**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 413 and 414**

**[CMS–1577–F]**

**RIN 0938–AQ27**

# Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies

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

**ACTION:** Final rule.

**SUMMARY:** This final rule updates and makes certain revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012. We are also finalizing the interim final rule with comment period published on April 6, 2011, regarding the transition budget-neutrality adjustment under the ESRD PPS,. This final rule also sets forth requirements for the ESRD quality incentive program (QIP) for payment years (PYs) 2013 and 2014. In addition, this final rule revises the ambulance fee schedule regulations to conform to statutory changes. This final rule also revises the definition of durable medical equipment (DME) by adding a 3-year minimum lifetime requirement (MLR) that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. Finally, this final rule implements certain provisions of section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) Competitive Acquisition Program and responds to comments received on an interim final rule published January 16, 2009, that implemented these provisions of MIPPA effective April 18, 2009. (See the Table of Contents for a listing of the specific issues addressed in this final rule.)

**DATES:** *Effective dates:* These regulations are effective on January 1, 2012. Also, effective January 1, 2012, we are finalizing the interim final rule with comment (''Medicare Programs: Changes to the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'') published on April 6, 2011 (76 FR 18930). Additionally, effective January 12, 2012 the interim rule amending 42 CFR Part 414, published on January 16, 2009 (74 FR 2873), is confirmed as final.

**FOR FURTHER INFORMATION CONTACT:**

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Hafsa Bora, (410) 786–7899 or Iffat Fatima, (410) 786–6709, for DMEPOS Competitive Acquisition Program issues related to comments received on an interim final rule that implemented provisions of MIPPA effective April 18, 2009.

**SUPPLEMENTARY INFORMATION:**

## Addenda Are Only Available Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: *http://www.cms.gov/ESRDPayment/PAY/list.asp*. Readers who experience any problems accessing any of the Addenda to the proposed and final rules that are posted on the CMS Web site identified above should contact Lisa Hubbard at (410) 786–4533.

## Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

**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 meanings in alphabetical order below:

AMCC Automated Multi-Channel Chemistry
ASP Average Sales Price
AV Arteriovenous
BLS Bureau of Labor Statistics
BMI Body Mass Index
BSA Body Surface Area
CY Calendar Year
CBSA Core-Based Statistical Area
CDC Centers for Disease Control and Prevention
CLABSI Central Line Access Bloodstream Infections
CFR Code of Federal Regulations
CIP Core Indicators Project
CMS Centers for Medicare & Medicaid Services
CPM Clinical Performance Measure
CPT Current Procedural Terminology
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
DFC Dialysis Facility Compare
DFR Dialysis Facility Report
DME Durable Medical Equipment
ESA Erythropoiesis stimulating agent
ESRD End-Stage Renal Disease
ESRDB End-Stage Renal Disease Bundled
FDA Food and Drug Administration
FI/MAC Fiscal Intermediary/Medicare Administrative Contractor
FY Fiscal Year
GDP Gross Domestic Product
HAI Healthcare-associated Infections
HCPCS Healthcare Common Procedure Coding System
HD Hemodialysis
HHD Home Hemodialysis
ICD–9–CM International Classification of Diseases, 9th Edition, Clinical Modifications
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Advisors
IGI IHS Global Insight
IPPS Inpatient Prospective Payment System
KDIGO Kidney Disease: Improving Global Outcomes
KDOQI Kidney Disease Outcome Quality Initiative
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large Dialysis Organization
MAP Medicare Allowable Payment
MCP Monthly Capitation Payment
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA Medicare and Medicaid Extenders Act of 2010 Public Law 111–309
MFP Multifactor Productivity
NHSN National Healthcare Safety Network
NQF National Quality Forum
PD Peritoneal Dialysis
PFS Physician Fee Schedule
PPS Prospective Payment System
PSR Performance Score Report
PY Payment Year
QIP Quality Incentive Program
REMIS Renal Management Information System
RFA Regulatory Flexibility Act
RUL Reasonable Useful Lifetime
SBA Small Business Administration
SIMS Standard Information Management System
SHR Standardized Hospitalization Ratio
SSA Social Security Administration
The Act Social Security Act
The Affordable Care Act The Patient Protections and Affordable Care Act
URR Urea reduction ratio
VBP Value Based Purchasing

## I. Calendar Year (CY) 2012 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

### *A. Background on the End-Stage Renal Disease Prospective Payment System*

On August 12, 2010, we published in the **Federal Register**, a final rule (75 FR 49030 through 49214), entitled, ''End-Stage Renal Disease Prospective Payment System'', hereinafter referred to as the CY 2011 ESRD PPS final rule. In the CY 2011 ESRD PPS final rule, we implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011, in accordance with section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

Also, section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, the Affordable Care Act, established that beginning CY 2012, and each subsequent year, the Secretary shall reduce the market basket increase factor by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

In the CY 2011 ESRD PPS final rule (75 FR 49030), the Centers for Medicare & Medicaid Services (CMS) finalized the following:

- A base rate of $229.63 per treatment for renal dialysis services (but postponed payment for oral-only renal dialysis drugs under the ESRD PPS until January 1, 2014) that applies to both adult and pediatric dialysis patients prior to the application of any case-mix adjustments. This amount included the 2 percent reduction for budget neutrality required by MIPPA, a one percent reduction for estimated outlier payments, and a reduction to account for estimated payments for case-mix and the low-volume payment adjustments.
- A 4-year transition period (for those ESRD facilities that elected to receive blended payments during the transition) during which ESRD facilities receive a blend of payments under the prior basic case-mix adjusted composite payment system and the new ESRD PPS. Although the statute uses the term ''phase-in'', we use the term ''transition'' to be consistent with other Medicare payment systems.
- A −3.1 percent transition budget-neutrality adjustment to ensure that overall spending under the ESRD PPS did not increase as a result of the provision that permits ESRD facilities to be excluded from the 4-year transition.
- Payment adjustments for dialysis treatments furnished to adults for patient age, body surface area (BSA), low body mass index (BMI), onset of dialysis, and six specified co-morbidities.
- A home or self-care dialysis training payment adjustment of $33.44 per treatment paid in addition to the case-mix adjusted per treatment amount, which is wage adjusted and applies to claims for patients trained by ESRD facilities certified to provide home dialysis training.
- Payment adjustments for dialysis treatments furnished to pediatric patients for patient age and dialysis modality.
- A low-volume payment adjustment for adult patients of 18.9 percent that applies to the otherwise applicable case-mix adjusted payment rate for facilities that qualify as low-volume ESRD facilities.
- An outlier payment policy that provides an additional payment to ESRD facilities treating high cost, resource-intensive patients.
- The wage index adjustment that is applied when calculating the ESRD PPS payment rates in order to account for geographic differences in area wage levels.
- An ESRD bundled (ESRDB) market basket index used to project prices in the costs of goods and services used to furnish outpatient maintenance dialysis.

In addition, on April 6, 2011, we published an interim final rule with comment period in the **Federal Register** (76 FR 18930), entitled ''Changes in the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'', which revised the ESRD transition budget-neutrality adjustment for CY 2011. In the interim final rule, we revised the 3.1 percent transition budget-neutrality adjustment reduction to a zero percent transition budget-neutrality adjustment for renal dialysis services furnished on April 1, 2011 through December 31, 2011.

### *B. Summary of the Proposed Provisions and Responses to Comments on the CY 2012 ESRD PPS*

The proposed rule entitled, ''Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment'' (76 FR 40498) (the ''proposed rule'') appeared in the **Federal Register** on July 8, 2011, with a comment period that ended on August 30, 2011 (76 FR 40498). In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2012, (2) implement the second year of the transition, (3) make several policy changes and clarifications, and (4) technical changes with regard to the CY 2011 ESRD PPS final rule. We received approximately 40 public comments on the ESRD PPS proposals, including comments from dialysis facilities, the national organizations representing dialysis facilities, nephrologists, patients, pharmaceutical manufacturers, hospitals and their representatives, and MedPAC. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and what we are finalizing for the CY 2012 ESRD PPS in this final rule.

#### 1. Updates to the Composite Rate and ESRD PPS Base Rate

##### a. Composite Rate

Section 1881(b)(14)(E)(i) of the Act requires a 4-year transition under the ESRD PPS. For CY 2012, under 42 CFR 413.239(a)(2), ESRD facilities that receive payment through the transition receive a blended rate equal to the sum of 50 percent of the ESRD PPS amount and 50 percent of the basic case-mix adjusted composite payment amount. Accordingly, we continue to update the composite rate portion of the blended payment during the 4-year transition (that is, CYs 2011 through 2013). For a historical perspective of the basic case-mix adjusted composite payment system for ESRD facilities, including the CY 2011 update to the composite rate portion of the blended rate, please see the CY 2011 Physician Fee Schedule (PFS) proposed rule, (75 FR 40164) and the CY 2011 PFS final rule (75 FR 49031 through 49033). In addition, we discuss the CY 2012 drug add-on and the updated wage index values for the composite rate portion of the blended payment in sections I.C.6 and I.C.7, respectively, of this final rule.

Under section 1881(b)(14)(F)(ii) of the Act, for years during which the transition applies, the composite rate portion of the blend shall be annually increased by the ESRDB market basket, which for CY 2012 and each subsequent year, shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In section I.B.2.b of this final rule, we are finalizing the CY 2012 ESRDB market basket update of 3.0 percent, based on the third quarter 2011 IGI forecast of the ESRDB market basket. In

section I.B.2.c of this final rule, we are finalizing the CY 2012 MFP adjustment of 0.9 percent based on the third quarter 2011 IGI forecast of the MFP.

We proposed to add the CY 2011 Part D per treatment amount (that is, $0.49) to the CY 2011 composite rate in order to update the Part D amount for CY 2012 using the ESRDB market basket minus the productivity adjustment (76 FR 40502). We believed this approach is preferable to applying a growth factor to the $0.49 that is based on the rates for overall prescription drug prices that were used in the National Health Expenditure Projections, as we did for the establishment of the CY 2011 ESRD PPS base rate, because it is consistent with the update applied to the ESRD PPS base rate, which includes a per treatment amount for former part D drugs (that is, $0.49). We sought comment on our proposal to add the CY 2011 part D payment amount (that is, $0.49) to the composite rate portion of the blended payment and update it using the ESRDB market basket minus productivity adjustment. The basis for the first part of the transition budget-neutrality adjustment (that is, the calculation of the $0.49 part D amount) was set forth in the CY 2011 ESRD PPS final rule at 75 FR 49082. The comments and our responses are set forth below.

*Comment:* Several commenters expressed concerns about the proposed methodology to add the former Part D oral drug amount ($0.49) to the composite rate and then apply the market basket reduced by the productivity adjustment. Some commenters believe that updating the payment for oral equivalents of injectable drugs by the ESRD market basket minus productivity could set a precedent that might affect access to care for preferred agents when oral drugs are included in the bundle in 2014. One commenter stated that it is inappropriate to apply the productivity adjustment to full transition blended payment. Instead, they believe the blended payment amount, for CY 2012, should be split with 50 percent of it paid at the PPI-inflated market basket rates and 50 percent of it adjusted using the update factors because the transition blended payment rate is based on 50 percent of the PPS payment rate and 50 percent on the old composite rate plus drug add-on rate. One commenter acknowledged that by using the split methodology, ESRD PPS would be updated differently than other payment systems, but the commenter believed that this distinction was appropriate because of the unique nature of the program and because drugs represent such a large portion of the overall costs incurred by dialysis facilities.

*Response:* Beginning in 2012, section 1881(b)(14)(F) of the Act, requires us to annually update the ESRD PPS payment amounts and the composite rate portion of the blended transition payment by an ESRD market basket increase that is reduced by the productivity adjustment described in section 1886(b)(3)(B)xi)(II) of the Act. Given that the same update is used for both ESRD PPS and transition blended payments, and given the ESRD PPS base rate includes a portion of former Part D drugs, we proposed to add the $0.49 part D drug amount to the composite rate portion of the blended payment because we wanted to update it consistent with how we update the ESRD PPS base rate. Further, because the statute requires an update using the ESRDB market basket less productivity and the ESRDB market basket is comprised of the Producer Price Index (PPI) for prescription drugs as a proxy for measuring price growth in ESRD-related drugs, we believe that our proposal to add the $0.49 to the composite rate and update it using the ESRDB market basket less productivity is appropriate. Therefore, for CY 2012, the composite rate payment, including the $0.49 Part D amount, will be updated by the ESRDB market basket less productivity. With regard to the commenter's concerns that the addition of $0.49 to the composite rate would set a precedent that might affect access to care for preferred agents when oral-only drugs are included in the bundle in 2014, we note that we did not propose any payment policies for the oral-only drugs in the proposed rule. We will address in future rulemaking oral-only drugs and the bundled amount established in CY 2011, and there will be an opportunity for public comment on any future proposals we may make.

Consequently, for CY 2012, the composite rate portion of the ESRD PPS blended payment is $141.94. The $141.94 reflects the addition of the CY 2011 part D per treatment amount ($0.49) to the CY 2011 composite rate of $138.53, and application of the ESRDB market basket minus productivity adjustment ($138.53 + 0.49 = $139.02; $139.02 × 1.021 = $141.94).

b. ESRD PPS Base Rate

We described the development of the ESRD PPS per-treatment base rate in the CY 2011 ESRD PPS final rule (75 FR 49071) and established Medicare regulations at 42 CFR 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget-neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively (75 FR 49071 through 49082). Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year), updated to CY 2011, and represented the average per treatment Medicare allowable payment (MAP) for composite rate and separately billable services. In addition, in accordance with § 413.230, the ESRD PPS base rate is adjusted for the patient-specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as any outlier payment or training add-on adjustments. For CY 2011, the ESRD PPS base rate was $229.63 (75 FR 49082).

As required by section 1881(b)(14)(F) of the Act, in this final rule, for CY 2012, we applied the 2.1 percent increase (ESRDB market basket update less productivity) to the CY 2011 ESRD PPS base rate of $229.63, which results in an ESRD PPS base rate for CY 2012 of $234.45 (229.63 × 1.021 = 234.45). The ESRD PPS base rate applies to the ESRD PPS portion of the blended payments under the transition and to the ESRD PPS payments. In addition, as discussed in section I.C.7.c of the proposed rule (76 FR 40509), we proposed to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate in CY 2012.

We did not receive any comments on this proposal. Therefore, we are finalizing the policy to apply the wage index budget-neutrality adjustment to the ESRD PPS base rate. For CY 2012, we apply the wage index budget-neutrality adjustment factor of 1.001520 to the updated base rate (that is, $234.45), yielding an ESRD PPS wage-index budget-neutrality adjusted base rate for CY 2012 of $234.81 ($234.45 × 1.001520 = 234.81).

2. ESRD Bundled Market Basket

a. Overview and Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute further provides that the market basket increase factor

should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. Under section 1881(b)(14)(F)(ii) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, the ESRD bundled (ESRDB) rate market basket increase factor will also be used to update the composite rate portion of ESRD payments during the ESRD PPS transition period from 2011 through 2013; though beginning in 2012, such market basket increase factor will be reduced by the productivity adjustment. As a result of amendments by section 3401(h) of the Affordable Care Act, a full market basket was applied to the composite rate portion of the blended payment in CY 2011 during the first year of the transition.

b. Final Market Basket Update Increase Factor and Labor-Related Share for ESRD facilities for CY 2012

As required under section 1881(b)(14)(F) of the Act, CMS developed an all-inclusive ESRDB input price index (75 FR 49151 through 49162). Although ''market basket'' technically describes the mix of goods and services used to produce ESRD care, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from that market basket. Accordingly, the term ''ESRDB market basket'', as used in this document, refers to the ESRDB input price index.

We proposed to use the same methodology described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2012 ESRDB market basket increase factor and labor-related share based on the best available data (76 FR 40503). Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Insight (IGI), Inc.'s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this method and the IGI forecast for the first quarter of 2011 of the CY 2008-based ESRDB market basket (with historical data through the fourth quarter of 2010), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2012 ESRDB market basket increase factor was 3.0 percent. We also proposed that if more recent data became subsequently available (for example, a more recent estimate of the market basket), we would use that data, if appropriate, to determine the CY 2012 update in the final rule. Therefore, we used the IGI's third quarter 2011 forecast with history through the second quarter of 2011, and as discussed below, the projected market basket update for CY 2012 that we are finalizing is 3.0 percent based on the 2008-based ESRDB market basket.

Additionally, we proposed to continue to use a labor-related share of 41.737 percent for CY 2012 for the ESRD PPS payment (76 FR 40503), which was finalized in the CY 2011 ESRD final rule (75 FR 49161). We also proposed to continue to use a labor-related share of 53.711 percent for the ESRD composite rate portion of the blended payment for all years of the transition (76 FR 40503). This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the 2005 PFS final rule (70 FR 70168), and is consistent with the mix of labor-related services paid under the composite rate, as well as the method finalized in the CY 2011 ESRD PPS final rule (75 FR 49116).

The comments we received on these proposals and our responses are set forth below.

*Comment:* Several commenters believe that there should be more transparency in the calculation of the market basket update and are concerned about the lack of data available to validate the calculations.

*Response:* We agree that the public should be able to replicate the methodology used to construct the ESRDB market basket. We disagree, however, that CMS has not been fully transparent in the calculation of the market basket update. In the CY 2011 ESRD final rule (75 FR 49151 through 49161), we provided the public with the cost shares for the ESRDB market basket and the data sources for the establishment of those cost shares. We also provided a detailed description of the data sources used to develop the ESRDB market basket cost weights and the price proxies used in the ESRDB market basket were listed for each cost category, which are based on data maintained and published by the Bureau of Labor Statistics (BLS). We refer the commenter to the BLS regarding any specific information on the detailed price proxies. In addition, to assist the commenter and other interested stakeholders in locating these price proxies on the BLS Web site, we have provided the individual BLS series codes for the indexes in the price proxy discussion of the final rule and the directions for obtaining the data through the BLS Web site. These two pieces of information, the cost weights and the price proxies, allow the public to replicate the historical time series of the ESRDB market basket.

The forecasts of the individual price proxies used in a market basket are developed independently by IGI, a nationally recognized economic and financial forecasting firm. We purchase IGI's detailed price proxy projections for use in the Medicare market baskets. As a matter of practice, we publish all of the underlying detail for each price proxy for the historical period. However, because the projections of each individual price proxy are proprietary, we aggregate those projections into higher level categories and then publish the results with a one-quarter lag on the CMS Web site. This is consistent with the level of data provided for other PPS payment system market baskets. The ESRDB market basket data, including the detail as described above, is published on the CMS Web site at the following link: (*https://www.cms.gov/MedicareProgramRatesStats/04_MarketBasketData.asp#TopOfPage*).

After considering the public comments received and for the reasons we previously articulated, we are finalizing our proposals to continue to use the ESRDB market basket forecasts for the ESRD PPS and transition payment updates. Therefore, we are finalizing the ESRDB market basket update of 3.0 percent, based on the IGI third quarter forecast of the ESRDB market basket. We did not receive any public comments regarding our proposal to continue to use the labor-related shares for the ESRD PPS portion and composite portion of the blended payment during the transition period. Therefore, we are also finalizing the proposal to continue to use the labor-related share of 41.737 percent for the CY 2012 ESRD PPS payment and the labor-related share of 53.711 percent for the CY 2012 ESRD composite rate portion of the blended payment, for those facilities that elected to transition to the bundled ESRD PPS.

c. Productivity Adjustment

The ESRDB market basket must be annually adjusted by changes in economy-wide productivity. Specifically, under section 1881(b)(14)(F) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity

adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). The BLS is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

CMS notes that the proposed and final methodology for calculating and applying the MFP adjustment to the ESRD payment update is similar to the methodology used in other payment systems, as required by section 3401 of the Affordable Care Act.

The projection of MFP is currently produced by IGI, an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. These models take into account a very broad range of factors that influence the total U.S. economy. IGI forecasts the underlying proxy components such as gross domestic product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology. In Table 1 below, we identify each of the major MFP component series employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined to be the best available proxies for the BLS series.

**TABLE 1—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT**

| BLS series | IGI series |
|---|---|
| Real value-added output, constant 2005 dollars | Non-housing non-government non-farm real GDP, Billions of chained 2005 dollars – annual rate |
| Private non-farm business sector labor input; 2005=100.00 | Hours of all persons in private nonfarm establishments, 2005=100.00, adjusted for labor composition effects |
| Aggregate capital inputs; 2005=100.00 | Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars |

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and therefore suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, please see the following link: *http://www.bls.gov/mfp/mprtech.pdf*.

At the time of the development of this CY 2012 final rule, the BLS published a historical time series of private nonfarm business MFP for 1987 through 2010, with 2010 being a preliminary value. Using this historical MFP series and the IGI forecasted series, IGI has developed a forecast of MFP for 2011 through 2021, as described below. We note that the historical MFP series and the IGI forcasted series are updates from those used at the time of the proposed rule (1987 through 2009, and 2010 through 2021, respectively).

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the ''non-housing, nongovernment, non-farm, real GDP,'' ''hours of all persons in private nonfarm establishments adjusted for labor composition,'' and ''real effective capital stock'' series (ranging from 2011 to 2021) are used to ''grow'' the levels of the ''real value-added output,'' ''private non-farm business sector labor input,'' and ''aggregate capital input'' series published by the BLS. Projections of the ''hours of all persons'' measure are calculated using the difference between the projected growth rates of real output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval.

Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the ''nongovernment total compensation'' and ''flow of capital services from the total private non-residential capital stock'' series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth is subtracted from total output growth to calculate the ''change in the growth rates of multifactor productivity:''

MFP = Total output growth − ((labor input growth * labor compensation share) + (capital input growth * capital income share))

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by

the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS' methodology. For benchmarking purposes, the historical growth rates of IGI's proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series, and therefore validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

The comments we received on this proposal and our response are set forth below.

*Comment:* One commenter stated that the factors used in the productivity adjustor, which are mostly derived from capital and labor related economic measures, are not appropriate for use to modify the market basket costs of drugs, which are consumable items. One commenter further believes that ESRD PPS should be treated differently than other PPS payment systems because drugs represent such a large portion of the overall costs incurred by dialysis services. One pharmaceutical company expressed concern about the proposal to apply the productivity adjustment to the Part D oral drug portion of the blended payment.

