	Vallejo-Fairfield, CA Solano County, CA	1.4936
46940	Vero Beach, FL Indian River County, FL	0.9434
47020	Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX	0.8160
47220	Vineland-Millville-Bridgeton, NJ Cumberland County, NJ	0.9827
47260	Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surry County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA	0.8799
47300	Visalia-Porterville, CA Tulare County, CA	1.0123
47380	Waco, TX McLennan County, TX	0.8518
47580	Warner Robins, GA Houston County, GA	0.8645
47644	Warren-Farmington Hills-Troy, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI	0.9871

CBSA Code	Urban Area (Constituent Counties)	Wage Index
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV	1.0926
47940	Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA	0.8557
48140	Wausau, WI Marathon County, WI	0.9590
48260	Weirton-Steubenville, WV-OH Jefferson County, OH Brooke County, WV Hancock County, WV	0.7819
48300	Wenatchee, WA Chelan County, WA Douglas County, WA	1.0070
48424	West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL	1.0067
48540	Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV	0.7161

CBSA Code	Urban Area (Constituent Counties)	Wage Index
48620	Wichita, KS Butler County, KS Harvey County, KS Sedgwick County, KS Sumner County, KS	0.9153
48660	Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX	0.8285
48700	Williamsport, PA Lycoming County, PA	0.8364
48864	Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ	1.0471
48900	Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC	0.9582
49020	Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV	1.0214
49180	Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC	0.8944
49340	Worcester, MA Worcester County, MA	1.1028
49420	Yakima, WA Yakima County, WA	1.0155
49500	Yauco, PR Guánica Municipio, PR Guayanilla Municipio, PR Peñuelas Municipio, PR Yauco Municipio, PR	0.4408
49620	York-Hanover, PA York County, PA	0.9347
49660	Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA	0.8603

CBSA Code	Urban Area (Constituent Counties)	Wage Index
49700	Yuba City, CA Sutter County, CA Yuba County, CA	1.0921
49740	Yuma, AZ Yuma County, AZ	0.9126

¹ At this time, there are no hospitals located in this CBSA-based urban area on which to base a wage index. Therefore, the wage index value is based on the methodology described in the FY 2006 IRF PPS final rule (70 FR 47880). The wage index value for this area is the average wage index for all urban areas within the state.

**Table 2.— INPATIENT REHABILITATION FACILITY WAGE INDEX
FOR RURAL AREAS FOR DISCHARGES OCCURRING
FROM OCTOBER 1, 2006 THROUGH SEPTEMBER 30, 2007**

CBSA Code	Nonurban Area	Wage Index
01	Alabama	0.7446
02	Alaska	1.1977
03	Arizona	0.8768
04	Arkansas	0.7466
05	California	1.1054
06	Colorado	0.9380
07	Connecticut	1.1730
08	Delaware	0.9579
10	Florida	0.8568
11	Georgia	0.7662
12	Hawaii	1.0551
13	Idaho	0.8037
14	Illinois	0.8271
15	Indiana	0.8624
16	Iowa	0.8509
17	Kansas	0.8035
18	Kentucky	0.7766
19	Louisiana	0.7411
20	Maine	0.8843
21	Maryland	0.9353
22	Massachusetts ²	1.0216
23	Michigan	0.8895
24	Minnesota	0.9132
25	Mississippi	0.7674
26	Missouri	0.7900

CBSA Code	Nonurban Area	Wage Index
27	Montana	0.8762
28	Nebraska	0.8657
29	Nevada	0.9065
30	New Hampshire	1.0817
31	New Jersey ¹	-----
32	New Mexico	0.8635
33	New York	0.8154
34	North Carolina	0.8540
35	North Dakota	0.7261
36	Ohio	0.8826
37	Oklahoma	0.7581
38	Oregon	0.9826
39	Pennsylvania	0.8291
40	Puerto Rico ²	0.4047
41	Rhode Island ¹	-----
42	South Carolina	0.8638
43	South Dakota	0.8560
44	Tennessee	0.7895
45	Texas	0.8003
46	Utah	0.8118
47	Vermont	0.9830
48	Virgin Islands	0.7615
49	Virginia	0.8013
50	Washington	1.0510
51	West Virginia	0.7717
52	Wisconsin	0.9509
53	Wyoming	0.9257
65	Guam	0.9611

¹All counties within the State are classified as urban.

²Massachusetts and Puerto Rico have areas designated as rural; however,

no short-term, acute care hospitals are located in the area(s) for FY 2007. As discussed in the FY 2006 IRF PPS final rule (70 FR 47880), we use the previous year's wage index value until more recent data is available for those areas.