*Response:* In accordance with section 1881(b)(14)(F)(i) of the Act, beginning in 2012, all renal dialysis services included in the ESRD bundle are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Therefore, CMS is statutorily required to update ESRD PPS payments by a market basket update less productivity. We also note that CMS is statutorily required to update the ESRD composite rate portion of the blended payment by the ESRDB market basket less productivity. During the transition, any items or services included in the bundle have been factored into the cost shares for the ESRDB market basket; as such, the costs associated with oral drugs that were formerly paid under Part D are included in the ESRDB market basket cost share weight for drugs. As finalized in the CY 2011 ESRD final rule (75 FR 49156), the market basket drug cost share weight accounts for all drugs included in the ESRD bundled payment, including ESRD-related oral drugs with injectable equivalents that were formerly covered under Medicare Part D as well as the costs associated with any other drugs as reported on the ESRD Medicare Cost Report. In 2014, any changes to the bundle will be factored into a revised ESRDB market basket and be subject to notice and comment rulemaking. Therefore, although drugs account for a larger proportion of expenses in the ESRDB market basket than in some other provider-type PPS market baskets, we will continue to update the ESRD payments as statutorily mandated by the Congress. As such, for CY 2012, the ESRD PPS payment rate and the composite portion of the blended payment will be increased by the estimated market basket update less productivity, 2.1 percent (3.0 percent ESRDB market basket less 0.9 percentage point MFP adjustment), which is described in more detail below.

After careful consideration of the public comments and to satisfy the statutory requirement for ESRD payment updates mentioned above, we are finalizing our proposed method for calculating and applying the MFP adjustment to the ESRDB market basket.

d. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2012

Under section 1881(b)(14)(F)(i) of the Act, beginning in 2012, ESRD PPS payment amounts and the composite rate portion of the transition blended payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by a productivity adjustment.

We proposed to estimate the ESRDB market basket percentage for CY 2012 based on the CY 2008-based ESRDB market basket (76 FR 40504). In order to calculate the MFP-adjusted update for the ESRDB market basket during the transition period, we proposed that the MFP percentage adjustment be subtracted from the CY 2012 market basket update calculated using the CY 2008-based ESRDB market basket (75 FR 40504). We proposed that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate CY update period. Since the market basket update is reduced by the MFP adjustment to determine the annual update for the ESRD PPS and the ESRD composite rate portions of the blended payment during the transition, we believe it is appropriate for the numbers associated with both components of the calculation (the market basket and the productivity adjustment) to coincide so that changes in market conditions are aligned. Therefore, for the CY 2012 update, we proposed that the MFP adjustment be calculated as the 10-year moving average of changes in MFP for the period ending December 31, 2012. We proposed to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we will round the number up; if the number we are rounding is followed by 1, 2, 3, or 4, we will round the number down).

Thus, in accordance with section 1881(b)(14)(F)(i) of the Act, the proposed market basket increase factor for CY 2012 for the ESRDB market basket was based on the 1st quarter 2011 forecast of the CY 2008-based ESRDB market basket update, which was estimated to be 3.0 percent. This market basket percentage was then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2012) of 1.2 percent, which is calculated as described above and based on IGI's 1st quarter 2011 forecast. The resulting proposed MFP-adjusted ESRDB market basket update for CY 2012 was equal to 1.8 percent, or 3.0 percent less 1.2 percent. We proposed that if more recent data were subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the CY 2012 market basket update and MFP adjustment in the CY 2012 ESRD PPS final rule. Consistent with historical practice and our proposal, we update the market basket increase factor estimate and the MFP adjustment in this final rule to reflect the most recent available data (75 FR 40505).

We received no public comments related to the proposed MFP-adjusted ESRDB market basket update for CY 2012. Therefore, we are finalizing our proposal to base the CY 2012 market basket update, which is used to determine the applicable percentage increase for the ESRD PPS and transition payments, on the most recent data available, which is the third quarter 2011 forecast of the CY 2008-based ESRDB market basket (estimated to be 3.0 percent). The MFP adjustment (the 10-year moving average of MFP for the period ending CY 2012) we are finalizing is 0.9 percent, which was calculated as described above and based on IGI's third quarter 2011 forecast.

Therefore, the final MFP-adjusted ESRDB market basket update for CY 2012 is 2.1 percent (3.0 percent ESRDB market basket less 0.9 percentage point MFP adjustment).

3. Transition Budget-Neutrality Adjustment for CY 2011

Section 1881(b)(14)(E)(iii) of the Act requires that an adjustment to payments be made for renal dialysis services provided by ESRD facilities during the transition so that the estimated total payments under the ESRD PPS, including payments under the transition, equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. In the CY 2011 ESRD PPS final rule, we explained that because we would not know the actual number of ESRD facilities that would elect to opt out of the transition prior to publishing the final rule, we would simulate payments under the existing basic case-mix adjusted composite payment system and under the ESRD PPS to determine how many ESRD facilities we believed would elect to receive payment under 100 percent ESRD PPS. Based on our simulations using 2007 data, we estimated that 43 percent of ESRD facilities would financially benefit from receiving full payment under the ESRD PPS. We indicated that based on the simulation of estimated payments, a 3.1 percent reduction would be applied to all payments made to ESRD facilities for renal dialysis services furnished on January 1, 2011 through December 31, 2011 (75 FR 49082 through 49083).

On April 6, 2011, we published an interim final rule with comment period in the **Federal Register** (76 FR 18930), entitled ''Changes to the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'', which revised the ESRD transition budget-neutrality adjustment finalized for CY 2011. In the interim final rule, we indicated that based upon the election data submitted by ESRD facilities, 87 percent of ESRD facilities elected to opt out of the transition. When we applied the actual number of ESRD facilities electing to receive payment under the ESRD PPS, the transition budget-neutrality adjustment was determined to be zero rather than a 3.1 reduction in payments. We revised the 3.1 percent transition budget-neutrality adjustment reduction to a zero percent transition budget-neutrality adjustment for renal dialysis services furnished on April 1, 2011 through December 31, 2011. We also indicated that we would respond to comments submitted on the interim final rule in the CY 2012 ESRD PPS final rule.

We received four comments during the IFC comment period and three comments in response to the CY 2012 ESRD PPS proposed rule. All comments were in support of the revised CY 2011 transition budget-neutrality adjustment factor. Therefore, we are finalizing the revised CY 2011 transition budget-neutrality adjustment factor of zero for ESRD claims for renal dialysis services furnished on April 1, 2011 through December 31, 2011.

4. Transition Budget-Neutrality Adjustment for CY 2012

Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a four-year phase-in of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS fully implemented for renal dialysis services furnished on or after January 1, 2014. We use the term ''transition'' rather than ''phase-in'' to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permitted ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elected to be excluded from the transition would receive payment for renal dialysis services provided on or after January 1, 2011, based on 100 percent of the payment rate under the ESRD PPS rather than a blended payment based in part on the payment rate under the basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS. Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. We refer to this provision as the transition budget-neutrality adjustment.

As described in the CY 2011 ESRD PPS final rule (75 FR 49082), the transition budget-neutrality adjustment is comprised of two parts. For the first part, we created a payment adjustment to the composite rate portion of the blended payment during the transition to account for the per treatment costs of drugs that were paid under Part D. For the second part, we computed a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal to the estimated total amount of payments that would otherwise occur without such a transition. In the proposed rule, we addressed both parts of the transition budget-neutrality adjustment (76 FR 40505 and 40506). The first part of the transition budget-neutrality adjustment was addressed in section I.C.1. of this final rule where we address updates to the composite rate and the ESRD PPS base rate.

For the second part of the transition budget-neutrality factor, we first determined the estimated increase in payments under the transition and then determined an offset factor, based on estimates of which facilities would choose to opt out of the transition (for a detailed description, see the CY 2011 ESRD PPS proposed rule, 74 FR 49946). We estimated the number of facilities that would choose to opt out of the transition by comparing payment under the transition to payment under the PPS and choosing the option that was financially beneficial to each facility. Using that approach, we estimated that 43 percent of facilities would choose to opt out of the transition and determined the transition budget-neutrality adjustment to be a reduction of 3.1 percent. In the April 6, 2011 interim final rule with comment (76 FR 18930 through 18934), however, we updated the number of facilities that chose to opt out of the transition to 87 percent, based on actual election data that we received and recalculated a transition budget-neutrality adjustment of zero percent.

Given that the transition budget-neutrality adjustment required under section 1881(b)(14)(A)(ii) of the Act applies in each year of the transition, we must update the transition budget-neutrality adjustment for CY 2012. In the proposed rule (76 FR 40506), we noted that we were not proposing for CY 2012 to change the methodology used to calculate the second part of the budget-neutrality adjustment. However, we proposed to use more updated data. In order to ensure that total payments under the transition equal total payment amounts without a transition, we would reduce all payments to ESRD facilities in CY 2012 by a factor that is equal to 1 minus the ratio of estimated payments under the ESRD PPS if there were no transition to the total estimated payments under the transition.

In the proposed rule, we explained that we started with 2009 utilization data from claims, as 2009 was the latest complete year of claims data available of complete claims data. In this final rule, we used 2010 claims as it is the latest available year. Using price growth factors for CY 2011 and CY 2012 that are discussed in the impact analysis in section I.VII.B.1 of this final rule, we updated the CY 2010 utilization data to

CY 2011 and CY 2012 payments. We then took the estimated CY 2012 payments under the full ESRD PPS and the blended payments under the transition based on actual facility election data and compared these estimated payments to the total estimated payments in CY 2012 as if all facilities had elected to receive payment under the full ESRD PPS. We then calculated the transition budget-neutrality factor to be 1 minus the ratio of estimated payments under the ESRD PPS if there were no transition to the total estimated payments under the transition, which results in zero percent. Therefore, for CY 2012, we proposed that a zero percent reduction to all payments would be made to ESRD facilities (that is, the zero percent adjustment would be applied to both the blended payments under the transition and payments made under the 100 percent ESRD PPS). We solicited comments on the proposed second part of CY 2012 transition budget-neutrality adjustment methodology. The comments and our responses are set forth below.

*Comment:* Several national associations and one dialysis organization supported the zero percent transition budget-neutrality adjustment for CY 2012. One commenter indicated that the proposed rule appropriately reflected that a greater percentage of ESRD facilities than estimated elected to receive payment under the ESRD PPS.

*Response:* We thank the commenters for their support. Therefore, in this final rule, we are finalizing the proposed second part of the transition budget-neutrality adjustment and the zero percent budget-neutrality adjustment for CY 2012.

5. Low-Volume Facility Provisions

Section 1881(b)(14)(D)(iii) of the Act requires a low-volume payment adjustment that ''reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent''. We established the low-volume payment adjustment, including the methodology we used to develop the low-volume treatment threshold in the CY 2011 ESRD PPS final rule (75 FR 49117 through 49125). Because the analysis included data that spanned a 3-year period, we defined a low-volume ESRD facility as a facility that is able to maintain its low-volume status each year of the 3-year period. This timeframe provided us with a sufficient span of time to view consistency in business operations through the data. Under 42 CFR 413.232(b), a low-volume facility is an ESRD facility that: (1) Furnished less than 4,000 dialysis treatments in each of the 3 years preceding the payment year and (2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. Under § 413.232(c), the number of treatments shall be equal to the aggregate number of treatments furnished by other ESRD facilities that are both under common ownership and 25 road miles or less from the ESRD facility in question. This geographic proximity criterion is only applicable to ESRD facilities that are Medicare certified on or after January 1, 2011. Section 413.232(f) requires an ESRD facility to provide an attestation statement to their respective fiscal intermediary or Medicare administrative contractor (FI/MAC) that the facility meets all the criteria in order to receive the low-volume adjustment. We note that furnishing 4,000 treatments in a year equates to approximately 25 patients per year receiving three dialysis treatments a week (or hemo-equivalent treatments).

In the proposed rule, we discussed § 413.232 and clarified that the ''payment year'' is the period of time that we use for determining payment to ESRD facilities, which is a calendar year, and that eligibility years mean the 3 years preceding the payment year and are based on cost reporting years (76 FR 40506). We made this clarification to ensure that ESRD facilities and their respective FI/MACs understand the distinction between eligibility (which is based on cost reporting years) and the payment year (when ESRD facilities can begin to receive the low-volume payment adjustment).

We did not seek comments on the clarifications of the payment and cost report years, however, we received three comments indicating the clarifications were helpful.

In the proposed rule (76 FR 40506 and 40507), we proposed to establish the process for CY 2012 and each year thereafter, that an ESRD facility would be required to follow when submitting its attestation to notify its FI/MAC that it is eligible for the low-volume payment adjustment. We further explained that the attestation is required because: (1) ESRD facility's cost reporting periods vary and may not be based on the calendar year; and (2) the cost reports are due 5 months after the close of the cost reporting period (that is, there is a lag in the cost reporting submission). Thus, the FI/MACS may not have the cost report for the third year to determine eligibility and would need to rely on the attestation for that year. We proposed that if an ESRD facility believes that it is eligible for the low-volume adjustment, the ESRD facility would be required to submit an attestation to its respective FI/MAC no later than November 1st of each year, and proposed to amend the regulation text at § 413.232(f) (76 FR 40507). We noted that this timeframe provides 60 days for a FI/MAC to verify the cost report information and update the systems (76 FR 40507). We explained that if ESRD facilities are receiving the low-volume adjustment for the CY 2011 payment year, those ESRD facilities should submit another attestation to their respective FI/MAC no later than November 1, 2011, to qualify for the low-volume adjustment for the CY 2012 payment year. An ESRD facility must continue to attest that it is a low-volume facility for each subsequent payment year it believes it is eligible for the low-volume facility adjustment.

We explained that if the FI/MAC does not receive an ESRD facility's attestation stating that the ESRD facility is eligible for the low-volume adjustment on or before November 1 prior to the payment year, the ESRD facility would not receive the low-volume adjustment for that payment year. We also noted that in the event a dialysis organization submits the low-volume attestation on behalf of its ESRD facilities, the dialysis organization will be required to identify each ESRD facility by name and provider number and submit them by the November 1 deadline.

We solicited comment on our proposal and the proposed regulation text changes at § 413.232(f).

We did not receive any comments and, therefore, in this final rule, we are finalizing a yearly November 1 deadline for attestation submission and we are revising the regulation at § 413.232(f) to reflect this date for CY 2012 and each year thereafter. However, because the CY 2012 final rule will not be effective before November 1, 2011, we are finalizing a later low-volume attestation submission deadline of January 3, 2012, for attestations that pertain to the CY 2012 low-volume adjustment. We believe this due date provides facilities sufficient time to submit an attestation and allows the agency (that is, the FI/MACs) time to process submissions. In addition, a later date is not possible since the CY 2012 payment year will be underway. Accordingly, we also are

revising the regulation at § 413.232(f) to reflect this change.

In the proposed rule, we indicated that the ESRD facility's cost reports for the cost reporting periods ending in the 3 years immediately preceding the payment year must report costs for 12-consecutive months (76 FR 40507). For example, an FI/MAC should not consider a short period cost report (that is, reporting costs for less than 12 months which may occur for new facilities or facilities under new ownership), for low-volume eligibility. Specifically, when an ESRD facility is assessing its eligibility for the low-volume adjustment and preparing its attestation, the ESRD facility should look at its 12-consecutive month cost reports for the cost reporting periods that end in the 3 years immediately preceding the payment year.

As we indicated previously, the FI/MAC may not have a final-settled cost report for all 3 years needed to complete the ESRD facility's verification and we provided examples of such situations (76 FR 40507). Therefore, we proposed to amend the regulations at § 413.232(b)(1) and (b)(2) to clarify the meaning of year with regard to the treatment threshold that is used for determining low-volume eligibility and how it relates to the payment year. This proposed change to the regulations would make clear that the ESRD facility's cost reports for the 3 years immediately preceding the payment year must report costs for 12-consecutive months, and provide clarification that in the absence of an ESRD facility's final settled cost report, an FI/MAC can review the ESRD facility's as-filed cost report when determining if an ESRD facility meets the low-volume criteria. We believe that it is appropriate for the FI/MAC to determine eligibility based upon an as-filed cost report because the number of total treatments should not change between submission of the as-filed cost report and the final settled cost report. We solicited comment on the proposed changes at § 413.232(b)(1) and (b)(2). We did not receive any comments and, therefore, we are finalizing these proposed changes to the regulation at § 413.232(b)(1) and (b)(2).

In the proposed rule, we explained that if an FI/MAC receives an ESRD facility's attestation stating that the ESRD facility believes that it qualifies for the low-volume payment adjustment and then finds that the ESRD facility did not meet the low-volume criteria, the FI/MAC will discontinue application of the low-volume adjustment (76 FR 40508). If the ESRD facility does not remain low-volume for each of the 3 years (12-consecutive month cost reporting periods) immediately preceding the payment year, the ESRD facility is not eligible for the low-volume adjustment until it can demonstrate again that for 3 years (12-consecutive month cost reporting periods) it has met the low-volume criteria. The comments we received and our responses are set forth below.

*Comment:* One independent ESRD facility asked if an ESRD facility was determined not to qualify for the low-volume adjustment, would the low-volume adjustment be discontinued without payment implication.

*Response:* Medicare is obligated to provide appropriate payment. If an ESRD facility has not met the eligibility requirements as described in 42 CFR 413.232, the ESRD facility would not be entitled to receive the low-volume adjustment and the inappropriate low-volume payments made in that payment year would be recouped.

*Comment:* One commenter indicated that in the CY 2011 ESRD PPS final rule, we defined a low-volume facility at § 413.232(b)(2) as an ESRD facility that has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year (75 FR 49118). The commenter pointed out that in the CY 2011 ESRD PPS final rule we did not finalize the phrase, ''or received a new provider number due to a change in ownership'' in the regulation text at § 413.232(b)(2) and in our discussion of the definition of a low-volume facility in this year's proposed rule we only referred to the phrase, ''or had a change in ownership'' (76 FR 40507). The commenter is concerned that if we do not include the phrase, ''or received a new provider number due to a change in ownership'' in the regulation text at § 412.232(b)(2) that it will negatively impact new owners of underperforming clinics that would otherwise wish to apply for the low-volume designation.

*Response:* We agree with the commenter that in the CY 2011 final rule we inadvertently omitted the phrase, ''or received a new provider number due to a change in ownership'' in the regulation text finalized at § 413.232(b)(2). In the preamble of both the CY 2011 ESRD PPS proposed and final rules (74 FR 49118 through 49919, 74 FR 49975), we made clear that under § 413.232(b), a low-volume facility is defined as an ESRD facility that ''has not opened, closed, or received a new provider number due to a change of ownership * * *''; however, we inadvertently omitted language from the regulation (74 FR 50024, 74 FR 49200). Therefore, in this final rule, we are making a technical correction to the regulation text at § 413.232(b)(2) to reflect that a low-volume facility is an ESRD facility that has not open, closed, or received a new provider number due to a change in ownership in the 3 years preceding the payment year.

*Comment:* One independent ESRD facility questioned the policy that ESRD facilities must remain low volume (that is, provide less than 4,000 dialysis treatments) for three years immediately preceding the payment year or risk not qualifying for the low-volume adjustment until it can once again demonstrate it is low volume for three consecutive years. The commenter further stated that many small or rural dialysis facilities provide the only access to care in a geographic area and this policy requires the established low-volume facility to choose between providing access to care and significant, long term payment reductions. The commenter further stated that this policy could result in dialysis facilities denying care to avoid crossing the 4,000 threshold. The commenter suggested that CMS consider reducing the eligibility timeline for small facilities that have met the low-volume eligibility criteria so that they could re-qualify for the low-volume adjustment in the following year if their treatments returned to less than 4,000 per year.

*Response:* We do not agree with the commenter's assertion of the negative effects of the low-volume eligibility criteria. The low-volume adjustment is intended for ESRD facilities that are located in areas that have a population base resulting in less than 4,000 treatments per year and is not intended to account for fluctuations or business decisions that increase or decrease the number of treatments that can or would be provided. We do not believe that these fluctuations or changes in the population from year to year would in most circumstances result in a facility not being eligible for the low-volume adjustment. As we indicated in the CY 2011 ESRD PPS final rule (75 FR 49118 and 49119), we believe the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care, but are concerned about potential disincentives that low-volume facilities could have regarding patient care. We are monitoring the number of facilities that are receiving the low-volume adjustment. Any changes in the low-volume methodology will be discussed in future rulemaking.

As for allowing facilities that lose low-volume status to requalify for low-volume status the next year, any changes in the low-volume eligibility

criteria would be addressed in future rulemaking.

6. Update to the Drug Add-On to the Composite Rate Portion of the ESRD Blended Payment Rate

Section 1881(b)(14)(E)(i) of the Act requires a four-year transition under the ESRD PPS. Under § 413.239, ESRD facilities were permitted to make a one-time election by November 1, 2011, to be excluded from the transition and receive full payment under the ESRD PPS. Under § 413.239, in CY 2012, ESRD facilities that elected to receive payment under the transition will be paid a blended amount that will consist of 50 percent of the basic case-mix adjusted composite payment system and 50 percent on the ESRD PPS payment. Thus, we must continue to update the composite rate portion of the blended payment amount during the ESRD PPS 4-year transition (CYs 2011 through 2013), which includes an update to the drug add-on.

Under section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system includes the services comprising the composite rate and an add-on to the composite rate component to account for the difference between pre-MMA payments for separately billed drugs and the revised drug pricing specified in the statute. For the drug add-on for CY 2012 (76 FR 40508 and 40509), we did not propose any changes to the methodology, but merely updated the data used in computing the drug add-on as described below.

a. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2012

Section 1881(b)(12)(F) of the Act specifies that the drug add-on increase must reflect ''the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable * * *''. By referring to ''expenditures'', we believe the statute contemplates that the update would account for both increases in drug prices, as well as increases in utilization of those drugs.

To account for increases in drug prices and utilization, we used the 5 years of drug expenditure data based on ASP pricing and proposed to use this data for trend analysis (76 FR 40508). We then removed growth in enrollment for the same time period from the expenditure growth so that the residual reflects the per patient expenditure growth (which includes price and utilization combined).

To estimate drug expenditure growth using trend analysis for CY 2012, we looked at the average annual growth in total drug expenditures between 2006 and 2010. First, we estimated the total drug expenditures for all ESRD facilities in CY 2010. We used the final CY 2006 through CY 2009 ESRD claims data and the latest available CY 2010 ESRD facility claims, updated through December 31, 2010 (that is, claims with dates of service from January 1 through December 31, 2010, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2010). We indicated that for this final rule, we intended to use additional updated CY 2010 claims with dates of service for the same timeframe (76 FR 40508). This updated CY 2010 data file would include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2011.

We inflated the CY 2010 drug expenditures to estimate the June 30, 2011 update of the 2010 claims file. The net adjustment to the CY 2010 claims data was an increase of 11.62 percent to the 2010 expenditure data, which allowed us to more accurately compare the 2009 and 2010 drug expenditure data to estimate per patient growth. Next, we calculated the average annual change in drug expenditures from 2006 through 2010. This average annual change showed an increase of 1.4 percent in drug expenditures from 2006 through 2010 (76 FR 40508). We used this 1.4 percent increase to project drug expenditures for both 2011 and 2012.

For the final rule, using the full-year 2010 drug expenditure figure, we calculated the average annual change in drug expenditure from 2006 through 2010. This average annual change showed an increase of 1.0 percent in drug expenditures from 2006 through 2010. We used this 1.0 percent increase to project drug expenditures for both 2011 and 2012. We note, the change in the drug expenditures increase is a result of updated data.

b. Estimating per Patient Growth

In the proposed rule, we explained that once we had the projected growth in drug expenditures from 2011 to 2012, we calculated per patient growth between CYs 2011 and 2012 by removing the estimated growth in enrollment data between CY 2011 and CY 2012 (76 FR 40508). We estimate a 4.2 percent estimated growth in enrollment between CY 2011 and CY 2012. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change between 2011 and 2012 (1.014) by enrollment growth of 4.2 percent (1.042) for the same timeframe. The result was a per-patient growth factor equal to 0.973 (1.014/1.042 = 0.973). Thus, we projected a 2.7 percent decrease (2.7 percent = .027 = 0.973 − 1) in per patient growth in drug expenditures between 2011 and 2012.

For this final rule, we estimate a 4.3 percent estimated growth in enrollment between CY 2011 and CY 2012. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change between 2011 and 2012 (1.010) by enrollment growth of 4.3 percent (1.043) for the same timeframe. The result is a per-patient growth factor equal to 0.968 (1.010/1.043 = 0.968). Thus, in this final rule, for CY 2012 we are projecting a 3.2 percent decrease ( − 3.2 percent = 1.010/1.043 − 1 = 0.968 − 1) in per patient growth in drug expenditures between 2011 and 2012.

c. Applying the Growth Update to the Drug Add-On Adjustment

In the CY 2006 PFS final rule (71 FR 69683), we applied the projected growth update percentage to the total amount of drug add-on dollars established for CY 2005 to establish a dollar amount for the CY 2006 growth update. In addition, we projected the growth in dialysis treatments for CY 2006 based on the projected growth in ESRD enrollment. We divided the projected total dollar amount of the CY 2006 growth by the projected growth in total dialysis treatments to develop the per treatment growth update amount. This growth update amount, combined with the CY 2005 per treatment drug add-on amount, resulted in an average drug add-on amount per treatment of $18.88 (or a 14.5 percent adjustment to the composite rate) for CY 2006.

In the CY 2007 PFS final rule with comment period (71 FR 69684), as a result of public comments, we revised our update methodology by applying the growth update to the per treatment drug add-on amount. That is, for CY 2007, we applied the growth update factor of 4.03 percent to the $18.88 per treatment drug add-on amount resulting in an updated per treatment drug add-on amount of $19.64 per treatment (71 FR 69684). For CY 2008, the per treatment drug add-on amount was updated to $20.33. In the CY 2009, 2010 and 2011 PFS final rule with comment period (73 FR 69755 through 69757, 74 FR 61923, and 75 FR 73485, respectively), we applied a zero update to the per treatment drug add-on amount resulting in a per treatment drug add-on amount of $20.33. As discussed in detail below, in this final rule, for CY 2012, we are finalizing a zero update to the per treatment drug add-on amount of $20.33 established in CY 2008.

d. Update to the Drug Add-On Adjustment for CY 2012

We estimated a 1.4 percent increase in drug expenditures between CY 2011 and CY 2012 (76 FR 40509). Combining this increase with a 4.2 percent increase in enrollment, as described above, we projected a 2.7 percent decrease in per patient growth of drug expenditures between CY 2011 and CY 2012. Therefore, we projected that the combined growth in per patient utilization and pricing for CY 2012 would result in a decrease to the drug add-on equal to 0.4 percentage points. This figure was derived by applying the 2.7 percent decrease to the CY 2011 drug add-on of $20.33. This resulted in a revised drug add-on of $19.78, which is 14.0 percent of the proposed CY 2012 base composite rate of $141.52. If we were to apply no decrease to the drug add-on of $20.33, this would result in a 14.4 percent drug add-on. However, similar to last year and as indicated above, we proposed a zero update to the drug add-on adjustment. We explained in the proposed rule that we believed this approach is consistent with the language under section 1881(b)(12)(F) of the Act, which states in part that ''the Secretary shall annually increase'' the drug add-on amount based on the growth in expenditures for separately billed ESRD drugs. Our understanding of the statute contemplates ''annually increase'' to mean a positive or zero update to the drug add-on. Therefore, we proposed to apply a zero update and maintain the $20.33 per treatment drug add-on amount for CY 2012. The comments and our responses are set forth below.

*Comment:* Two commenters supported our proposed zero drug-add.

*Response:* We thank the commenters for their support.

*Comment:* One commenter indicated that ESA usage is overstated in 2006 through 2010 and that this would have an effect on the drug add-on and the ESRD PPS base rate calculations. The commenter recommended that we develop an ESA adjuster for the ESRD PPS base rate.

*Response:* We used the best available data to compute the drug add-on and the base rate. We continue to believe that the information on ESRD claims represent the best information currently available to the agency. Because we are required under section 1881(b)(14)(A)(ii) of the Act to use the lowest utilization year (which we determined to be 2007), we did not have discretion on the data we used in calculating the ESRD PPS base rate. We note that it is common for utilization of services to change after implementation of a PPS. That is why we periodically review our payment systems to determine if a refinement is warranted. In addition, if we were to adjust for ESA over usage in computing the drug add-on, this would lower the trend and the drug add-on would become more negative. As we discussed above, section 1881(b)(12)(F) of the Act, precludes a reduction of the drug add-on because the statute requires that we annually increase the drug add-on.

In this final rule, for CY 2012, we estimate a 1.0 percent increase in drug expenditures between CY 2011 and CY 2012. Combining this increase with a 4.3 percent increase in enrollment, we project a 3.2 percent decrease in per patient growth of drug expenditures between CY 2011 and CY 2012. Therefore, we project that the combined growth in per patient utilization and pricing for CY 2012 would result in a decrease to the drug add-on equal to 0.4 percentage points. This figure is derived by applying the 3.2 percent decrease to the CY 2011 drug add-on of $20.33. This results in a revised drug add-on of $19.69, which is 13.9 percent of the final CY 2012 base composite rate of $141.94. If we were to apply no decrease to the drug add-on of $20.33, this would result in a 14.3 percent drug add-on. Similar to last year and as discussed above, for CY 2012, we are finalizing a zero update to the drug add-on and maintaining the $20.33 per treatment drug add-on amount.

The current $20.33 per treatment drug add-on reflected a 14.7 percent drug add-on adjustment to the composite rate in effect for CY 2011. Using the latest ESRDB market basket minus productivity adjustment to update the composite rate portion of the ESRD PPS payment (forecast of 2.1 percent in 2012 effective January 1, 2012, as discussed in section I.B.2.b. of this final rule), results in a decrease to the CY 2012 drug add-on adjustment from 14.7 to 14.3 percent in order to maintain the drug add-on at $20.33. This decrease occurs because the drug add-on adjustment is a percentage of the composite rate. Since the final CY 2012 composite rate is higher than the CY 2011 composite rate, and since the drug add-on remains at $20.33, the percentage decreases. Therefore, we are finalizing for CY 2012 the drug add-on adjustment of 14.3 percent to the composite rate.

7. Updates to the Wage Index Values and Wage Index Floor for the Composite Rate Portion of the Blended Payment and the ESRD PPS Payment

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic wage index, such as the index referred to in section 1881(b)(12)(D) of the Act. In the CY 2011 ESRD PPS final rule (75 FR 49117 through 49117) and CY 2011 PFS final rule (75 FR 73486), we finalized the wage index policy under the ESRD PPS. Specifically, under the ESRD PPS, we have adopted the same method and source of wage index values used previously for the basic case-mix adjusted composite payment system.

We use the Office of Management and Budget's (OMB's) Core Based Statistical Area (CBSA)-based geographic area designations to define urban and rural areas and corresponding wage index values (76 FR 40509). In addition, the wage index values used under the ESRD PPS are the inpatient prospective payment system (IPPS) wage index values calculated without regard to geographic reclassifications authorized under sections 1881(d)(8) and (d)(10) of the Act, and utilize pre-floor hospital data that are unadjusted for occupational case mix. The CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and are available online at *http://www.whitehouse.gov/omb/bulletins/b03–04.html*. In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. All ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index used to determine the current ESRD wage index. The OMB bulletins may be accessed online at *http://www.whitehouse.gov/omb/bulletins/index.html*.

Under the ESRD PPS, we adopted a wage index floor during the transition, though we intended to gradually reduce the ESRD wage index floor (76 FR 40509, 75 FR 49117, 75 FR 73486). In the proposed rule (76 FR 40502–40503), we did not propose any changes to the labor-related share for the ESRD PPS and the composite rate portion of the blend and proposed to continue to use a labor-related share of 41.737 percent for CY 2012 for the ESRD PPS. If an ESRD facility elected to transition to the PPS, the labor-related share for the

composite rate portion of the blended payment is 53.711 percent. We proposed to continue to use the labor-related share of 53.711 percent for the composite rate portion of the blended payment for all the years of the transition. As discussed in section I.2.b of this final rule, we finalized the proposed labor-related share for the ESRD PPS and the composite rate portion of the blended payment. Finally, the wage data used to construct the wage index under the ESRD PPS is updated annually, based on the most current data available and based on OMB's definitions and corresponding wage index values.

As we previously indicated, because ESRD facilities could elect to receive a blended payment during the transition, we continue to update the composite rate portion of the ESRD PPS blended payment, including adjusting payments for geographic differences in area wage levels (76 FR 40509, 75 FR 40163). We did not propose any changes to the methodology for the wage index used to adjust the composite rate portion of the ESRD PPS blended payment. However, we did propose to update the wage index values and the wage index budget-neutrality adjustment factor for CY 2012. We did not receive any comments pertaining to our proposal to update the wage index values and the wage index budget-neutrality adjustment factor for CY 2012 for the composite rate portion of the blended payment under the transition. Consequently, we are finalizing our proposal.

Although we did not propose to make any changes to the methodology for updating the CY 2012 wage index under the ESRD PPS (that is, for full ESRD PPS payments and the ESRD PPS portion of the blended payment under the transition), we did propose a wage index budget-neutrality adjustment factor to be applied in CY 2012 and in subsequent years for the ESRD PPS (76 FR 40509).

We received one comment as set forth below.

*Comment:* One independent ESRD facility indicated that it based its decision to receive payment under the transition because the CY 2011 composite rate wage index value for the facility's area was higher than the wage index value for the ESRD PPS. The commenter stated that the higher composite rate wage index would be beneficial to those facilities that opted to receive payment under the transition. The commenter indicated that the variances between the CY 2012 proposed composite rate and ESRD PPS wage index values are not as great as compared to the CY 2011 variance, which was not anticipated by the commenter at the time the election was made to transition into the ESRD PPS and stated that this is not beneficial for those dialysis facilities transitioning to the ESRD PPS.

*Response:* The commenter is correct that the differences in the CY 2012 composite rate and ESRD PPS wage index values in the proposed rule are not as significant as they were in the CY 2011 ESRD PPS final rule. The principle reason for the differences in the composite rate and ESRD PPS wage index values in the CY 2011 final rule is that the wage index budget neutrality adjustment was applied to the composite rate values, while budget neutrality for the ESRD PPS was achieved through the overall 98 percent budget-neutrality requirement (76 FR 40510). The reason the variances between the CY 2012 proposed composite rate and ESRD PPS wage index values are less pronounced is because the proposed wage index budget-neutrality adjustment for CY 2012 for the composite rate portion of the blended payment is lower than the budget-neutrality adjustment factor for CY 2011. As we discussed above, in detail and in section I.C.1 of this final rule, the wage index budget-neutrality adjustment for the ESRD PPS and the ESRD PPS portion of the blended payment is not applied to the wage index values, but rather to the ESRD PPS base rate. Therefore, the variance described by the commenter is related solely to the wage index budget-neutrality adjustment for the composite rate portion of the blended payment. A comparison to the ESRD PPS wage index value is not appropriate because the composite rate wage index has a wage index budget-neutrality adjustment applied while the ESRD PPS wage index does not.

Since we did not receive any comments pertaining to our proposals regarding the method of applying the wage index budget-neutrality adjustment, that is, applying the wage index budget-neutrality adjustment to the wage index values for the composite rate portion of the blended payment and applying the wage index budget-neutrality adjustment to the ESRD PPS base rate for the PPS portion of the blended payment and the ESRD PPS payment, and for the reasons we discussed previously, we are finalizing those policies.

a. Reduction to the ESRD Wage Index Floor

The wage index floor for CY 2011 is 0.600 (75 FR 49116 and 49117 and 75 FR 73487). For CY 2012 and CY 2013, we proposed to continue to reduce the wage index floor by 0.05 for each of the remaining years of the transition (that is, for CY 2012, the wage index value would be reduced from 0.600 to 0.550, and further reduced to 0.500 for CY 2013) (76 FR 40510). The ESRD wage index floor value of 0.550 would be applied to areas with wage index values that are below the proposed wage index floor. Beginning January 1, 2014, we proposed that the wage index floor would no longer be applied because the wage index floor would be lower than areas with low wage index values. In the CY 2012 ESRD PPS proposed rule, we stated that we continue to believe that a gradual reduction in the floor is needed to support continuing patient access to dialysis in areas that have low wage index values, especially in areas where the wage index values are below the current wage index floor—specifically, ESRD facilities located in Puerto Rico (76 FR 40510). We solicited comments on the proposal to continue to gradually reduce the wage index floor in CYs 2012 and 2013 and, the elimination of the floor in CY 2014. The comments we received and our responses are set forth below.

*Comment:* Three commenters responded regarding our proposal to reduce and eventually eliminate the wage index floor. One commenter requested that the wage index floor be maintained for rural dialysis facilities due to their higher staffing costs, which could aggravate disparities in care and might impair access to care in rural areas. One independent ESRD facility indicated that the reduction of the wage index floor threatens facilities with low wage index values and may result in access to care problems. One ESRD organization requested that we reconsider establishing a wage index floor after the transition because the commenter believes that eliminating the floor would be detrimental to small dialysis organizations (SDOs). The commenter also stated that some small facilities are located in a single community and, as such, are not able to spread their operating costs as larger organizations. The commenter further stated that these facilities are in parts of the country where the wage index is lowest, and the absence of a floor threatens their survival and negatively impacts access to care.

*Response:* In the proposed rule, we proposed to reduce the floor by 0.05 for CYs 2012 and 2013 and to eliminate the floor beginning in 2014 (76 FR 40509 through 40510). We have been reducing the wage index floor since CY 2006 when ESRD facilities began to transition

to the CBSAs and the wage index floor was 0.900 (70 FR 45799). We have reduced the wage index floor by 0.05 each year since then. In CY 2011, the floor is 0.600 and only impacts ESRD facilities located in Puerto Rico, because no other ESRD facilities are located in areas with a wage index value below 0.600. This is also the case in CY 2012, when the 0.05 reduction will bring the floor to 0.550. We continue to believe that artificially adjusting wage index values by substituting a wage index floor is not an appropriate method to address low wages in certain geographic locations. However, we are willing to take the points made by the commenters into consideration for future rulemaking with regard to the issue of eliminating the wage index floor in the future.

With regard to the comment that small facilities are located in areas with the lowest wage index values and the negative effects of eliminating the floor, we note that the commenter is located in West Virginia and in CY 2011, has a wage index value of 0.7055, well above the wage index floor of 0.600. Therefore, the reduction of the floor does not impact this provider. With regard to areas that are impacted by the reduction of the wage index floor (that is Puerto Rico), we note that the overall impact (discussed in section VII.B of this final rule) of the changes in the outlier policy discussed in section I.C.10 of this final rule and the wage index results in a 0.3 percent increase in estimated payments. Therefore, we do not believe that ESRD facilities will be negatively impacted by the reduction in the wage index floor. We note that the wage index values reflects\ hospital wages, unadjusted for occupational mix. Therefore, we believe it reflects ESRD facility staff wages. With regard to the comment that some small facilities are located in a single community and, as such, are not able to spread their operating costs as larger organizations can, we do not understand the relationship between the wage index floor and limitations a facility may have to spread its operating costs.

After considering the comments received, we are finalizing the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.550 and a wage index floor of 0.500, respectively. Although we continue to believe that artificially adjusting the wage index value using a floor, which does not reflect actual wages paid in that area, we will reconsider the floor in CY 2014.

b. Policies for Areas With No Hospital Data

In CY 2006, while adopting the CBSA designations for the basic case-mix adjusted composite payment system, we identified a small number of ESRD facilities in both urban and rural areas where there are no hospital data from which to calculate wage index values. Since there were ESRD facilities in these areas, we developed policies for each of these areas. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the methodology we have used for urban areas with no hospital data, that is, we compute the average wage index value of all urban areas within the State and use that value as the wage index. We also finalized the methodology established for rural areas with no hospital data originally adopted in the CY 2008 PFS final rule (72 FR 66283), in which we computed the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. For rural Massachusetts, we determined that the borders of Dukes and Nantucket Counties are continguous with Barnstable and Bristol counties. Under the methodology, the values for these counties are averaged to establish the wage index value for rural Massachusetts. For rural Puerto Rico, we finalized a policy to use the wage index floor as the wage index value, since all rural Puerto Rico areas were subject to the floor.

In the proposed rule, we did not propose to change these methodologies. We proposed for CY 2012 and for future years, to continue to use the methodologies we adopted for establishing wage index values in both urban and rural geographic areas where there are no hospital wage data from which to calculate wage index values for ESRD facilities (76 FR 40510).

We did not receive any comments on our proposed methodology for computing a wage index value for areas without hospital data for urban and rural geographic areas, or for Puerto Rico. Therefore, for CY 2012 and future years, we are finalizing our methodologies for computing a wage index value for areas without hospital data for urban and rural geographic areas and for Puerto Rico. For urban areas, we will compute the average wage index value of all urban areas within the State; for rural areas, we will compute the wage index using the average wage index values from all contiguous CBSAs; and for rural Puerto Rico, we will use the wage index floor.

c. Wage Index Budget-Neutrality Adjustment

We have broad discretion under section 1881(b)(14)(D)(iv)(II) of the Act to develop a geographic wage index. In addition, that section cites the wage index under the basic case-mix adjusted composite payment system as an example. We have previously interpreted the statute for the basic case-mix adjusted composite payment system (section 1881(b)(12)(D) of the Act) as requiring that the geographic adjustment be made in a budget-neutral manner. In CY 2011, we did not apply a wage index budget-neutrality adjustment factor under the ESRD PPS because budget-neutrality was achieved through the overall 98 percent budget-neutrality requirement in section 1881(b)(14)(A)(ii) of the Act.

Given our authority to develop a wage index under section 1881(b)(14)(D)(iv)(II) of the Act, as well as the authority to use the geographic index under section 1881(b)(12)(D) of the Act, we proposed to apply the wage index in a budget-neutral manner under the ESRD PPS using a wage index budget-neutrality adjustment factor (76 FR 40510). However, as we discuss in greater detail below, we proposed that under the ESRD PPS, we would apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

Under the basic case-mix adjustment composite payment system, we began applying the wage index budget-neutrality adjustment factor in CY 2006 (70 FR 70171). During the ESRD PPS transition, we proposed to continue to apply the wage index budget-neutrality adjustment to the wage index values for the composite rate portion of the ESRD PPS blended payment for CYs 2012 and 2013 (76 FR 40510). We noted that continuing to apply the budget-neutrality adjustment to the wage index for the composite rate portion of the ESRD PPS blended payment allows ESRD facilities going through the transition to continue to use a methodology to which they are accustomed.

However, under the ESRD PPS, we believed that applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate would be consistent with the application of the wage index budget-neutrality adjustment factor in other prospective payment systems. We also believed that applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate is simpler and more straightforward in application and calculation. Applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate produces results that are not measurably different from applying the adjustment factor to the wage index, as is done for the composite rate portion of the blended payment during the transition. We sought

comment on our proposal to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate for purposes of the ESRD PPS payments and the ESRD PPS component of the blended payments during the transition.

We did not receive any comments on our proposal to apply the wage index budget-neutrality adjustment to the ESRD PPS base rate and to continue to apply the wage index budget-neutrality adjustment to the wage index values for the composite rate portion of the blended payment. Therefore, for CY 2012 and subsequent years, we are finalizing our proposal to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate for the purposes of the ESRD PPS payments and the ESRD PPS portion of the blended payment during the transition. We are also finalizing our proposal to continue to apply the wage-index budget-neutrality adjustment factor directly to the ESRD wage index values for the composite rate portion of the blended payment for CY 2012 and CY 2013.

Because the ESRD wage index is only applied to the labor-related portion of the composite rate, we computed the wage index budget-neutrality adjustment factor based on that portion. That is, the labor-related share of the composite rate portion of the blended payment of 53.711 percent. This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the 2005 PFS final rule (70 FR 70168). The labor-related share of the ESRD PPS is 41.737 percent labor (that is, the portion of the ESRD PPS payment rate and the ESRD PPS portion of the blended payment). As discussed in the CY 2011 ESRD PPS final rule (75 FR 49161), we used the 2008-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities under a bundled system. Under the ESRDB market basket, the labor-related share for ESRD facilities is 41.737. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the weight for Professional Fees and, 46 percent of the weight for Capital-related Building and Equipment expenses.

To compute the proposed CY 2012 wage index budget-neutrality adjustment factors, we proposed to use the fiscal year (FY) 2012 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2010 outpatient claims (paid and processed as of December 31, 2010), and geographic location information for each facility which, may be found through Dialysis Facility Compare (76 FR 40510–40511). Dialysis Facility Compare can be found at the Dialysis Facility Compare Web page on the CMS Web site at *http://www.cms.hhs.gov/DialysisFacilityCompare/*. The FY 2012 hospital wage index data for each urban and rural locale by CBSA may also be accessed on the CMS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp*. The wage index data are located in the section entitled, ''FY 2012 Final Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA.''

We did not receive any comments on the methodology used to compute the budget-neutrality adjustment factors. Therefore, for CY 2012 and beyond, we are finalizing the methodology we proposed for computing the CY 2012 wage index budget-neutrality adjustment factors (76 FR 40510 and 40511). Using treatment counts from the 2010 claims and facility-specific CY 2011 payment rates, we computed the estimated total dollar amount each ESRD facility would have received in CY 2011. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2012. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final ESRD wage index for CY 2012. The total of these payments becomes the new CY 2012 amount of wage-adjusted payment rate expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by the new CY 2012 amount), we calculated two wage index budget-neutrality adjustment factors that, when multiplied by the applicable CY 2012 estimated payments, would result in aggregate payments to ESRD facilities that would remain budget-neutral when compared against the target amount of payment rate expenditures. The first factor was applied to the ESRD PPS base rate. The second factor was applied to the wage index values for the composite rate portion of the blended payment. Therefore, in this final rule, we are finalizing for CY 2012, the wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.002830, which is applied directly to the ESRD wage index values. For the ESRD PPS (that is, for the full ESRD PPS payments and the ESRD PPS portion of the blended payments during the transition), we are finalizing the wage index budget-neutrality adjustment factor of 1.001520 which is applied to the ESRD PPS base rate. Under the ESRD PPS, the wage index floor for CY 2012 is 0.550 because the wage index budget-neutrality adjustment factor is applied to the base rate.

As we indicated in the proposed rule (76 FR 40511), because we apply the wage index budget-neutrality adjustment factor to the wage index values to ensure budget-neutrality under the composite rate portion of the blended payment, we also apply the wage index budget-neutrality adjustment factor to the wage index floor. We note this would apply to areas in Puerto Rico subject to the floor. Therefore, for the composite rate portion of the blended payment, we are finalizing for CY 2012 to apply the wage index budget-neutrality adjustment factor to the wage index floor of 0.550 which results in an adjusted wage index floor of 0.552 ($1.002830 \times 0.550$).

d. ESRD PPS Wage Index Tables

The CY 2012 ESRD wage index tables, referred to as Addendum A (ESRD facilities located in urban areas), and Addendum B (ESRD facilities located in rural areas) are posted on the CMS Web site at: *http://www.cms.gov/ESRDPayment/PAY/list.asp*. The wage index tables list two separate columns of wage index values. One column represents the wage index values for the composite rate portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. The other column lists the wage index values for the ESRD PPS, which does not reflect the application of the wage index budget-neutrality adjustment factor, because as we discussed above, we apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

8. Drugs

a. Vancomycin

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49052), we stated that antibiotics used for the treatment of venous access infections and peritonitis, are renal dialysis services under the ESRD PPS. Payments for anti-infective drugs in injectable forms (covered under part B) and oral or other forms of administration (formerly covered under part D) used in the treatment of ESRD, were included in computing the final ESRD PPS base rate and, would not be separately paid under the ESRD PPS. We also noted that the oral versions of vancomycin are not used for ESRD-related conditions and, therefore, would not be considered a renal dialysis

service. We further stated that any anti-infective drug or biological used for the treatment of ESRD-related conditions would be considered a renal dialysis service and, not eligible for separate payment. We noted this policy also applies to any drug or biological that may be developed in the future. We established edits to ensure that separate payment could not be made to ESRD facilities for vancomycin which has traditionally been used by ESRD facilities to treat access infections.

In the proposed rule (76 FR 40511), we acknowledged that since the publication of the CY 2011 ESRD PPS final rule, we had received numerous comments indicating that vancomycin is indicated in the treatment of both ESRD and non-ESRD conditions, such as skin infections. We further stated that after consultation with our medical experts, we concurred with the commenters. Therefore, we proposed to eliminate the restriction on vancomycin to allow ESRD facilities to receive separate payment by placing the AY modifier on the claim for vancomycin when furnished to treat non-ESRD-related conditions. In accordance with ICD–9 guidelines, as described in the ESRD PPS final rule (75 FR 49107), the ESRD facility would also be required to indicate the diagnosis code for which the vancomycin is indicated. We noted that treatment of any skin infection that is related to renal dialysis access management would be considered a renal dialysis service and would continue to be paid under the ESRD PPS, and no separate payment would be made. We sought public comments on our proposal to eliminate the restriction on vancomycin to allow ESRD facilities to receive separate payment for these drugs when furnished to treat non-ESRD-related conditions. The comments we received and our responses are set forth below:

*Comment:* Two commenters suggested that we allow for separate payment for daptomycin when furnished by ESRD facilities for non-ESRD related conditions.

*Response:* We thank the commenter for the suggestion to allow for separate payment of daptomycin when used for non-ESRD related conditions. As noted above, we had established system edits to ensure that ESRD facilities could not be paid separately for both vancomycin and daptomycin. We will consider removing the system edit for daptomycin in future rulemaking.

*Comment:* We received six comments in support of our proposal to eliminate the restriction on vancomycin and allow for separate payment when furnished for non-ESRD-related conditions.

*Response:* We thank the commenters for their support. Consequently, in this final rule we are finalizing the proposal to eliminate the restriction on vancomycin to allow ESRD facilities to receive separate payment by placing the AY modifier on the claim for vancomycin when furnished to treat non-ESRD related conditions. In accordance with ICD–9 guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), the ESRD facility must indicate the diagnosis code for which the vancomycin is indicated. We reiterate that treatment of any skin infection that is related to renal dialysis access management would be considered a renal dialysis service and would continue to be paid under the ESRD PPS, and no separate payment would be made.

b. Drug Overfill

In the CY 2011 PFS final rule (75 FR 73466), we explained the methodology for Part B payment for drugs and biologicals that include intentional overfill, and that the Medicare average sales price (ASP) payment limit is based on the amount of drug conspicuously indicated on the labeling approved by the Food and Drug Administration (FDA). We indicated that we had become aware of situations where manufacturers intentionally included a small amount of overfill in drug containers, and that this overfill is provided at no extra charge to the provider. We also noted that we understood the intent of the intentional overfill was to compensate for product loss during the proper preparation and administration of a drug. We explained that ASP calculations are based on data reported by manufacturers, including ''volume per item''. Therefore, providers may only bill for the amount of drug product actually purchased and the cost that the product represents (75 FR 73467).

We stated in the proposed rule (76 FR 40511) that this part B provision applies under the ESRD PPS. We explained that ESRD facilities receiving blended payments under the transition would receive payments based on ASP for separately billable ESRD drugs and biologicals for the composite rate portion of the blend. In addition, under the ESRD PPS outlier policy, the ESRD-related drugs that ESRD facilities report on claims are priced for the outlier policy using ASP prices. Therefore, ESRD facilities may only report units and charges for drugs or biologicals actually purchased.

*Comment:* Three commenters expressed concern that the drug overfill policy was not appropriate under the ESRD PPS. One commenter stated that the use of overfill is an efficient operation and expressed concern that the new policy would lead to excessive wastage. A commenter disagreed with our assertion that overfill is provided by manufacturers without charge to the provider and stated that there would be additional costs if facilities are not allowed to maximize drug usage. The commenter believes the cost to providers includes the full amount of drug in each vial. One commenter stated that dialysis providers may and should administer overfill if clinically appropriate to reduce costs and waste. The commenter cited the administration of EPO as an example. One commenter stated that, ''* * * providers have been purchasing drugs with overfill amounts and use of the overfill amount has long been known by both the Office of Inspector General (OIG) and CMS.''

*Response:* We disagree with the commenters that believe our proposal would restrict the clinical use of intentional overfill. As we indicated in the CY 2011 PFS final rule (75 FR 73467), our policy here is not intended to limit the use of intentional overfill during the care of beneficiaries or in medical practice; such measures are beyond CMS' authority. Rather, the proposed rule merely set forth how and under what conditions we would make payment under the ESRD PPS outlier policy. Consistent with prior rulemaking, under our authority in section 1881(b)(14)(D)(ii) of the Act, we are adopting the ASP policy on overfill for purposes of calculating the outlier payment. We believe the use of the ASP policy for purposes of calculating the outlier payment is appropriate because, for the reasons stated, we believe overfill does not represent a cost to the facility; thus, overfill should not factor into our determination of outlier payments. This rule does not purport to regulate the use of overfill, only whether it is reimbursed under our outlier policy and the composite rate portion of the blended payment during the transition. Thus, whether we or the OIG had information about certain providers' purchase and use of overfill is irrelevant.

*Comment:* A large dialysis organization indicated that the drug overfill policy should not apply to ESRD facilities because the ASP payment regulation applies to drugs ''not paid on a cost or prospective payment system basis.'' The commenter contends it would not apply under the ESRD PPS even though outlier eligible drugs are priced using the ASP prices established under section 1847A of the Act. The commenter stated that CMS cannot

substitute the ASP method for a portion of the ESRD PPS. The commenter further contends that because dialysis providers may administer overfill, but CMS's proposal would prohibit them from submitting a claim that includes overfill, it appears that CMS expects providers either to inaccurately state the services furnished on the claims form or incur significant expense to separately track overfill amounts, which may be used for thousands of patients daily, resulting in unnecessary burden. The commenter opined that applying the ASP payment rule under the ESRD PPS is inconsistent with the policy objectives of a PPS leading to wastage if facilities continue to use single-use vials or extra expenses if facilities migrate to multi-dose vials.

*Response:* We disagree with these comments. First, as noted above, we proposed to incorporate into our outlier policy the policy for overfill under the ASP methodology; however, our authority to determine an outlier policy is found in section 1881(b)(14) of the Act, which calls for a prospective payment basis for renal dialysis services and authorizes an outlier payment adjustment. Thus, contrary to the commenter's assertion, we are paying for drugs subject to the ESRD PPS outlier policy under a prospective payment system, not under section 1847A of the Act. Under the outlier policy, we use the ASP methodology, which is based upon manufacturer reporting of the labeled amount of a drug and not any other amount (that is, overfill amount). Therefore, we are establishing that the ESRD PPS outlier policy does not include an amount for overfill. Further, the outlier policy was designed to provide additional payments for high cost patients. To the extent a patient receives drug amounts at no cost to the facility (that is, overfill amounts), that amount may not be attributed to the cost of that patient. Finally, because we are continuing to pay under the composite rate portion of the blended payment for separately billable drugs using the ASP payment methodology, we should continue to utilize the methodology for pricing drugs for the outlier policy.

Second, the commenter's contention about the scope of the ''incident to'' benefit reflects a misunderstanding of our proposal. We refer the commenter to discussion of the overfill policy in the CY 2011 PFS final rule (75 FR 73469), where we stated that our ASP overfill policy is not based on the ''incident to'' rules, but rather applies to all drugs and biologicals paid under section 1847A of the Act, regardless of setting. The ''incident to'' rules are similarly irrelevant to our proposal here. Our policy pertains only to how and whether we pay for drugs under our outlier policy under authority of section 1881(b)(14)(D)(ii) of the Act.

Third, we disagree with the commenters that our policy will require ESRD facilities to inaccurately reflect the services they furnish. We expect that providers will continue to maintain accurate medical records for all beneficiaries as well as accurate inventory records of all drugs that were actually purchased and appropriately billed to Medicare. We acknowledge that separate tracking of overfill may increase burden on ESRD facilities that were not doing so before. However, given that we have adopted ASP policies generally for outliers under the ESRD PPS and we rely on data reported under the ASP methodology to determine the outlier thresholds, even if we believed overfill were something other than free product, we would have no ability to account for it separately.

Finally, we disagree that our policy is inconsistent with waste reduction. As noted above, our policy does not apply to the use of overfill; rather, it applies only to whether we pay for overfill under our outlier policy. ESRD facilities remain free to take steps to reduce drug wastage and in doing so, reduce their costs in providing ESRD services—our policy only prevents an ESRD facility from accounting for something for which it incurred no cost in determining whether it met the high cost outlier policy.

We are finalizing our proposal to incorporate the ASP overfill policy into our outlier policy and for purposes of the composite rate portion of the blended payment during the transition. Thus, ESRD facilities may only report units and charges for drugs and biologicals actually purchased.

9. Revisions to Patient-Level Adjustment for Body Surface Area (BSA)

Under section 1881(b)(14)(D)(i) of the Act, the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into account patient weight, body mass index (BMI), body surface area (BSA), and other appropriate factors. In the proposed rule (76 FR 40511 and 40512), we explained that we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size: BSA and BMI. We further explained that both body size measures are strong predictors of variation in payment for ESRD patients. As a result, in developing the ESRD PPS, we established a case-mix patient level adjustment for BSA that would be applied to each 0.1 m2 change in BSA compared to the national average.

In the proposed rule (76 FR 40511 and 40512), we proposed to make one change related to the use of the national BSA average value used in the calculation of the BSA adjustment applied to the composite rate portion of the blended payment during the transition. This change was necessary because we believe that the BSA national average used to compute payment under the composite rate portion of the blended rate and under the ESRD PPS should be both the most recent and consistent measurement available. We further explained that for CY 2011, the BSA adjustment we calculated for the composite rate portion of the blended payment used the BSA national average of 1.84, which reflected the average among Medicare dialysis patients in 2002. However, the BSA national average we used for computing the BSA under the ESRD PPS was 1.87, which reflected the national average among Medicare dialysis patients in 2007. We did not realize that we had used 2 different national averages in CY 2011, nor was it brought to our attention during the comment period. For CY 2012 and in subsequent years, we proposed to use one national average for computing the BSA under the composite rate portion of the blended payment during the transition and under the ESRD PPS.

In the CY 2004 PFS final rule (69 FR 66329), we explained that the BSA factor was defined as an exponent equal to the value of the patient's BSA minus the reference. For example, for a beneficiary with a BSA of 1.94, using the CY 2011 national average of 1.84 under the composite rate would yield a BSA adjustment factor of 1.0370. For the same patient, using the national average of 1.87 used for the CY 2011 ESRD PPS BSA computation would yield a BSA adjustment factor of 1.0258. A ratio or proportional difference of 1.0258 divided by 1.0370 equals .9892 difference the between the two BSA adjustment factors. This corresponds to a reduction of 1.08 percent ($1 - 0.9892 = 0.0108$) in the composite rate payment for adult patients by increasing the BSA reference value from 1.84 to 1.87.

In Table 3 of the proposed rule (76 FR 40512), we showed the impact of increasing the composite rate BSA reference value from 1.84 to 1.87 for each year from 2011 to 2014, on facility payments for ESRD facilities going through the transition. The impact on facility payments are greatest in 2011, where the blended payment during the transition period is weighted more

heavily towards the basic case-mix adjusted composite payment system, and declines through 2014 when there is no impact on facility payments under a fully implemented PPS.

Therefore, for CY 2012, we proposed to use the latest national average (that is, 1.87) as the reference point for the computation of the BSA adjustment for both the composite rate portion of the blended payment and for the ESRD PPS (76 FR 40512). We also proposed to review the BSAs on CY 2012 claims (and every 5 years thereafter) to determine if any adjustment to the national average would be required in the future. We sought comments on these proposals. The two comments we received and our responses are set forth below:

*Comment:* One organization that represents small dialysis organizations supported the proposals to use the 1.87 reference point for computing the BSA and to review the BSA calculation every five years. One independent ESRD facility opposed the change in the reference point stating that it will negatively impact facilities that opted to receive payment under the transition because it will reduce the composite rate payment. The commenter referenced the table in the proposed rule that displays the negative effect.

*Response:* We thank the national organization for its support of our proposals and appreciate the concerns expressed by the ESRD facility. We regret that we had not identified the discrepancy in the values used in the CY 2011 ESRD PFS and CY 2011 ESRD PPS final rules. However, as we indicated in the CY 2012 proposed rule, we believe the change is necessary because the BSA national average used to compute the composite rate portion of the blended payment and under the ESRD PPS should be both the most recent and consistent measurement available.

After considering the public comments and for the reasons noted above, in this final rule, for CY 2012, we are finalizing our proposal to use the BSA national average of 1.87, which is the latest national average, as the reference point for the computation of the BSA adjustment for both the composite rate portion of the ESRD PPS blended payment and for the ESRD PPS. We are also finalizing our proposal to review the BSA national average on the CY 2012 claims and every 5 years thereafter to determine if any adjustment to the national average will be required in the future.

10. Revisions to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. In the CY 2011 ESRD PPS final rule, we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item on the monthly claim (75 FR 49142).

Medicare regulation § 413.237(a)(1) provides that ESRD outlier services include: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare part B; (3) medical/surgical supplies, including syringes used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs. Drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, issued August 20, 2010 under Transmittal 2033. Transmittal 2033 was rescinded and replaced by Transmittal 2094, dated November 17, 2010. The replacement document involved the (1) Deletion of several drugs; (2) identified drugs that may be eligible for ESRD outlier payment; (3) provided a list of laboratory tests that comprise the AMCC tests; (4) deleted several laboratory tests; and (5) included the latest version of the ESRD PRICER layout file. Transmittal 2094 was subsequently rescinded and was replaced by Transmittal 2134 issued January 14, 2011. That transmittal was issued to correct the subject on the transmittal page and made no other changes.

Medicare regulations at § 413.237(a)(2) through (a)(6), and (b) specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with § 413.237(c) of the regulation, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

a. Revisions Related to Outlier ESRD Drugs and Biologicals

Attachment 3 of Change Request 7064 issued August 20, 2010 under Transmittal 2033, as modified by Transmittal 2094 issued November 17, 2010 and Transmittal 2134 issued January 14, 2011, specified the former separately billable Part B drugs that are recognized as ESRD-related eligible outlier services and, the former Part D drugs by National Drug Code (NDC) for the three vitamin D analogues (calcitriol, paracalcitol, and doxercalciferol) and levocarnitine that are recognized as eligible outlier service drugs.

In the proposed rule (76 FR 40513), we indicated that we had intended to update both the lists of former part B drugs and biologicals and former part D drugs that are outlier services (75 FR 49138). However, we concluded that any CMS prepared lists of drugs and biologicals recognized as outlier services may be difficult to keep up-to-date. We recognized that this is attributed to the lag in the receipt of claims data; changes in ESRD practice patterns; and inadvertent omissions and oversights. Because the regulation defines eligible outlier service drugs, we believe there is no need for CMS to issue a list of former separately payable part B ESRD outlier services drugs. Furthermore, because the list of drugs is

derived from paid ESRD claims, it would not be comprehensive, completely represent drugs and biologicals furnished to ESRD patients, accurate, or up-to-date. We noted that, consistent with current policy, all composite rate drugs, as defined in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, would not be eligible for an outlier payment, as these drugs would not have been separately paid under Part B or Part D prior to January 1, 2011, and do not meet the definition of outlier services. Consequently, we proposed to eliminate the issuance of a list of former separately payable Part B drugs and biologicals that would be eligible for outlier payments. Accordingly, we solicited public comments on our proposal to eliminate the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011.

The comments on our proposal and our responses are summarized below.

*Comment:* Two national associations supported the proposal to eliminate the drug and biological list. Both commenters supported the creation of a list through guidance. One commenter indicated that the list would maintain transparency, but recognized that this would create a rulemaking burden. The commenter further requested that CMS ensure that process remains transparent and subject to input from stakeholders.

*Response:* We thank the commenter's for their support of our proposal. As we indicated, any CMS prepared lists of drugs and biologicals recognized as outlier services may be difficult to keep up-to-date due to the factors described above.

Because we are concerned that a failure to include a drug or biological on the outlier services list will negatively impact ESRD facilities by limiting the drugs eligible for the outlier policy, in this final rule, we are finalizing the proposal to eliminate the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare part B prior to January 1, 2011. However, under separate guidance, we plan to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services.

With respect to the comment regarding transparency, we recognize the need to be transparent and have sought input from stakeholders. We believe that we have been transparent by the inclusion of proposed changes to outlier drugs and biologicals under the ESRD PPS in the proposed rule, (76 FR 40513 and 40514) and our request for comments.

Under current policy, antibiotics furnished in the home are considered to be composite rate drugs and therefore, not eligible for outlier payment. In the proposed rule (76 FR 40513), we discussed that Pub. 100–02, chapter 11, section 30.4.1 lists the drugs covered under the composite rate. The list includes a statement that antibiotics when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis are considered composite rate drugs. Because composite rate drugs and their administration (both the staff time and the supplies) are covered under the composite rate, antibiotics furnished in the patient's home used for the reasons noted above may not be billed and paid separately. However, antibiotics furnished in an ESRD facility are considered separately payable in accordance the Medicare Claims Processing Manual, Pub. 100–04, chapter 8, section 60.2.1.1.

We also noted that Pub. 100–02, chapter 11, section 50.9 states that an antibiotic used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis is covered as home dialysis supplies included in the Method II (Direct Dealing) payment cap for home dialysis supplies administered by the Durable Medical Equipment (DME) Supplier. Prior to January 1, 2011, under Method II, durable medical equipment suppliers received direct payment from Medicare for furnishing dialysis services to home dialysis patients. Effective January 1, 2011, as indicated in § 413.210(b) of the regulations, CMS does not pay any entity or supplier other than ESRD facilities for covered items and services furnished to a Medicare beneficiary. Therefore, payment to DME suppliers for antibiotics under Method II can no longer be made. Additionally, under the ESRD PPS, the dialysis facility is responsible for furnishing all renal dialysis services, regardless of the site of service. Under the ESRD PPS, there is no payment distinction made as to the site where a renal dialysis service is provided (that is, in the home or in a facility).

Therefore, in the proposed rule, (76 FR 40513 and 40514), we indicated that we did not believe that it would be appropriate to have a distinction in which antibiotics administered in an ESRD facility, used to treat an infection of the catheter or other access site, or peritonitis associated with peritoneal dialysis, would be considered as separately billable under the composite rate portion of the blended payment and eligible for outlier payments under the ESRD PPS, while antibiotics used at home by home patients for the same purpose would be considered to be included in the composite rate and not eligible for outlier payments. We proposed to eliminate the inclusion of antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as part of the composite rate drugs, and allow them to be separately paid under the composite portion of the blended payment for ESRD facilities receiving payment during the transition. We also proposed that antibiotic drugs used at home to treat catheter site infections or peritonitis associated with peritoneal dialysis would be eligible as ESRD outlier services. Antibiotics furnished in facility would continue to be recognized as ESRD outlier services.

We solicited comments on our proposal. The comments and our responses are summarized below.

*Comment:* One national association and one dialysis organization agreed with the proposal that home antibiotics to treat catheter site infections or peritonitis associated with peritoneal dialysis would qualify as eligible for outlier payment.

*Response:* We thank the commenter for their support.

In this final rule, we are finalizing the proposal to recognize antibiotics furnished in the home to treat catheter site infections or peritonitis associated with peritoneal dialysis as eligible for outlier payment. We believe the inclusion of antibiotics used by home dialysis patients as outlier services will reduce confusion over drugs and biologicals that are eligible outlier services and eliminate the distinction in the eligibility of a drug for outlier eligibility based on where it is furnished. As new drugs emerge, we intend to update the HCPCS codes corresponding to new drugs and biologicals for billing purposes, and to determine whether any of those drugs would have been considered to be composite rate drugs. Drugs and biologicals which were or would have been considered composite rate drugs are not eligible ESRD outlier services under § 413.237.

In the proposed rule (76 FR 40514), we proposed two modifications to the computation of the separately billable MAP amounts used to calculate outlier payments for the reasons described below. We explained that subsequent to the publication of the CY 2011 ESRD PPS final rule, our clinical review of the

2007 ESRD claims used to develop the ESRD PPS revealed that dialysis facilities routinely used alteplase and other thrombolytic drugs for access management purposes. Under the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, drugs used as a substitute for any of the listed items, or are used to accomplish the same effect, are covered under the composite rate. Because heparin is a composite rate drug and could be used for access management, any drug or biological used for the same purpose may not be separately paid. Because outlier payments are restricted under § 413.237(a) to those items or services that were or would have been considered separately billable prior to January 1, 2011, we proposed to recalculate the average outlier services MAP amounts to exclude these composite rate drugs (that is, we proposed to exclude thrombolytics from the computation).

We also explained in the proposed rule that in developing the outlier service MAP amounts for 2011, we excluded testosterone and anabolic steroids. We subsequently learned from discussions with clinicians and ESRD facilities, that these drugs can be used for anemia management. Because drugs used for anemia management in ESRD patients were or would have been considered separately billable under Medicare part B, these drugs would be considered outlier services under § 413.237(a)(1). Consequently, we have recomputed the outlier service MAP amounts for CY 2012 to include these drugs. As shown in Table 2, when comparing the outlier service MAP amounts based on the current definition of ESRD outlier services to the revised ESRD outlier definition, the net effect of these two revisions (the exclusion of thrombolytic drugs and inclusion of anabolic steroids) results in an decrease to the outlier service MAP amounts by $4.00 for adult patients and a decrease of $0.50 for pediatric patients.

We solicited comment on the two modifications to the computation of the separately billable MAP amounts used to calculate outlier payments we proposed. The comments received and our responses are set forth below.

*Comment:* We received several comments opposing the proposal to exclude thrombolytic drugs used for access management from the outlier services MAP amounts and therefore, not eligible for outlier payments. One national organization believes that there should be a longer experience with the use of thrombolytics under a bundled system before excluding them from outlier payments. The commenter stated that when properly used, these agents may help avoid unnecessary (and expensive) access procedures and interventions. The commenter further believes that the outlier payment policy could adversely impact their proper use and lead to greater vascular access procedures outside of the dialysis unit and could be ''detrimental to patients' outcomes.''

*Response:* We do not understand the value that longer experience with the use of thrombolytics under a bundled system before excluding them from the outlier policy would provide. We believe that the determination the furnishing of a drug should be based upon the patient's needs and remain independent of the outlier policy. We believe that maintaining vascular access is a renal dialysis service and ESRD facilities would continue to be responsible for furnishing the service. We also expect that ESRD facilities would refer patients to another setting if medically necessary and we would not expect ESRD facilities to address any and all vascular access complications if doing so would be unsafe.

With regard to the comment about proper use of thrombolytics, the efficacy or merit of thrombolytics is not in question with their exclusion from the outlier policy. We believe that the ESRD PPS provides an opportunity for ESRD facilities to make decisions based on the medical need of patients and not on the basis of financial gain. That is, under current policy, a facility may choose to use a thrombolytic (alteplase) because those drugs are eligible under the outlier policy, rather than using an anticoagulant (heparin) which is not eligible. By no means are we implying that thrombolytics or any access management drug should not be used when clinically indicated. But rather, we are saying that payment policy is not intended to dictate, determine, or influence clinical practice or favor one course of treatment over another. It is intended to ensure that decisions are not made solely on the basis of financial gain but based on clinical judgment.

Finally, as we discussed above, the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, states that drugs used as a substitute for any of the listed items or are used to accomplish the same effect are covered under the composite rate. Because heparin is included in the composite rate and is used to ensure patency of an access site and proper flow during the dialysis treatment, as we discuss in greater detail below, we interpret this provision to mean that any drug used to ensure patency of an access site and proper flow during the dialysis treatment and, therefore, would be more properly considered a composite rate drug.

*Comment:* An independent ESRD facility noted that alteplase was separately billable under the composite rate and was not considered ''interchangeable with heparin''. The commenter further indicates that alteplase had been included in the CY 2011 MAP. Finally, the commenter indicated that the decision made by this facility to receive payment under the transition was made in part because alteplase was separately paid under the composite rate system and CMS included alteplase and other thrombolytics under the outlier policy.

*Response:* The commenter is correct that alteplase was separately billable under the composite payment system and was included in the CY 2011 MAP amounts for the outlier policy. Because we did not propose to alter that policy with regard to the composite rate portion of the blended payment and the policy was only discussed in the context of the outlier policy, we do not believe it would be appropriate to make the change at this time. Therefore, as indicated above, in CY 2012, thrombolytics furnished by an ESRD facility will continue to receive separate payment under the composite rate portion of the blended payment.

While we acknowledge that in the development of the ESRD PPS, alteplase was included in the computation of the MAP amounts and eligible for outlier payments, we proposed to rectify this situation in the proposed rule because we believe that making one access management drug eligible for outlier payment while making another ineligible should not exist. We also note that since heparin predated the use of thrombolytics in dialysis access patency and management and heparin was included in the composite rate, we believe that any drug or biological including other anticoagulants, thrombolytics or any other type of drug that may be used in the future for access patency and management would also be considered a composite rate drug.

*Comment:* One pharmaceutical company indicated that it did not promote the ''off-label'' use of alteplase in the dialysis setting. The commenter expressed concern that the proposed change for outlier payments for alteplase will provide a disincentive for appropriate vascular access practices and management, resulting in a negative effect on patients. The commenter stated that the manual cited in the proposed rule includes a list of specific drugs, heparin is listed but does not include alteplase or other thrombolytic. The

commenter further stated that the next section of the manual requires separate billing for thrombolytics used to declot central venous catheters. The commenter acknowledged that heparin and alteplase are used for access management, but the commenter maintained that does not mean that one substitutes for the other. One example provided by the commenter is that heparin has been used for 30 years as an anticoagulant to prevent the blood from clotting as it is being filtered through the dialyzer and states that the substitute for heparin flushing is saline, which may be contraindicated in the dialysis population due to potential blood pressure effects. The commenter further stated that alteplase is used as a salvage therapy when a catheter becomes dysfunctional due to presumed thrombosis. The commenter maintained that alteplase is the ''only thrombolytic currently marketed that can help lyse a clot and potentially restore blood flow to a poorly functioning catheter''. The commenter included Kidney Dialysis Outcomes Quality Initiative (KDOQI) guidelines that all catheters are ''locked'' with an anticoagulant such as heparin to prevent thrombosis. The commenter provided the physiological response to the heparin which they state could result in thrombus formation and further stated that the guidelines recommend thrombolytic therapy directed at salvaging the catheter before access replacement. The commenter cited the pharmacological and indication differences between the two drugs, as well as potential quality problems that they believe will occur with the proposed change Finally, the commenter distinguished between heparin and alteplase by indicating that patient care technicians (PCTs) administer intravenous heparin while alteplase is prescribed by a physician and cannot be administered by PCTs.

*Response:* We did not state in the proposed rule that alteplase was sometimes used off-label in the dialysis setting; however, we believe that the commenter may be referring to our statement that ESRD facilities routinely used thrombolytic drugs for access management purposes.

In the development of the ESRD PPS, we knew that alteplase and heparin were pharmacologically different (that is, one is a thrombolytic lysing clots and the other is an anticoagulant preventing clots, respectively). However, we believe that both drugs enable the catheter or graft to function either through clot prevention or clot degradation and provide effective dialysis vascular access. We are aware that heparins and thrombolytics have a different mode of action, with heparin preventing thrombosis and thrombolytics lysing a thrombus after it has formed. We are also aware that formation of a thrombus in or around the tip of central venous catheters used for dialysis is one reason for catheter dysfunction. Appropriate use of heparin by dialysis facilities can prevent thrombus formation, thus reducing the likelihood of catheter dysfunction. Heparin use in dialysis has long been part of the ESRD composite payment system, is relatively inexpensive, and is widely used as an effective technique for primary prevention of hemodialysis catheter dysfunction. Thrombolytics (including alteplase), can be used to lyse or dissolve thrombus, restoring catheter function in some cases. These agents are very costly and, according to FDA package insert information, can result in significant bleeding complications. From the perspective of achieving a clinical result, maintenance of hemodialysis catheter function, either inexpensive primary prevention or costly intervention produces interchangeable results. We believe that payment policy should encourage achievement of the desired results in the most cost-effective manner, particularly when the prevention approach reduces risk to Medicare beneficiaries. We believe that the significant expenditures for thrombolytics suggests that there are ESRD facilities that may not be adequately applying established preventive methods (that is, use of heparin) to maintain hemodialysis catheter access. Inclusion of thrombolytics in the definition of outlier services and potentially making a facility eligible for outlier payments supports the continuation of this practice.

As for the statement about negative outcomes, we believe maintaining vascular access is a renal dialysis service and therefore, is included in the ESRD PPS. ESRD facilities are responsible for furnishing the service. We expect that ESRD facilities would not refer patients to another healthcare setting for the purpose of maintaining vascular access. We expect patients to be referred to another setting if medically necessary. We are not suggesting that ESRD facilities are expected to address any and all vascular complications, if doing so would be unsafe for the patient. Finally, as we indicated, we plan to monitor whether ESRD facilities are continuing to maintain vascular access as they currently perform.

With regard to the comment on the disincentive to use alteplase properly, as we noted above, payment policy is not intended to dictate, determine, or influence clinical practice. We believe that the policy that any drug or biological used for access management would not be considered eligible under the outlier policy (that is, excluding thrombolytics from the outlier policy), would support decision-making based on medical need and not based upon financial incentives. We believe that continuing to recognize expensive thrombolytics as outlier services for purposes of computing outlier payments for ESRD facilities could create perverse financial incentives to underutilize clot prevention techniques and overutilize clot lysis techniques in the course of vascular access maintenance by ESRD facilities.

The commenter is correct that Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, does not explicitly list alteplase or other thrombolytics as composite rate drugs; however, it does state that drugs used as a substitute for any of the listed composite items or are used to accomplish the same effect (that is, access patency) are covered under the composite rate. As we explained in previous responses, we believe that alteplase and other thrombolytic drugs are used for access management as is heparin, though we acknowledge that the physiological action is different. As we explained above, we based our decision to propose the elimination of thrombolytic drugs from outlier eligibility because both thrombolytics and anticoagulants are used to maintain the patency of the dialysis access site. We note that, at this point, we are not aware of another ESRD-related drug category which has some drugs covered under the composite while others in the category are separately billable.

For example, for the category of bone and mineral metabolism, there are various drugs that can be used. These drugs have the same outcome, but have different physiological actions to accomplish bone integrity; some are calcium or calcium analogues while others are phosphorus. The difference in the bone and mineral metabolism category is that all of the drugs were separately billable and therefore, eligible under the outlier policy. Another example is antihypertensives. There are many antihypertensive drugs which have the same clinical effect of lowering blood pressure, but how the effect is achieved differs. Beta blockers by blocking beta adrenergic receptors slow the heart rate and thereby reduce the force in which the heart muscle contracts leading to a decrease in blood pressure. Hydrochorothiazide increases the amount of water removed from the

blood, causing a decrease in blood pressure. Ace inhibitors prevent the conversion of ACE I and ACE II. ACE II causes the blood vessels to constrict. By preventing the conversion, the blood vessels dilate and lead to a decrease in blood pressure. Antihypertensives are in the composite rate.

The commenter is also correct that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.2 does list thrombolytics for declotting central venous catheters as being separately paid. We cannot address why this payment distinction was made under the composite rate payment system. However, we do not believe that allowing some drugs in a drug category (that is, for access management) to be eligible under the outlier policy while other drugs in the category are not is sound payment policy. Because a drug was paid separately under the composite rate system does not mean that it has to be eligible under the outlier policy under the ESRD PPS. We are not saying that thrombolytics should or should not be used as their use is a medical determination. We are merely saying that as a result of classifying drugs and biologicals into categories (for example, access management), thrombolytics would no longer be eligible under the outlier policy beginning January 1, 2012.

As we discussed earlier and in the CY 2011 ESRD PPS final rule (76 FR 49050), under the ESRD PPS, we did not provide a specific ESRD-related drug list because we recognized that drugs and biologicals change over time. That is the reason that we categorized drugs and biologicals based on function, such as access management. In that regard, heparin (and other clot prevention drugs) and thrombolytics such as alteplase, despite their pharmacological differences, are all categorized as access management drugs.). Because there may be other drugs and biologicals that may be used for access management in the future that may also have different physiological differences, we also stated that any drug or biological furnished for the purpose of access management will be considered a renal dialysis service under the ESRD PPS. In other words, even if a new drug has a physiological action that differs from anticoagulants (as heparin) or thrombolytics (as alteplase), but is used to maintain access patency, we would not consider such drug to be eligible under the outlier policy.

We disagree with the commenter's argument that patient care techs (PCTs) can administer heparin as part of standing orders while alteplase is prescribed by a physician implies that they should not be considered in the same category. We believe that any medication or any protocol used for dialysis is prescribed by a medical practitioner and that differences in who may administer a drug is not an appropriate distinction that should impact CMS payment determinations.. We are monitoring access management and will continue to do so.

We have not been convinced by the commenters that we should not implement the policy to exclude thrombolytic drugs from the outlier policy. Therefore, in this final rule, we are finalizing our policy to exclude thrombolytic drugs from the outlier policy and have recomputed the outlier MAP amounts to reflect this policy change. However, because we did not propose to exclude separate payment of thrombolytic drugs under the composite rate portion of the blended payment, separate payment will be made for thrombolytic drugs under the composite rate portion of the blended payment in CY 2012.

*Comment:* One national organization opposed the inclusion of testosterone and anabolic steroids in the anemia management category citing that it is not recognized as the standard of care. The commenter indicated that the forthcoming Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Anemia and CKD makes a strong (level 1B) recommendation that testosterone and anabolic steroids not be used. The commenter further states that the use of these drugs is not the recognized standard of care and the KDIGO guidelines would discourage the financial incentives associated with their use.

*Response:* We appreciate the concerns expressed by the commenter. The determination to include drugs in or exclude drugs from a category is made based on the overall effect of the drug. Standards of care and appropriate use of any item or service is not within the scope of payment policy. As we have indicated in responses to comments above, we expect that ESRD facilities will make decisions based on patient need and appropriateness of the items and services they furnish. That means we would not expect that a drug would be furnished for financial purposes but rather that the drug is medically necessary for the patient. We expect that medical practitioners will make prescribing decisions based on appropriate medical decision making. Finally, we believe that the renal community will work towards achieving the best medical practice. Nonetheless, we determined that such drugs were included in the 2007 claims (though the dollar amount was small) and as a result, proposed to modify the outlier policy.

Therefore, in this final rule, we are finalizing a policy to include testosterone and anabolic steroids that are used for anemia management as eligible outlier services and have recomputed the outlier MAP amounts to reflect this policy change.

b. Exclusion of Automated Multi-Channel Chemistry (AMCC) Laboratory Tests From the Outlier Calculation

Medicare regulations at § 413.237 provide that ESRD-related laboratory tests that were or would have been considered separately billable under Medicare part B prior to January 1, 2011, are eligible outlier services. Those laboratory tests were specified in Attachment 3 of Change request 7064 issued under Transmittal 2033, as modified by Transmittals 2094 and 2134. In the CY 2011 ESRD PPS final rule (75 FR 49135 through 49138), we indicated that in order to compute the outlier payment for laboratory tests, the 50 percent rule is required. In addition, because the 50 percent rule is necessary to calculate the composite rate portion of the blended payment during the transition period, we retained the 50 percent rule to determine whether Automated Multi-Channel Chemistry (AMCC) panel tests would be considered composite rate or separately billable for the ESRD PPS portion of the blended payment (75 FR 49137). The AMCC panel tests and an explanation of the 50 percent rule are identified in Pub. 100–2, chapter 11, section 30.2.2. ESRD laboratory billing rules can be found in Pub. 100.04, chapter 16, section 40.6.

The 50 percent rule provides that if 50 percent or more of covered laboratory tests comprising a panel of AMCC tests are included under the composite rate payment, then all submitted tests are included within the composite rate payment and, therefore, none of the laboratory tests are considered separately billable. Conversely, if less than 50 percent of the covered panel tests are composite rate tests, then all AMCC tests submitted for the date of service for that beneficiary are considered separately billable. In addition, Pub. 100–2, chapter 8, section 60.1 provides that an AMCC test that is a composite rate test, but is furnished beyond the normal frequency covered under the composite rate, is separately billable based on medical necessity.

We explained in the CY 2012 ESRD PPS proposed rule (76 FR 40514 and 40515), that after publication of the CY 2011 ESRD PPS final rule, we received

numerous requests to eliminate the 50 percent rule due to the commenters' assertions that they were confused about its application. Unlike specific drugs which are classified as either composite rate or separately billable for purposes of eligibility under the outlier policy as discussed above, AMCC laboratory tests may be classified as either composite rate or separately billable depending upon the application of the 50 percent rule or the frequency at which the laboratory test is ordered. Therefore, the determination of ESRD-related laboratory tests as eligible outlier services depends upon the number of panel tests furnished or their subsequent classification based on the application of the 50 percent rule.

Because the AMCC laboratory tests included as eligible under the outlier policy are determined by the 50 percent rule, and in the interests of administrative simplification and minimizing confusion, we proposed to eliminate use of the 50 percent rule for the outlier policy and exclude the 23 AMCC laboratory tests from the definition of ESRD outlier services and from the computation of outlier payments. We proposed that the elimination of the 50 percent rule for the AMCC panel tests under the ESRD PPS outlier payment policy would result in the de facto treatment of those tests as composite rate tests. Accordingly, we proposed to revise § 413.237(a)(1)(ii) of the regulations to exclude these laboratory tests from the definition of ESRD outlier services. The 50 percent rule would continue to apply, however, to AMCC laboratory tests for classification as either composite rate or separately billable for the purpose of computing the composite rate portion of the blended rate for ESRD facilities that elected to receive payments under the transition, because the transition period under the ESRD PPS would be time limited, and would expire when the transition period ends. This would occur because all in 2014 ESRD payments would be based 100 percent on the ESRD PPS and there would no longer be a need to maintain the distinction between composite rate and separately billable laboratory services for purposes of applying the 50 percent rule. The comments we received and our responses are set forth below:

*Comment:* Two commenters expressed support of the elimination of the 50 percent rule under the outlier policy. One renal dialysis organization welcomed the elimination of the 50 percent rule. However, the commenter indicated that, of the 23 AMCC tests, twelve were part of the composite rate prior to January 1, 2011. The commenter believes that the other eleven tests should not be considered part of the composite rate as they are not routinely performed for evaluation of ESRD. The commenter further explained that it is rare to see all eleven tests ordered on one patient.

*Response:* We thank the commenters for their support of our proposal to eliminate the 50 percent rule under the outlier policy. As we discussed in the proposed rule (76 FR 40514 through 40515), all 23 laboratory tests were included on the outlier list for the purpose of the 50 percent rule only. Under our proposal to eliminate the 50 percent rule from the outlier policy, the twelve composite rate laboratory tests in the AMCC panel would no longer be considered eligible under the outlier policy. Of the remaining 11 laboratory tests in the AMCC panel, the majority would not be considered ESRD related. Therefore, these tests are not eligible under the outlier policy.

Because we did not propose to alter that policy with regard to the composite rate portion of the blended payment and the policy was only discussed in the context of the outlier policy, we do not believe it would be appropriate to make the change at this time. Therefore, in CY 2012, we are retaining the 50 percent rule and the 23 AMCC laboratory tests for the composite rate portion of the blended payment during the transition, because the transition period under the ESRD PPS would be time limited, and will expire when the transition period ends.

In the preamble of the proposed rule (76 FR 40515), we proposed to revise § 413.237(a)(1)(ii) of the regulations to exclude these laboratory tests from the definition of ESRD outlier services. However, in the proposed regulation text of the proposed rule (76 FR 40550), we proposed revisions to § 413.237 by adding paragraph (a)(1)(v) to exclude these laboratory tests from the definition of outlier services. In this final rule, we are finalizing our proposal, but are finalizing the revision of § 413.237 by adding paragraph (a)(1)(v) to indicate that as of January 1, 2012, the laboratory tests that comprise the AMCC panel are excluded from the definition of outlier services.

c. Impact of Final Changes to the Outlier Policy

In the proposed rule (76 FR 40515 and 40516), we showed the impact of the proposed changes in the outlier policy which were to: (1) Exclude vascular access management drugs and include anabolic steroids as eligible outlier service drugs; and (2) exclude the 23 AMCC laboratory tests from the ESRD outlier services definition. In this final rule, we are finalizing the revised ESRD outlier services definition and changes to the outlier policy. The outlier services MAP amounts and fixed dollar loss amounts included in the proposed rule were based on 2009 data. In this final rule, we are updating the outlier services MAP amounts and fixed dollar loss amounts based on 2010 data. The impact of this update is shown in Table 2, which compares the outlier services MAP amounts and fixed dollar loss amounts in the proposed rule with the updated estimates for this final rule. All estimates in Table 2 were inflation adjusted to reflect projected 2012 prices for outlier services.

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**Table 2**
**Outlier policy: Impact of using updated data to define the outlier policy^**

| | Outlier policy in proposed rule (based on 2009 data price inflated to 2012)* | | Outlier policy for CY2012 (based on 2010 data price inflated to 2012)* | |
|---|---|---|---|---|
| | Age < 18 | Age >= 18 | Age < 18 | Age >= 18 |
| Average outlier services MAP amount per treatment[1] | $46.27 | $87.83 | $46.26 | $81.73 |
| Adjustments | | | | |
| Standardization for outlier services[2] | 1.0136 | 0.9728 | 1.0024 | 0.9738 |
| MIPPA reduction | 0.98 | 0.98 | 0.98 | 0.98 |
| Adjusted average outlier services MAP amount[3] | $45.96 | $83.73 | $45.44 | $78.00 |
| Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold[4] | $82.58 | $145.25 | $71.64 | $141.21 |
| Patient months qualifying for outlier payment | 5.0% | 5.5% | 5.7% | 5.4%% |

^ The revised ESRD outlier services definition and policy excludes vascular access management drugs and includes anabolic steroids. Vascular access management drugs billed separately include the following: alteplase, reteplase, heparin, lepiridun, and urokinase. Anabolic steroids billed separately include the following: testosterone and nandrolone. Payments for separately billable automated multi-channel chemistry (AMCC) tests were identified using modifier codes 'CE' and 'CF' (where 'CE' indicates composite rate tests beyond the frequency covered under the rate but separately billable based on medical necessity, and 'CF' indicates tests that are separately billable).
* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect 2012 prices for outlier services.

[1]Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2010 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in place under the ESA claims Monitoring policy were applied.
[2]Applied to the average outlier MAP per treatment. Standardization for outlier services is based on existing Case Mix Adjusters for adult and pediatric patient groups.
[3]This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.
[4]The fixed dollar loss amounts were calculated using 2010 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

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Based on the use of updated data for 2010, the average outlier services MAP per treatment amounts have decreased from $87.83 to $81.73 for adult patients and slightly from $46.27 to $46.26 for pediatric patients. These updates largely reflect changes in the utilization of outlier services for adult and pediatric patients between 2009 and 2010. These changes result in a smaller outlier services MAP amount for adult patients (decrease from $83.73 to $78.00) and very little change in the outlier services MAP amount for pediatric patients.

Similarly, the fixed dollar loss amounts which are added to the predicted MAP amounts per treatment to determine the outlier thresholds are being updated from $145.25 to $141.21 for adult patients and from $82.58 to $71.64 for pediatric patients. We estimate that the percentage of facilities with patient months qualifying for outlier payments under the current policy will be slightly lower for adult patients (from 5.5 to 5.4 percent) and higher for pediatric patients (from 5.0 to 5.7 percent) based on our use of 2010 data.

The update based on 2010 data has a somewhat greater impact on the outlier policy for pediatric patients compared to adult patients. There is generally greater sensitivity in the pediatric results due to the relatively small number of pediatric Medicare dialysis patients overall (approximately 800 patients nationally). This is especially the case with the pediatric fixed dollar loss amounts, since the magnitude of the pediatric fixed dollar loss amounts is basically determined by a relatively small number of the highest cost pediatric patients. The somewhat lower pediatric fixed dollar loss amounts based on data from 2010 (as compared with 2009), reflect the tendency to have somewhat less extreme high cost cases for pediatric patients in the 2010 claims. The expected result based on this update is that a somewhat larger percentage of pediatric claims are expected to qualify for outlier payments

based on 2010 data, but the average outlier payment among the pediatric outlier cases will be somewhat lower.

*D. Technical Corrections*

1. Training Add-On

In the CY 2011 ESRD PPS final rule (75 FR 49062 through 49063), we explained the rationale for costs associated with self-dialysis training. On page 49063 of the CY 2011 ESRD PPS final rule, the correct training add-on amount of $33.44 is listed in our response in column. However, we inadvertently listed an incorrect training add-on amount of $33.38 in the third column of page 49063. The correct training add-on amount is $33.44. Therefore, we are correcting the training add-on amount to $33.44 in the third column on page 49063 of the CY 2011 ESRD PPS final rule, for costs associated with self-dialysis training on or after January 1, 2011. The geographic wage index is applied to the $33.44. As described in the CY 2011 ESRD PPS final rule (75 FR 49063), the training add-on amounts after application of the wage index would range from $20.03 to $45.84.

Although we did not propose any changes to the current training add-on (other than noting the technical correction), we received 12 comments from patients and a home training organization. The comments we received and our responses are set forth below:

*Comment:* Two commenters supported the technical correction to the training add-on amount. Some comments recommended changes to the training add-on which included updating the training add-on to keep pace with inflation by applying the update directly to the training add-on or by re-calculating the hourly nurses time using the methodology employed in the CY 2011 ESRD PPS final rule. One commenter stated that the training add-on is outside of the bundled base rate and therefore, is not captured in the annual market basket update. One home training organization stated that they were disappointed with home training reimbursement. The commenter also indicated that the allowable home training payments cannot be billed because of issues with the submission requirements for the ESRD Medical Evidence form for new patients. A home training organization, patients, families and a national association believe that training treatments should be paid at the prescribed frequency and not limited to three days per week, up to the allowable number of days. One commenter maintained that her clinic was losing money on training and therefore their time should be compensated appropriately. Another commenter believes that the home training add-on adjustment did not come close to capturing the costs of training. Several commenters maintained that training should be for more than one hour of nursing time. Several commenters believe that the training add-on adjustment is inadequate.

*Response:* As we indicated in the proposed rule (75 FR 40516), we were providing a technical correction to note the correct amount of $33.44 for training treatments furnished on or after January 1, 2011. We did not propose any change in the methodology or the training add-on adjustment. Thus, the suggestions and comments received are beyond the scope of this final rule. However, we will take these comments into account in future rulemaking. Also note, the training add-on adjustment is adjusted by geographic wage index to account for a nurse's salary for one-hour of home dialysis training. This adjustment applies to both hemodialysis and peritoneal dialysis home training and is paid in addition to the ESRD PPS payment. That is, ESRD facilities receive a per-treatment payment, that accounts for case-mix, geographic location, low-volume and outlier payments, regardless if the patient receives dialysis at home or in a facility, plus the training add-on. We also note that staff time is included in the per treatment payment amount and, the training add-on is in addition to that amount.

2. ESRD-Related Laboratory Test

In the proposed rule (76 FR 40516), we noted that we inadvertently omitted an ESRD-related laboratory test from Table F: ESRD-Related Laboratory Tests of the Appendix in the CY 2011 ESRD PPS final rule. We explained that the ''Assay of protein by other source,'' which is identified by the Current Procedural Terminology code 84157, was a composite rate service under the basic case-mix adjusted composite payment system and, consequently, is considered a renal dialysis service under the ESRD PPS effective January 1, 2011. Therefore, the ''Assay of protein by other source'' should be furnished by the ESRD facility, either directly or under arrangement by another entity, to the ESRD patient and paid for under the ESRD PPS payment.

We did not receive any comments. In this final rule, we are correcting Table F of CY 2011 ESRD PPS final rule by adding, ''Assay of protein by other source'' identified by the Current Procedural Terminology code 84157.

*E. Clarifications to the CY 2011 ESRD PPS*

1. ICD–9–CM Diagnosis Codes

In the proposed rule, we discussed the ICD–9–CM diagnosis codes that are eligible for the co-morbidity payment adjustments (76 FR 40516). We provided the list of ICD–9–CM codes that are recognized for purposes of the co-morbidity payment adjustments in Table E: ICD–9–CM Codes Recognized for a Co-morbidity Payment Adjustment of the Appendix of the CY 2011 ESRD PPS final rule (75 FR 49211). Although we discussed ICD–9–CM coding to be used to identify co-morbidity conditions on ESRD claims, we did not indicate that we would update the existing diagnostic categories and ICD–9–CM codes on an annual basis.

We clarified that the ICD–9–CM codes are subject to the annual ICD–9–CM coding changes that occur in the hospital inpatient PPS final rule and effective October 1st of every year (76 FR 40516). We explained that any changes that affect the categories of co-morbidities and the diagnoses within the co-morbidity categories that are eligible for the co-morbidity payment adjustments will be communicated to ESRD facilities through sub-regulatory guidance. In the proposed rule, we also explained that in response to comments we have received, we believed that it was important to reiterate the discussion of co-morbidities that was detailed in the CY 2011 ESRD PPS final rule (75 FR 49094 through 49107). Therefore, we explained that ESRD facilities should continue to provide documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, because this is a requirement to receive the co-morbidity payment adjustment. As we discussed in the proposed rule, we have been and will continue to monitor the prevalence of any co-morbidity diagnoses recognized for the co-morbidity payment adjustments under the ESRD PPS as compared to the prevalence of these categories over the past several years. Therefore, we would be able to identify any changes in the prevalence of any of the co-morbidity diagnoses recognized for purposes of the co-morbidity payment adjustment as compared to previous trends. We are monitoring the co-morbidities eligible for payment adjustment to determine if the co-morbidity adjustments need to be refined in future rulemaking. We did not receive any comments on this clarification.

2. Emergency Services to ESRD Beneficiaries

In the CY 2011 ESRD PPS final rule (75 FR 49056), we explained that inpatient services, emergency services, and outpatient services furnished in a hospital or in an ambulatory surgical center furnished to ESRD beneficiaries were not included in the ESRD PPS base rate, and none of these services are considered renal dialysis services for inclusion in the ESRD PPS payment bundle. These services are reimbursed under other Medicare payment systems. We also explained that certain outpatient procedures necessary to maintain vascular access (that is, those which cannot be addressed by the ESRD facilities using procedures that are considered part of routine vascular access care), are excluded from the definition of renal dialysis services and are not included in the ESRD PPS payment. However, we consider the furnishing of certain medications, such as those used to flush a vascular access site of an ESRD patient, to fall within the definition of renal dialysis services.

As we discussed in the section on consolidated billing rules and edits in the CY 2011 ESRD PPS final rule (75 FR 49168), the ESRD PPS payment is an all-inclusive payment for renal dialysis services and the ESRD facility is responsible for all of the ESRD-related services that a patient receives. Payment for renal dialysis services under the ESRD PPS, including those that were formerly paid separately under the basic case-mix adjusted composite payment system, is no longer made to entities other than the ESRD facility (such as laboratories and DME suppliers).

In the proposed rule (76 FR 40517), we noted that after the publication of the CY 2011 ESRD PPS final rule, we received requests that we further clarify whether certain renal dialysis services furnished in an emergency room or emergency department are considered renal dialysis services covered under the ESRD PPS. Accordingly, we further clarified that renal dialysis services defined at § 413.171 of the regulations include diagnostic laboratory tests. In developing the ESRD PPS base rate, we included payments for outpatient laboratory tests billed on ESRD facility claims, as well as laboratory tests ordered by monthly capitation payment (MCP) physicians and billed on carrier claims (75 FR 49055), because we believe that these diagnostic laboratory tests furnished by ESRD facilities and MCPs meet the definition of renal dialysis services. We did not include laboratory tests ordered for Medicare ESRD patients undergoing treatment in hospital emergency departments or emergency rooms, because these tests are usually administered as part of a patient's clinical assessment of the condition requiring emergency room admission, which we believe are not generally related to the treatment of ESRD. Therefore, laboratory tests that are performed for Medicare ESRD beneficiaries in an emergency situation in an emergency room or emergency department as part of the general work-up of the patient, were excluded from the ESRD PPS payment bundle, and would not be considered renal dialysis services under the ESRD PPS.

We acknowledged in the proposed rule that laboratory tests that could be used during dialysis and ordered for the treatment of ESRD also may be ordered for ESRD patients in an emergency department or emergency room for other reasons (that is, as part of the assessment of the patient to obtain a diagnosis of the underlying condition which required emergency intervention). Although such tests could also be used in dialysis treatment and in the treatment of ESRD, because laboratory tests ordered for ESRD patients treated in emergency departments or emergency rooms are needed to arrive at a diagnosis of the condition requiring emergency treatment, we did not consider the laboratory tests as renal dialysis services under the ESRD PPS. Accordingly, these laboratory tests were not used to develop the ESRD base rate. We indicated that we would not expect that the laboratory tests provided in that circumstance to be subject to consolidated billing edits, resulting in denial of payment. That is, we would not consider such tests to be renal dialysis services in those emergency situation because they were not ordered for the treatment of ESRD, but instead, furnished as part of the general work-up of the patient necessary for diagnosis.

We further explained in the proposed rule that the exclusion of laboratory tests ordered in hospital emergency rooms or emergency departments from the consolidated billing edits did not mean that renal dialysis facilities should attempt to circumvent the application of the bundled ESRD PPS rate by directing patients to emergency rooms or emergency departments for obtaining ESRD-related laboratory tests, or the provision of other renal dialysis services. Because ESRD facilities are financially responsible for all renal dialysis laboratory tests, referring ESRD patients to the emergency room or emergency department for ESRD-related laboratory tests would be inappropriate. We noted that it would also be inappropriate for ESRD facilities to refer its patients to the emergency room or emergency department for maintenance of access sites (including treatment for access infections) which they had treated prior to the ESRD PPS for the purpose of diverting costs of providing renal dialysis services to their patients, or the administration of drugs that are considered renal dialysis services under the ESRD PPS. We also stated that we are monitoring the provision of renal dialysis services to ESRD patients in emergency rooms or emergency departments.

We did not solicit comments on emergency services to ESRD beneficiaries; however, we received four comments from national organizations. A summary of the comments we received and our responses to comments are set forth below.

*Comment:* Several commenters representing hospital organizations endorsed CMS' policy not to apply the consolidated billing rules to items and services furnished to ESRD patients in hospital emergency rooms or emergency departments for reasons other than the treatment of ESRD. One commenter supported CMS's recognition that the ESRD PPS consolidated billing rules do not apply to patients in the emergency department. One commenter supported the exclusion of services provided in an emergency room from the definition of renal dialysis services under the ESRD PPS. One commenter appreciated the clarification that''''legitimate'' non-ESRD laboratory tests in emergency rooms, hospitals, and ambulatory care centers are not part of the ESRD PPS. Another commenter agreed that hospital emergency department claims are excluded from the ESRD consolidated billing edits. The commenter suggested modeling specific guidance from the skilled nursing facility (SNF) consolidated billing guidance. The commenter believed that that medication administration should not be included in the ESRD PPS consolidated billing stating that the administration of medications other than EPO or Aranesp would be directly related to the emergency condition. The commenter stated that the application of the AY modifier is a huge operational burden for hospitals and often they are unaware that patients have ESRD.

*Response:* We thank the commenters who supported our clarification of consolidated billing under the ESRD PPS. However, some commenters have misunderstood our clarification. In the proposed rule (76 FR 40517), we explained that we understood that laboratory tests that could be used for dialysis could also be ordered for ESRD

patients in an emergency room or emergency department for reasons other than the treatment of ESRD in order to arrive at a diagnosis. We stated that we recognize that laboratory tests ordered for ESRD patients in emergency room or emergency department that are needed to arrive at a diagnosis would not be considered renal dialysis services under the ESRD PPS and, therefore, would not be subject to consolidated billing. We further explained that the exclusion of laboratory tests that are ordered in an emergency room or emergency department and excluded from consolidated billing edits does not mean that renal dialysis facilities should attempt to circumvent the ESRD PPS bundled payment rate by directing patients to the emergency room or emergency department for ESRD-related laboratory tests.

We have not included drugs or any other renal dialysis item or service in the consolidated billing rule exemptions when furnished in an emergency room or emergency department. In other words, the only services that we have excluded from the consolidated billing edits are laboratory tests that are performed in an emergency room or emergency department to determine a diagnosis. We are not discussing any other outpatient setting other than an emergency room or emergency department. We will consider the inclusion of renal dialysis drugs (that is, drugs used for ESRD-related conditions) furnished in the emergency room or emergency department exemption in future rulemaking.

With regards to the suggestion that we follow the SNF consolidated billing guidelines, we will be issuing guidance on the consolidated billing exemption of laboratory tests ordered in an emergency room or emergency department for the purpose of establishing a diagnosis. Finally, with regard to the comment on the burden of using an AY modifier for non-ESRD-related items and services, we believe it is important that we assure that duplicate payments are not being made for items and services that have been included in the ESRD PPS bundled payment. At the current time, the use of the AY modifier is the only means that can be used in order to clearly identify items and services that are not ESRD-related.

*F. Miscellaneous Comments*

*Comment:* One commenter expressed disappointment that CMS did not remind ESRD facilities of the November 1, 2011 deadline to elect to be excluded from the transition.

*Response:* We believe that the decision to receive a blended payment under the transition or to receive payment under the ESRD PPS was a very important business decision for ESRD facilities and that a reminder was not necessary.

*Comment:* One national association urged CMS to consider the concerns of facilities in the transition and make adjustments to the proposed rule when it may impact their financial viability and ability to provide quality patient care.

*Response:* We always assess the degree to which our proposed policies negatively impact categories of ESRD facilities such as rural, independent, pediatric, and transitioning ESRD facilities and are committed to developing payment policies that are fair and lead to increased payment accuracy under the ESRD PPS.

*Comment:* One independent ESRD facility did not believe that ESRD facilities should be held to the one-time election if changes are made annually. The commenter proposed that the one-time election be made on an annual basis or for those facilities that will be ''disproportionately negatively impacted'' by the proposed changes. The commenter further stated that the ability to rescind decisions made in 2010 should be made available.

*Response:* Section 1881(b)(14)(E)(ii) of the Act prohibits us from allowing facilities to submit annual elections or to rescind elections. Therefore, we are unable to allow changes to the election under any circumstance. With regard to annual changes to the ESRD PPS, we did not state that CMS would not make any changes to the composite rate portion of the blended payment or to the ESRD PPS. We believe there are changes finalized in this rule (such as eliminating a site of service distinction with regard to separate payment for antibiotics used for access infection and, eliminating the 50 percent rule under the outlier policy) that will result in positive effects to transitioning facilities.

*Comment:* One patient organization stated that bundling has already negatively impacted patients. The commenter further states that providers have in large part changed prescribed medications to the detriment of patients. The commenter cited changing practices of providing analog vitamin D and iron as examples.

*Response:* We are concerned about the comments made by this organization. We expect that ESRD facilities through their interdisciplinary teams and through the patient's nephrologist will ensure that patients receive the care that they require. We are monitoring many aspects of the ESRD PPS, including outcomes. We encourage patients to contact their ESRD Network if they are concerned about the care that they are receiving from their ESRD facilities.

*Comment:* Several commenters requested that the rate-setting and impact files at the provider level be provided to allow for transparency. The commenters indicated that they did not have the data to evaluate the proposed rule and offer suggestions to improve the bundled system. One commenter cited the need for the rate-setting file to allow for evaluating the proposed changes to the low-volume adjuster. The commenter further stated that their findings differed from CMS and expressed concern that CMS may have overestimated the low-volume adjuster in the standardization calculation leading to funds being taken out of the payment system inappropriately. One dialysis organization expressed their concern that small providers may not have the resources to identify outliers and place them on claims. The commenter urged CMS to show data that outlier payments were helping small providers. The commenter further stated that if small providers were not receiving outlier payments, then it may be best for funds allocated for outliers be made part of the base rate. One commenter stated that they remain concerned that some proposed policies continue to result in a loss of funds from the ESRD program that exceeds the Congressionally-mandated two percent for CY 2011.

*Response:* We do not agree with the assertions that CMS provided inadequate data to evaluate and comment on the proposals described in the proposed rule. We believe that the discussions and explanations in the proposed rule are sufficiently detailed to provide an adequate explanation as to how values were computed. In addition, we posted a provider-level impact file on the ESRD Payment Web site which was used to create the proposed impact analysis. We acknowledge that we may not have provided sufficient notification that the files were available and, therefore, in the future, we plan to provide a listserv notification to inform stakeholders when these files are available on the ESRD Payment Web site. As we did for CY 2011, we will post the provider-level file that will allow further analysis of the impact of the final outlier and wage index changes for CY 2012 on individual providers.

We have not made the rate setting file available because the release of patient identifiable data is not necessary to accomplish the purpose of analyzing our proposals. Applicable Federal privacy laws and regulations, including

the Privacy Act and HIPAA Privacy Rule only permit us to disclose personal identifiable information when it is necessary to administer the program, or for health care operations and payment.

We believe that some of the concerns raised by the commenters are related to the assumptions we made in computing the final base rate for CY 2011 where we standardized the base rate to account for the projected payments for the ESRD PPS adjustments. These concerns are beyond the scope of this final rule.

With regard to the commenters' claims that we had overstated the low-volume adjustment in the standardization calculation leading to funds being inappropriately taken out of the payment system, we explained the low volume methodology in great detail in the CY 2011 ESRD PPS proposed rule (74 FR 49969 through 49978) and in the CY 2011 ESRD PPS final rule (75 FR 49117 through 49125). We did not propose to change or modify the low-volume adjuster methodology for CY 2012. We note that we are monitoring the extent to which the low-volume and other ESRD PPS adjustments are consistent with the assumptions we made in developing the ESRD PPS. We will address this issue in future rulemaking.

We do not understand the comment that suggested that the proposed policies continue to result in a loss of funds from the ESRD program that exceeds the Congressionally-mandated two percent, because the two-percent reduction only applied to CY 2011.

*Comment:* Some commenters provided comments on issues that were not addressed in the proposed rule. These are summarized as follows. Some commenters suggested that the extra costs associated with patient non-compliance should be addressed. Some commenters advocated for inclusion of their products in the ESRD bundled payment. Other commenters believed that there should be a new technology adjustor and provided suggestions such as including new pharmaceutical agents into the base rate; providing for incremental payments for innovations that improve clinical outcomes, but do not reduce costs to dialysis facilities immediately; and a non-budget-neutral pass-through for new technology. One commenter suggested that we include over-the-counter nutritional support in the PPS as of January 1, 2012. Several commenters maintained that oral drugs for long term residents with ESRD should be dispensed by the Long Term Care pharmacy. Several commenters declared that CMS provide a statement indicating that future updates to items and services in the bundle will be made through rulemaking rather than guidance and, requested that CMS specify how future changes to the system will be handled. One commenter supported a race/ethnicity adjuster and provided their rationale on its inclusion. Another commenter urged CMS to examine time on machine, nutritional services, social work services and nursing services. One commenter requested that CMS explore broader ESRD bundles, such as integrated care models. Several commenters expressed difficulty of documenting co-morbidities and suggested that CMS provide the adjusters to the providers. Finally, some commenters expressed concerns about the ESRD cost report and with the anticipated funding of oral-only drugs.

*Response:* Because these comments were not in response to any proposals or discussions in the proposed rule, they are beyond the scope of this final rule. However, we refer the commenters to the CY 2011 ESRD PPS final rule where we believe that we addressed many of these issues (75 FR 49030). We also note that we will review all of the comments and may address them in future rulemaking.

*Comment:* One individual commenter supported the proposed rule. One national association supported the case-mix adjusted PPS. Another national association expressed their pleasure with the way in which CMS has implemented the first year of the ESRD PPS and the agency's willingness to work with the ESRD community.

*Response:* We thank the commenters for their support and willingness to work with CMS in implementing the ESRD PPS.

## II. End-Stage Renal Disease Quality Incentive Program for Payment Years (PYs) 2013 and 2014

### *A. Background for the End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014*

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients and provider/facility accountability have been important components of the Medicare ESRD payment system. The ESRD Quality Incentive Program (QIP), required by section 1881(h) of the Social Security Act (the Act), is the next step in the evolution of the ESRD quality program that began more than three decades ago. The first year for which the ESRD QIP payment reduction will be implemented is PY 2012. The PY 2012 ESRD QIP was finalized in two regulations: one that finalized the three performance measures (75 FR 49030, 49182 (August 12, 2010) (hereinafter referred to as the ''CY 2011 ESRD PPS final rule'')); and one that finalized other aspects of the 2012 ESRD QIP such as the scoring methodology and payment reduction scale (76 FR 628 through 646) (hereinafter referred to as the ''2012 ESRD QIP final rule''). Section 1881(h) of the Act, as added by section 153(c) of MIPPA, generally requires that the Secretary establish an ESRD QIP by (i) Selecting measures; (ii) establishing the performance standards that apply to the individual measures; (iii) specifying a performance period with respect to a year; (iv) developing a methodology for assessing the total performance of each provider/facility based on the performance standards with respect to the measures for a performance period; and (v) applying an appropriate payment reduction to providers and facilities that do not meet or exceed the established Total Performance Score.

As we have stated, the first year for which the ESRD QIP payment reduction will be implemented is PY 2012, and we selected one measure for the PY 2012 ESRD QIP of dialysis adequacy and two measures of anemia management. The following are the three measures (finalized in the CY 2011 ESRD PPS final rule) for the PY 2012 ESRD QIP:

- Percentage of Medicare patients with an average hemoglobin less than 10.0 g/dL (Hemoglobin Less Than 10 g/dL measure).
- Percentage of Medicare patients with an average hemoglobin greater than 12.0 g/dL (Hemoglobin Greater Than 12 g/dL measure).
- Percentage of Medicare patients with an average urea reduction ratio (URR) equal to or greater than 65 percent (URR Hemodialysis Adequacy measure).

A full description of the methodologies used for the calculation of the measures can be reviewed at: *http://www.dialysisreports.org/pdf/esrd/public/Guide_to_the_PY_2012_ESRD_QIP_PSR.pdf* (see the ''Inclusion Criteria'' and ''Calculation Process'' sections of the document).

Other aspects of the 2012 ESRD QIP finalized in the PY 2012 ESRD QIP final rule include the establishment of performance standards for these measures (including applying the special rule under section 1881(h)(4)(E) of the Act) and establishing a scoring methodology for calculating individual Total Performance Scores ranging from 0–30 points based on the three finalized measures. As part of our methodology for calculating the provider/facility Total Performance Score, we weighted the Hemoglobin Less Than 10 g/dL

Measure at 50 percent of the score, while the Hemoglobin Greater Than 12 g/dl measure and the URR Hemodialysis Adequacy measure were each weighted at 25 percent of the score. We also finalized a policy under which providers/facilities that did not meet or exceed a Total Performance Score of 26 points would receive a payment reduction ranging from 0.5 percent to 2.0 percent.

*B. Summary of the Proposed Provisions and Responses to Comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2013 and PY 2014*

On July 8, 2011, a proposed rule entitled ''Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment'' (76 FR 40498) (the ''proposed rule'') appeared in the **Federal Register**. In the proposed rule, we expanded upon the PY 2012 ESRD QIP framework by proposing to adopt new ESRD QIP requirements for PYs 2013 and 2014.

We received approximately 88 public comments on the proposed rule that were related to the ESRD QIP. Interested parties that submitted comments included dialysis facilities, national organizations representing dialysis facilities, nephrologists, nurses, nutritionists, home health agencies, dialysis corporations, clinical laboratories, pharmaceutical manufacturers, hospitals and their representatives, individual dialysis patients, advocacy groups, and the Medicare Payment Advisory Commission (MedPAC). In this section of the final rule, we provide a summary of each proposed requirement for the PY 2013 and PY 2014 ESRD QIP, a summary of the public comments received on those requirements, our responses to these comments, and the final policies that will apply to the PY 2013 and the PY 2014 ESRD QIP.

1. PY 2013 ESRD QIP Requirements

In the proposed rule, we outlined the proposed requirements for the two proposed measures for the PY 2013 ESRD QIP. We proposed that ESRD providers and facilities that do not meet these requirements would receive a reduction, based on their Total Performance Score, to the payments otherwise made under section 1881(b)(14) with respect to PY 2013 services, in accordance with section 1881(h)(1)(A) of the Act. We proposed to calculate these payment reductions by assigning each provider/facility a Total Performance Score, ranging from 0–30 points, in accordance with its individual performance on the two proposed measures. We proposed that a provider/facility that does not achieve a Total Performance Score of 30 points would receive a payment reduction in PY 2013 ranging from 1.0 percent to 2.0 percent, depending upon how far below this minimum Total Performance Score its performance falls. Our specific proposals, responses to comments, and finalized policies based on comments, are discussed below.

a. Performance Measures for the PY 2013 ESRD QIP

Section 1881(h)(2)(A) of the Act requires that the measures specified for the ESRD QIP include measures on anemia management that reflect the labeling approved by the FDA for such management; measures on dialysis adequacy; to the extent feasible, a measure or measures on patient satisfaction; and such other measures that the Secretary specifies, including (to the extent feasible) measures on iron management, bone mineral metabolism, and vascular access, including maximizing the placement of arterial venous fistula. In selecting measures for the PY 2013 ESRD QIP, we examined whether it would be feasible to propose to adopt any new measures for the program. In light of our proposal to select CY 2011 as the performance period (discussed more fully below), we determined that it is not feasible to adopt any of the new measures mentioned above until the PY 2014 ESRD QIP. We also carefully reexamined the three measures that we adopted for the PY 2012 ESRD QIP, and for the reasons discussed below, proposed to continue including only two of them, (i) The Hemoglobin Greater Than 12 g/dL measure and (ii) the URR Hemodialysis Adequacy measure, in the PY 2013 ESRD QIP measure set.

We also proposed to retire the Hemoglobin Less Than 10 g/dL measure beginning with the PY 2013 ESRD QIP. As we explained in more detail in the proposed rule (76 FR 40519), we have recently reassessed the evidence for the use of erythropoiesis stimulating agents (ESAs) in patients with kidney disease through a National Coverage Analysis (CAG–00413N) and, while we did not seek to limit the coverage of these agents at this time, we could not identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs. In addition we believe that retiring the Hemoglobin Less Than 10 g/dL measure is reflective of the new labeling approved by the FDA for the use of ESAs (*http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). We discussed with the FDA our proposal to retire the Hemoglobin Greater Than 10 g/dL measure starting in PY 2013. Because this measure encourages providers/facilities to keep hemoglobin above 10 g/dL, the FDA agreed that retiring this measure is consistent with the new labeling for ESAs approved by the FDA.

We proposed to maintain the Hemoglobin Greater Than 12g/dL measure as a measure of anemia management. As we explained in more detail in the proposed rule (76 FR 40519), the studies continue to show that targeting hemoglobin levels above 12 g/dL through the use of ESAs can contribute to adverse patient outcomes.[1] This measure, consistent with the requirement under section 1881(h)(2)(A)(i) of the Act, also continues to reflect the labeling approved by the FDA for anemia management.

We also proposed to retain the URR Hemodialysis Adequacy measure, which assesses the percentage of Medicare patients with an average URR equal to or greater than 65 percent. Section 1881(h)(2)(A)(i) of the Act states that the measures specified under the ESRD QIP for a payment year shall include measures on dialysis adequacy. We noted that, for the reasons stated in the CY 2011 ESRD PPS final rule (75 FR 49182), we believe that the URR Hemodialysis Adequacy measure is an appropriate and accurate measure of hemodialysis adequacy.

The comments we received on these proposals and our responses are set forth below. The comments on and the responses to the Hemoglobin Greater Than 12 g/dL measure also apply to the proposal to include this measure in the PY 2014 ESRD QIP.

*Comment:* Many commenters urged CMS to retire the URR Hemodialysis Adequacy measure for PY 2013 in favor of a Kt/V measure because Kt/V is widely accepted, is used extensively by the renal community as a measure of dialysis adequacy, and is the basis for a measure endorsed by the National Quality Forum (NQF). One commenter specifically noted that there are situations in which patients may have a Kt/V within an acceptable range, but not a URR equal to or greater than 65 percent. One commenter suggested that, if CMS does retire the URR dialysis adequacy measure for the PY 2013

[1] KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target, *American Journal of Kidney Diseases,* 50(3): Pages 471–530 (September 2007).

ESRD QIP, the agency should consider allowing facilities to report either URR or Kt/V.

*Response:* We thank the commenters for their input on this issue. We agree that a Kt/V dialysis adequacy measure would more accurately measure how much urea is removed during dialysis because the calculation takes into account the amount of urea removed with excess fluid. We asked providers/facilities to begin submitting Kt/V data on July 1, 2010, and plan to incorporate measure(s) based on Kt/V as soon as we can to ensure the validity and consistency of these data. In the interim, for the reasons stated in the CY 2011 ESRD PPS final rule (75 FR 49182), we believe that the URR Hemodialysis Adequacy measure is, overall, an appropriate and accurate measure of hemodialysis adequacy.

*Comment:* Many commenters voiced concern over CMS' proposal to retire the Hemoglobin Less Than 10 g/dL measure. One commenter specifically stated that CMS should consider the effects of retiring this measure on pediatric patients. Commenters noted that without a lower bound for hemoglobin in the ESRD QIP, the bundled payment system financially incentivizes providers/facilities to provide less ESAs, driving hemoglobin down. Commenters argued that decreased hemoglobin will lead to a rise in transfusions, hospitalization, morbidity, and mortality, endanger vascular access due to the need for additional venipuncture, and decrease quality of life, appetite of patients, and consistency of care, shifting care to hospitals and outpatient infusion centers. Further, one commenter argued that dropping the hemoglobin floor will increase the burden of ESRD patients because, as a result of the negative consequences, it will require more appointments and travel to receive transfusions; another commenter stated that retiring the measure will have a ''chilling effect'' on the ability to pursue innovation in the treatment of patients with chronic kidney disease (CKD). Commenters also noted that a rise in transfusions could result in worse transplant outcomes and a higher likelihood of infection. They also argued that quality of life issues may cause individuals to be less active and eat less nutritious foods, possibly resulting in patients who are less healthy and need more care. Some commenters noted that many of these consequences would be disproportionately suffered by the African-American community and encouraged CMS to collect and analyze data on health disparities.

*Response:* We thank commenters for their input. As we stated in the proposed rule (76 FR 40519), we have recently reassessed the evidence for the use of ESAs in patients with kidney disease through a National Coverage Analysis (CAG–00413N), and we could not identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs. We are also not aware of, nor did the comments note, any studies that identify a specific hemoglobin level which should be maintained to increase quality of life or minimize transfusions or hospitalizations. However, if any new evidence or studies emerge, we will take such evidence into consideration in adopting future measures for the ESRD QIP. We have discussed our proposal to retire the Hemoglobin Less Than 10 g/dL measure with the FDA and they concur that retiring the measure is consistent with the new labeling for ESAs. Factors that impact anemia management, including optimal iron stores, dialysis adequacy, avoidance of infections, reduction of inflammation, and other factors should be addressed by the health care team to improve patient health. We urge patients and providers to work together to achieve optimal hemoglobin levels for each individual patient. We will continue to monitor and evaluate practice patterns and outcomes for all segments of the Medicare ESRD population as we develop and refine our measurement of the quality of anemia management. Additionally, we note that pediatric patients are excluded from the anemia management measures we have thus far adopted and are adopting in this final rule for the ESRD QIP, so the retirement of this measure does not directly affect the pediatric population.

*Comment:* As an alternative to retiring the measure, some commenters argued that CMS should reduce the lower bound from 10 g/dL to 9 g/dL or 8 g/dL or decrease the financial penalty. Commenters also suggested that the measure not be limited to those on ESAs because there are other means of maintaining hemoglobin levels. Other commenters suggested that the root cause of health issues related to high hemoglobin is the overuse of ESAs, and, therefore, CMS should create an anemia management measure monitoring ESA usage or other outcomes such as transfusion avoidance rather than hemoglobin levels. One commenter recommended that CMS set a range for hemoglobin of 10–11 g/dL, and, if a patient's hemoglobin is higher than 11 g/dL, CMS should require the ESA dosage to be decreased and not discontinued. One commenter proposed that, in the event the Hemoglobin Less Than 10 g/dL measure remains in the ESRD QIP, the weighting for this measure be decreased until an accurate baseline is determined reflecting current medical evidence and drug labeling. One commenter suggested that this weighting decrease to zero. Commenters also asked CMS to continue to monitor hemoglobin levels, perhaps through a reporting measure or as a condition for coverage, and publicly report low hemoglobin levels even if the measure is retired from the ESRD QIP.

*Response:* As we noted above, we did not find scientific evidence to identify an appropriate and safe quality standard for a minimal achieved hemoglobin level. Therefore, in the absence of this evidence, we do not believe it is appropriate to simply decrease the lower bound. Additionally, continuing to employ the measure in the program, but decreasing its weight to zero may signal to beneficiaries that this measure is valid, although less important, and that it is, therefore based in scientific evidence. As noted above, we are actively monitoring trends in anemia management as well as patient outcomes, and we strongly encourage patients and providers to work together to develop anemia management strategies appropriate for individual patient circumstances. We note that the Hemoglobin Less Than 10 g/dL measure results are currently reported on Dialysis Facility Compare, and that we are exploring the options and feasibility of continuing to publicly report anemia management trends.

We agree with commenters that we should consider anemia management measures that apply to patients not on ESAs, and, under 42 CFR 494.180(h), we asked providers/facilities to begin providing data for these patients on January 1, 2012. In addition, we are considering ways to incorporate achieved hemoglobin levels, ESA usage, and other important factors in our anemia measurement strategy for future years of the ESRD QIP; we welcome community input and would like to encourage measure development in this area.

*Comment:* Some commenters agreed with our proposal to retire the Hemoglobin Less Than 10 g/dL measure. Commenters noted that such a proposal reflects the new labeling approved by the FDA for the use of ESAs, is consistent with the lack of scientific evidence for a lower bound, and will allow providers more latitude, providing room for more patient-centered care. Several commenters also suggested that, while CMS should retire

the measure, the agency should also conduct additional clinical studies to establish optimal dose strategies, targets, and the long term safety of various ESA therapies, and reinstate a lower bound as soon as possible.

*Response:* We thank commenters for their support. As we noted above, we will continue to monitor practice patterns in the area of anemia management and develop and evaluate additional measures for future years of the ESRD QIP. We will also continue to work with our Federal partners and external stakeholders to advance knowledge in this area.

*Comment:* One commenter suggested that the agency include text in the ESRD QIP certificates to be posted in December 2011 to acknowledge the changing guidance in anemia management so patients and caregivers are aware that the data are dated and not necessarily relevant in today's environment. Another commenter stated that CMS should develop Performance Score Report (PSR) mechanisms to adjust for unusual patient demographics and dialysis facility census.

*Response:* The PY 2012 ESRD QIP certificates will clearly state that ''the information communicated * * * is based on 2010 data.'' Our regulations do not preclude providers/facilities from providing patients with more explanatory detail, and we encourage providers/facilities to engage patients in discussions of this information.

As we have stated, we continue to monitor the effects of the ESRD QIP on all segments of the Medicare ESRD population, and we will continue to evaluate our scoring and public reporting methodology for any necessary modifications.

*Comment:* Some comments suggested that the Hemoglobin Greater Than 12 g/dL measure should be retired from the PY 2013 and PY 2014 ESRD QIP measure set because some patients may benefit from a higher hemoglobin level and there is a lack of scientific evidence for an upper hemoglobin bound. Commenters argued that, generally, higher hemoglobin leads to better quality of life and patients and doctors should be able to weigh risks and benefits, leading to a more patient-centered definition of quality. These commenters noted that CMS should only be regulating those providers/facilities that are clear outliers. Some commenters requested that, should CMS retain the measure, the bound be raised to Greater Than 12.5 or Greater Than 13 g/dL. Another commenter stated that, given recent clinical practice changes already addressing the concern for high hemoglobin and high ESA doses, it may be reasonable for CMS to decrease the weighting for the Hemoglobin Greater Than 12 g/dL measure.

*Response:* Studies continue to show that targeting hemoglobin levels above 12 g/dL through the use of ESAs can contribute to adverse patient outcomes including an increased risk of myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and overall mortality, and, in patients with a history of cancer, tumor progression or recurrence. Given the significance of these outcomes, we do not believe it is appropriate either to retire the measure or reduce the weight of the measure. In addition, as explained further below, this measure is consistent with new labeling for ESAs approved by the FDA that directs providers to reduce or interrupt the dose of ESAs if the hemoglobin level approaches or exceeds 11 g/dL.

*Comment:* Some commenters argued that the only anemia management measure should be Hemoglobin Greater Than 11 g/dL, replicating the FDA guidelines. Commenters suggested that such a measure is consistent with current scientific evidence, provides the best level of care for patients, and lowers Medicare costs.

*Response:* New labeling approved by the FDA for the use of ESAs addresses targeted hemoglobin levels while we measure achieved hemoglobin levels. The achieved hemoglobin level is a function of the target but also reflects patient factors such as the underlying causes of anemia which determine how sensitive the patient is to ESAs and whether the target is actually achieved. These patient factors can vary unpredictably over time even within an individual patient which means that patients will sometime exceed (or fall short of) the hemoglobin level target despite clinician diligence. The FDA label recognizes this hemoglobin variability and states that, if the hemoglobin approaches or exceeds 11 g/dL, ESA dosing should be reduced or interrupted, but the label does not state that hemoglobin levels should never exceed this value. We believe that the current anemia measure allows for some deviations of the achieved hemoglobin while highlighting that higher hemoglobin targets can result in adverse patient outcomes.

*Comment:* Some commenters supported the Hemoglobin Greater Than 12 g/dL measure.

*Response:* We thank commenters for their support.

*Comment:* One commenter requested clarification on the meaning of ''on ESA,'' and another commenter requested that CMS explicitly state that the Hemoglobin Greater Than 12 g/dL measure applies only to those patients on ESAs. Specifically, one commenter inquired whether it is applied based on one bill indicating ESA administration after 90 days of dialysis and the submission of four bills for dialysis within a 12 month period for adult patients. In addition, the commenter asked how patients with untreated Hemoglobin Greater Than 12 g/dL will be identified and excluded from the measure calculation.

*Response:* We assume that the commenters are referring to data extracted from claims. As outlined in the measure specification, ''on ESA'' means that a patient is receiving ESAs during the month covered by a claim, as identified by the presence of an ESA dose and hemoglobin on the claim. This measure applies only to months for which a patient has received an ESA agent. Patients are attributed to a facility only after they have four months of eligible claims from that facility. To be eligible for the Hemoglobin Greater Than 12 g/dL measure, among other criteria, (i) The beginning date of the claim must have been at least 90 days since the date of first ESRD service for the patient and (ii) the claim must include a line item reporting the administration of an ESA in that month. These inclusion criteria are unchanged from the PY 2012 ESRD QIP. The measures specifications are available at *http://www.dialysisreports.org/ESRDMeasures.aspx.*

*Comment:* Some commenters believe that the Hemoglobin Less Than 10 g/dL measure should be retired from the PY 2012 measure set because it would be unfair to penalize dialysis providers/facilities for their nephrologists' interpretation of the medical literature. One commenter argued that CMS knew of published studies in 2006 and 2009 which signaled that no lower bound could be identified and noted that these studies changed behavior in the industry. One commenter also stated its belief that if CMS does not retire the measure for the PY 2012 ESRD QIP, the public may erroneously conclude that the provider's/facility's PY 2012 ESRD QIP total performance score reflects CY 2012 data, as opposed to the data utilized for the performance period. Commenters also argued that the legislative language requiring the Secretary to reflect the FDA labeling applies to the labeling in the payment year rather than the performance year.

*Response:* Based on the available evidence in 2006 regarding the treatment of anemia in the ESRD population, we developed a consensus-based measure which was endorsed by

the NQF in 2008 (NQF #0370). This measure formed the basis for the Hemoglobin Less Than 10 g/dl measure which was adopted for the ESRD QIP (76 FR 628). This measure remained consistent with clinical practice guidelines and the labeling approved by the FDA for the use of ESAs in effect until June 2011. In June 2011, new labeling for ESAs was approved by the FDA. We will retire the Hemoglobin Less Than 10 mg/dL measure beginning in PY 2013 in accordance with this new labeling.

Although measures are adopted for a specific payment year, we evaluate performance on those measures during a performance period that precedes the payment year so that we can collect and evaluate the data for these measures and allow providers/facilities adequate time to review their scores before payment reductions occur. Therefore, to the extent that the anemia management measures under section 1881(h)(2)(A)(i) reflect the labeling approved by the FDA for such management, we believe that those measures must reflect the labeling and guidance in effect and the care provided during the performance period which, with respect to the PY 2012 program, was CY 2010.

Finally, as we noted above, the PY 2012 ESRD QIP certificates state that ''the information communicated * * * is based on 2010 data.''

For the reasons discussed above, for the PY 2013 ESRD QIP, we finalize use of the following two measures previously adopted for the PY 2012 ESRD QIP:

- Hemoglobin Greater Than 12g/dL measure
- URR Hemodialysis Adequacy measure

b. Performance Period and Case Minimum for the PY 2013 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. In the proposed rule, we discussed in detail the factors that we considered in determining what performance period to select for the PY 2013 ESRD QIP (76 FR 40519). We also noted that, in light of the new ESRD PPS, we believe that it is important to assess the quality of care being furnished to ESRD patients and that basing this assessment on a year of data will provide an accurate and fair determination of whether a provider/facility has met or exceeded the proposed performance standards with respect to the proposed measures. Therefore, we proposed to select all of CY 2011 as the performance period for the PY 2013 ESRD QIP.

Consistent with what we finalized for the PY 2012 ESRD QIP, we also proposed to require that providers/facilities have at least 11 cases that meet the reporting criteria for a measure in order to be scored on the measure.

The comments we received on these proposals and our responses are set forth below.

*Comment:* Several commenters expressed concern that both the PY 2013 and PY 2014 programs will use data more than a year old and penalize facilities that have since improved; commenters encouraged the use of methodologies that recognize changes in performance over time and use the most recently available data as comparison data. Another commenter recommended that CMS establish CY 2012 as the performance year for PY 2013 because it would allow dialysis facilities and providers to gauge their performance using clinically relevant, timelier, and prospective data.

*Response:* For both PY 2013 and PY 2014, we have determined that data derived from claims is the most appropriate source on which to score providers/facilities. Claims data allows us to implement a variety of measures which can be used to evaluate the greatest number of facilities. In order to assure completeness of this claims data, there is a lag between when the data is generated and when we are able to use it in the ESRD QIP. This time period is lengthened because we believe it is important to allow providers/facilities a period of time to review their scores before the payment period. We are considering how we might be able to shorten this timeline in the future, such as by collecting data through CROWNWeb or by some other method, such as the NHSN or electronic health records, and we will continue to take the commenters concerns into account as we do so.

*Comment:* Several commenters argued that, under section 1881(h)(4)(C) of the Act, the ESRD QIP performance periods must be prospective, but nearly all of the PY 2013 performance period will have ended by the time the performance standards are finalized. Commenters also argued that finalizing performance standards when the performance period is nearly complete impermissibly creates a retroactive rule. Comments also noted that a retrospective performance period does not allow a provider/facility to change its practices to meet standards, thereby increasing quality of care. Other commenters, however, voiced support for the proposed PY 2013 performance period.

*Response:* We acknowledge that section 1881(h)(4)(C) of the Act requires the Secretary to establish performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved. However, we are establishing the performance standard that will affect ESRD payments in PY 2013 in accordance with section 1881(h)(4)(E), which does not impose the limitation suggested by the commenters. We believe that setting a CY 2011 performance period for the initial ESRD QIP will ensure that the performance scores are based on a robust set of data, and will allow us sufficient time to analyze that data, determine whether provider/facilities met the performance standards, provide providers/facilities with an opportunity to preview their performance scores and submit related inquiries, and implement the applicable payment reductions for PY 2013. We also note that, beginning with the PY 2014 program, we will set performance standards under section 1881(h)(4)(A) of the Act.

*Comment:* Commenters voiced concerns about CMS' approach to including low-volume facilities in the program because one patient could significantly affect a score for reasons unrelated to quality of care, such as patient comorbidities, and decrease the ability of a provider/facility to score well on a measure. This scoring could, in turn, affect patient volume if consumers judge facilities based on their scores. Commenters suggested different minimum case thresholds such as 20 cases or 25 cases or that providers with fewer cases be scored differently; some commenters also noted that their studies showed that the sample size rather than overall performance is driving the results for facilities and requested that CMS raise the case minimum to 20. Another commenter urged CMS to research the reliability of a measure to set the minimum number of cases, publish minimum case reliability data, and use this data to set a minimum number of cases for all value-based purchasing programs. One commenter urged CMS to re-consider its scoring methodology to analyze for statistical significance. Another commenter stated its belief that the ESRD QIP methodology does not appropriately account for low patient census, unusual treatment setting, or patient case-mix, and recommended that CMS develop a mechanism to adjust for circumstances in which facilities with an unusual care setting, atypical case-mix, or small patient census may be at high risk of incurring

penalties for failure to meet performance standards.

*Response:* We appreciate the commenters' concerns regarding the potential impact of patient case mix on smaller providers/facilities. The goal of the ESRD QIP is to accurately assess the quality of care provided by a provider/facility. However, we recognize that a quality measure score could be impacted by one or more factors unrelated to the care furnished by the provider/facility, and that the potential of such factors to greatly skew the calculation decreases as the number of cases included in the measure increases. Similarly, a provider/facility with a small number of patients could find that one patient's outcome determined its score on a quality measure. Thus we proposed that a provider/facility would need to have a minimum of eleven cases that meet the eligibility criteria for a measure in order to be scored on that measure. This eleven case minimum allows as many providers/facilities as possible to participate in the program. This minimum case number is also consistent with the reporting of these measures on Dialysis Facility Compare. We will continue to closely monitor beneficiary access to care, including evaluating the rate of facility closures. We will also continue to assess the impact of the program on facilities of all sizes, and we will change the methodology if we believe it is necessary to ensure that the program adequately measures quality. Additionally, we continue to monitor and evaluate the reliability of all of our value-based purchasing programs; we note, however, that each of these programs has its own set of requirements which must be considered during any assessment of reliability.

*Comment:* One commenter expressed concern that new facilities without a complete data set available for the measures will be unfairly penalized.

*Response:* Like all ESRD QIP providers/facilities, new facilities will only be included in the program if they have the requisite amount of data. Any provider/facility must have adequate data to calculate performance rates on both PY 2013 measures to be included in the PY 2013 ESRD QIP. For each of these measures, there must be at least eleven cases each with four claims, regardless of whether the facility is new or established.

Additionally, under the special rule in section 1881(h)(4)(E), we will be setting the initial performance standard as the lesser of the provider's/facility's performance during 2007 or the 2009 national performance rates. If a provider/facility was not in existence in 2007, we will assign a score of zero for purposes of assessing which of the two standards applies to the provider/facility. The provider/facility's performance in 2011 will then be compared against that initial performance standard.

For the reasons discussed above, we are finalizing all of CY 2011 as the performance period for the PY 2013 ESRD QIP.

c. Performance Standards for the PY 2013 ESRD QIP

In the proposed rule, we discussed in detail what performance standards we planned to select for the PY 2013 ESRD QIP. We noted that comparing provider/facility performance over time based on data from successive years would be beneficial as this method would allow the public to most accurately gauge provider/facility improvement. As we discussed above, we also noted that due to operational issues, it is not feasible for us to establish performance standards prior to the beginning of the proposed performance period, as is required if the performance standards are established under section 1881(h)(4)(A). Therefore, we proposed to continue using the performance standard under section 1881(h)(4)(E) of the Act for the PY 2013 ESRD QIP. Under this proposed standard, providers/facilities would be evaluated based on the lesser of (i) the performance of the provider/facility in 2007, which is the year selected by the Secretary under the second section of section 1881(b)(14)(A)(ii), or (ii) a performance standard based on the national performance rates for the measures in a period determined by the Secretary. With respect to the second prong, we proposed selecting CY 2009 because that is the most recent year-long period for which data would be publicly available prior to the beginning of the proposed performance period. At the time we published the proposed rule, the 2009 national performance rates for the Hemoglobin Greater Than 12 g/dL measure and the URR Hemodialysis Adequacy measure were:

- For the Hemoglobin Greater Than 12g/dL measure: 16 percent.
- For the URR Hemodialysis Adequacy measure: 96 percent.

The comments we received on the proposed selection of this performance standard and our responses are set forth below.

*Comment:* One commenter recommended rounding the average hemoglobin to one decimal place because this method is the industry standard and more decimal places exaggerates the precision of the laboratory tests. One commenter also stated that CMS should allow rounding to the tenth to address ''between instrument variability within a single laboratory.''

*Response:* For Dialysis Facility Compare (DFC) and Dialysis Facility Reports (DFR), we have traditionally not rounded the average patient hemoglobin values or the values resulting from the hematocrit to hemoglobin conversion. The final rule for the first year of the ESRD QIP stated that we would calculate the hemoglobin measure rates as they have been calculated for purposes of DFC and DFR in order to maintain consistency (76 FR 629). In light of this comment, however, we have concluded that beginning with the PY 2013 program, it is reasonable to round the patient average hemoglobin value to one decimal place to better reflect the precision of the original laboratory data prior to determining performance on the measure. We will also round the hematocrit to hemoglobin conversion to one decimal place. Using this new rounding convention, the 2009 national performance rate for the Hemoglobin Greater Than 12 g/dL measure using this new rounding convention rate is 14 percent.

*Comment:* One commenter suggested that CMS use a baseline period of 2009 for the Hemoglobin Greater Than 12 g/dL measure because data from 2009 is the most currently available data. This commenter also argued that, because of the change in FDA approved labeling and guidance from the baseline period to the performance period, this measure will cause confusion and not accurately measure quality and improvement.

*Response:* We proposed to use CY 2009 as the source of data for the national comparative performance standard for scoring the PY 2013 ESRD QIP measures. Although we recognize that the FDA-approved label for ESAs changed in CY 2011, we note that this change did not directly impact this measure. The Hemoglobin Greater Than 12 g/dL measure reflects both the prior and new labels for ESAs.

*Comment:* One commenter requested that CMS employ the PY 2014 achievement and improvement scoring methodology for PY 2013. One commenter voiced support for the change in methodology to equally weight the measures in PY 2013. One commenter stated that performance standards for PY 2013 should be less stringent to decrease the incentive to game the system.

*Response:* As explained above, we are using the special rule for PY 2013. Under this standard, providers/facilities would be evaluated based on the lesser

of (1) The performance of the provider/facility in 2007, which is the year selected by the Secretary under the second section of section 1881(b)(14)(A)(ii), or (2) a performance standard based on the national performance rates for the measures in a period determined by the Secretary (for PY 2013, this is CY 2009). We do not believe that the performance standards are too stringent; a provider/facility is scored on the lesser of its own performance or the national performance rate. We will be monitoring providers/facilities to assess any incentives to game the system.

After considering the comments, and for the reasons stated above, we are finalizing following performance standards. For the PY 2013 ESRD QIP, providers/facilities will be evaluated based on the lesser of (i) Their individual performance on the measures in 2007 or (ii) the national performance rates for the measures in 2009. We also finalize that we will round the values obtained when we convert hematocrit values to hemoglobin values and the average patient hemoglobin values used in the Hemoglobin Greater Than 12 g/dL measure to one decimal place.

Based on our new rounding methodology and the most recent 2009 data, the 2009 national performance rates vary slightly from those in the proposed rule. The national performance rate in 2009 for the Hemoglobin Greater Than 12 g/dL measure is 14 percent, and the national performance rate in 2009 for the URR Hemodialysis Adequacy measure is 97 percent.

d. Methodology for Calculating the Total Performance Score and Payment Reduction for the PY 2013 ESRD QIP

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on performance standards with respect to the measures selected for a performance period. Section 1881(h)(3)(A)(iii) of the Act states that the scoring methodology must include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

For the PY 2012 ESRD QIP, we finalized a scoring methodology under which we calculated the performance of each provider and facility by assigning 0–10 points for each measure. The full rationale for this scoring methodology is presented in detail in the PY 2012 ESRD QIP final rule (76 FR 629 through 634).

For the PY 2013 ESRD QIP, we proposed to adopt the same methodology for scoring provider/facility performance on each of the measures. We noted that, we believe that it is important to provide a clear-cut method for calculating scores initially while providers and facilities are becoming familiar with the program. We proposed to calculate the performance of each provider/facility on each measure by assigning points based on how well it performed on the measure in CY 2011 relative to the proposed performance standard (discussed above). If a provider or facility meets the performance standard for a measure, then it would receive 10 points for that measure. If a provider/facility does not meet the performance standard for a measure, we would award points for each measure based on a 0 to 10 point scale and would subtract 2 points for every 1 percentage point the provider or facility's performance falls below the performance standard during CY 2011, the performance period for PY 2013.

For the PY 2013 ESRD QIP, we proposed to weight the Total Performance Score for each provider/facility such that 50 percent would reflect the Hemoglobin Greater Than 12g/dL measure and 50 percent would reflect the URR Hemodialysis Adequacy measure. To be consistent with the scoring methodology that we finalized for the PY 2012 ESRD QIP, we proposed to award up to 30 points to a provider/facility based on its performance on the proposed measures. However, because we only proposed to adopt two measures for the PY 2013 ESRD QIP measure set, we proposed to calculate a provider's/facility's Total Performance Score by multiplying each measure score (0–10 points) by 1.5, adding both measure scores together and rounding this number to the nearest integer (with 0.50 rounded-up), resulting in a 0–30 point range.

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments among providers and facilities achieving different levels of Total Performance Scores, with providers and facilities achieving the lowest Total Performance Scores receiving the largest reductions.

For the PY 2012 ESRD QIP, we implemented a sliding scale of payment reductions, setting the minimum Total Performance Score that providers/facilities will need to achieve in order to avoid a payment reduction at 26 points (76 FR 634). Providers/facilities that score between 21–25 points will receive a 0.5 percent payment reduction; between 16–20 points, a 1.0 percent payment reduction; between 11–15 points, a 1.5 percent payment reduction; and for a score between 0–10 points, providers/facilities will receive the full 2.0 percent payment reduction (76 FR 634).

To ensure that providers/facilities are properly incentivized to provide quality care, we proposed to implement a more rigorous sliding scale of payment reductions for the PY 2013 ESRD QIP and raise the minimum Total Performance Score that providers/facilities would need to achieve in order to avoid a payment reduction from 26 to 30 points. We noted that providers/facilities that score between 26–29 points would receive a 1.0 percent payment reduction; between 21–25 points, a 1.5 percent payment reduction; and between 0–20 points, providers/facilities would receive the full 2.0 percent payment reduction (see Table 3 below). We believe that applying a payment reduction of 2.0 percent to providers/facilities whose performance falls significantly below the performance standards, coupled with applying two intermediate payment reduction levels to providers/facilities based on lesser degrees of performance deficiencies, will provide proper incentives for all providers/facilities to improve the quality of their care.

**Table 3. Proposed PY 2013 Payment Reduction Scale**

| Total Performance Score | 2013 Percent of Payment Reduction |
|---|---|
| 30 Points | 0.0 Percent |
| 26-29 | 1.0 Percent |
| 21-25 | 1.5 Percent |
| 0-20 | 2.0 Percent |

The comments we received on this proposed scoring, weighting, and payment methodologies and our responses are set forth below.

*Comment:* Several commenters expressed concern that the PY 2013 scoring methodology and resulting payment reductions are too aggressive and would overly penalize facilities, draining them of monetary resources and morphing the ESRD QIP into a cost-cutting program. Several commenters suggested either doubling the penalty or requiring more points to avoid a penalty, but not both, stating that it is unreasonable of CMS to expect facilities to improve so rapidly from PY 2012 to PY 2013. Commenters also argued that CMS should reassess its PY 2013 scoring because nearly all of the performance period will have passed before the rule is finalized, not allowing providers/facilities enough time to make the necessary adjustments, and a facility that does not meet the performance standard for one measure may be significantly and unduly penalized because the program only evaluates two measures. Other commenters noted that many other quality programs have a broader sliding scale which gives more incentive for improvement and suggested that the PY 2012 payment scale of 0.5–2.0 percent also be used for PY 2013. This broader range was also suggested because it may take patients a period of time to stabilize or larger penalties might result from outliers, and the penalty structure should be more forgiving of these patients. Other commenters also stated that, because of the change in scoring from PY 2012, patients will be unable to compare facilities' scores and note progress.

*Response:* We believe that providers/facilities should always be striving to improve the quality of care they provide to patients. Therefore, we believe it is appropriate, in the second year of the program, to set a higher standard to further encourage improvement. Because both of the measures that we adopted for the PY 2013 ESRD QIP were included in the PY 2012 ESRD QIP measure set, we believe that it is reasonable to expect providers/facilities to have implemented practices to improve their performance on these measures. Additionally, because we are using the special rule, providers/facilities will be evaluated based on the lesser of two standards, which should help alleviate the concerns expressed by the commenters.

We designed the scoring based on a scale similar to what we are using for the PY 2012 ESRD QIP to make it easier for Medicare beneficiaries to compare providers'/facilities' performance in PY 2012 and PY 2013. Although we are using one less measure and weighting the measures differently in PY 2013, we believe that Medicare beneficiaries will still be able to compare both the overall quality of provider/facility performance (for example, whether the performance improved as a whole from PY 2012 to PY 2013), and the degree to which provider/facility performance on each of the two PY 2013 measures may have changed (because the certificates will display individual measure scores).

*Comment:* Some commenters voiced their support for the PY 2013 scoring methodology, including the more rigorous scale and the equal weighting of the PY 2013 measures.

*Response:* We thank the commenters for their support. For the reasons stated above, we are finalizing the proposed scoring, weighting, and payment methodology for the PY 2013 ESRD QIP.

2. Proposed PY 2014 ESRD QIP

a. Proposed Performance Measures for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we proposed to continue using the Hemoglobin Greater Than 12g/dL measure, adopt seven new measures (Kt/V Dialysis Adequacy, Vascular Access Type (VAT), Vascular Access Infections (VAI), Standard Hospitalization Ration (SHR)-Admissions, National Healthcare and Safety Network (NHSN) Dialysis Event reporting, Patient Experience of Care (ICH CAHPS) reporting, and Mineral Metabolism reporting) and to retire the URR Hemodialysis Adequacy measure. We also proposed to adopt measures under section 1881(h)(2)(A)(iii) of the Act. In specifying such measures, we recognize that section 1881(h)(2)(B)(i) of the Act requires that they must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity is currently the NQF) unless the exception in clause (ii) applies. That provision provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practicable measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by consensus organizations identified by the Secretary.

i. Anemia Management Measure

Section 1881(h)(2)(A)(i) of the Act requires that the measures specified for the ESRD QIP include measures on anemia management that reflect the labeling approved by the FDA for such management. For the PY 2014 ESRD QIP, we proposed to retain the Hemoglobin Greater Than 12g/dL measure that we adopted for the PY 2012 ESRD QIP and are finalizing in this final rule for the PY 2013 ESRD QIP. We made this proposal for the same reasons that supported our proposal to retain this measure for the PY 2013 ESRD QIP measure set.

The comments we received on this proposed measure are discussed above in the section discussing the PY 2013 ESRD QIP. For the reasons stated above, we finalize the Hemoglobin Greater Than 12 g/dL measure for the PY 2014 ESRD QIP. The specifications for this measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-HGB12-2013-2014-FR.pdf.*

ii. Dialysis Adequacy Measure

Section 1881(h)(2)(A)(i) of the Act requires that the ESRD QIP include measures on dialysis adequacy. For the PY 2014 ESRD QIP, we proposed to retire the URR Hemodialysis Adequacy measure we adopted for the PY 2012

ESRD QIP and are finalizing in this final rule to retain for the PY 2013 ESRD QIP. In its place, we proposed to adopt a measure of dialysis adequacy based on Kt/V (K = dialyzer clearance, t = dialysis time, and V = volume of distribution) for the PY 2014 ESRD QIP. Kt/V has been advocated by the renal community as a more widely accepted measure of dialysis adequacy. Specifically, Kt/V more accurately measures how much urea is removed during dialysis, primarily because the Kt/V calculation also takes into account the amount of urea removed with excess fluid. Further, the proposed measure assesses Kt/V levels in both hemodialysis (HD) patients (in-center and home (HHD)) and peritoneal dialysis (PD) patients, and is based on two Kt/V measures of dialysis adequacy that have been endorsed by the NQF (#0249 [2] and #0318 [3]). Specifically, the proposed measure assesses the percent of Medicare dialysis patients (PD, HD and HHD) meeting the modality specific Kt/V threshold. For hemodialysis patients (HHD and in-center patients), we proposed to measure the percentage of adult (≥ 18 years old) Medicare patients dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the Urea Kinetic Modeling (UKM) or Daugirdas II formula) was a Kt/V of at least 1.2 during the proposed performance period. For PD patients, we proposed to measure the percentage of adult (≥ 18 years old) Medicare patients whose average delivered PD dose was a weekly Kt/V urea of at least 1.7 (dialytic + residual) during the proposed performance period. The specifications for the proposed measures exclude pediatric patients. The NQF has since endorsed a separate pediatric hemodialysis adequacy measure (#1423), and we are considering how to best incorporate this measure into future years of the QIP.

The comments we received on the proposed Kt/V measure and our responses are set forth below.

*Comment:* Several commenters expressed concern that providers/facilities use different methodologies to calculate Kt/V and asked CMS to indicate which methodology should be used. Several commenters noted that this disparity in formulas and specifications may lead to disparate baseline standards and requested that CMS standardize requirements for Kt/V values for performance standards instead and/or wait until PY 2015 to implement the measure. Some commenters asked CMS to acknowledge that Daugirdas II or UKM formulas should be used for those patients receiving thrice weekly hemodialysis care. One commenter urged CMS to rigorously validate comparison calculation methods to assure that if different equations are used, they provide comparable results for Kt/V. Another commenter suggested that it would be extremely difficult, if not impossible, for the agency to correct the lack of standardization in the base year and asked instead that CMS take this into account in weighting this measure.

*Response:* Beginning January 1, 2012, we have asked providers and facilities to report Kt/V values on claims using the Daugirdas II or UKM formulas, which are also the formulas specified in the NQF-endorsed hemodialysis adequacy measures based on Kt/V (CR 7460). We have also stated that residual renal function should be included in the peritoneal dialysis Kt/V value but not included in the hemodialysis Kt/V value. We recognize the commenters' concerns and agree that it would be difficult, if not impossible, to create accurate, comparable Kt/V measure scores for providers/facilities that might not have used either the Daugirdas II or UKM formula in their Kt/V reporting or that may have incorporated residual renal function differently. In light of this concern, we are not finalizing our proposal to adopt the Kt/V dialysis adequacy measure for the PY 2014 ESRD QIP. We intend to propose to adopt a Kt/V dialysis adequacy measure for future years of the ESRD QIP and welcome public input as we proceed with this process.

We recognize that we are required under section 1881(h)(2)(A)(i) to include measures on dialysis adequacy in the ESRD QIP. For this reason, we are also not finalizing our proposal to retire the URR Hemodialysis Adequacy measure for the PY 2014 ESRD QIP and will continue to include this measure in the PY 2014 measure set. For the reasons stated in the CY 2011 ESRD PPS final rule (75 FR 49182) we believe that the URR Hemodialysis Adequacy measure continues to be an appropriate and accurate measure of hemodialysis adequacy.

*Comment:* Many commenters strongly supported CMS' proposal to use Kt/V to measure dialysis adequacy beginning with the PY 2014 ESRD QIP because it is widely accepted, is used extensively by the renal community as a measure of dialysis adequacy, and is the basis for measures endorsed by the NQF. One commenter stated a belief that Kt/V is a substandard measure as it does not adequately reflect the patient's quality of life. One commenter noted that CMS should also promote the understanding that minimal Kt/V levels may not be optimal levels and should develop a method for assessing dialysis adequacy across all modalities; another commenter argued that CMS should use the last Kt/V value of the month for each patient to calculate the measure rate because it is the best clinical indicator of the actual dialysis dose delivered to a patient during the month. Some commenters stated that the measure specifications excluding Kt/V values exceeding 2.5 for patients receiving thrice weekly in-center nocturnal hemodialysis may not be appropriate because many patients achieve such values and asked that this exclusion be removed from the measure. Commenters also suggested that adjustments should be made in the Kt/V measure for short daily, more frequent, and nocturnal treatments. Commenters asked CMS to exclude residual renal function (RRF) because it could result in patients being under dialyzed, and it carries operational burdens such as requiring patients to collect urine during a 48-hour period. Some commenters, however, asked CMS to consider RRF in the calculation so that the Kt/V measure does not cause over-treatment. One commenter asked for clarification of the Kt/V specifications in two areas: (i) For PD patients, (a) does CMS require that facilities report the average of all available values for the year; (b) should the facilities record Kt/V every 3 or 4 months; and (c) when should the RRF be measured; and (ii) for both HD and PD, (a) What are the requirements related to urea clearance; and (b) can facilities use creatinine clearance as an alternative? Although not specific, some commenters noted that some of the measure specifications were not clear or were confusing and asked for clarification. One commenter suggested that the proposed Kt/V dialysis adequacy measure be calculated as the average of twelve months Kt/V values in an index year. One commenter questioned the functionality of CROWNWeb to collect Kt/V measurements in CY 2012.

*Response:* For the reasons stated above, we will not finalize this measure for the PY 2014 ESRD QIP but we intend to propose to adopt a Kt/V dialysis adequacy measure for the program as soon as possible. We will take the many comments regarding the use of Kt/V and questions regarding the measure

[2] Note that in the proposed rule, we mistakenly referred to this measure as #0250.

[3] Note that in the proposed rule, we mistakenly referred to this measure as #0321.

specifications into account as we develop this future proposal.

*Comment:* Some commenters urged CMS to develop a dialysis adequacy measure for hemodialysis patients who dialyze more or less than three times per week, either at home or in a clinic.

*Response:* We agree with the commenter that a dialysis adequacy measure for hemodialysis patients who dialyze more or less than three times per week, either at home or in a clinic, is an important quality indicator that should be part of the ESRD QIP. At this time there is no consensus within the ESRD stakeholder community as to what the correct formula or target value should be for this population. We are committed to working with the stakeholder community to achieve consensus on the correct formulas and target values for this population and to developing measures for future years of the ESRD QIP that accurately assesses the adequacy of hemodialysis for this population.

For the reasons stated above, we are not finalizing the proposed Kt/V Dialysis Adequacy measure for the PY 2014 ESRD QIP. We are also not finalizing our proposal to retire the URR Hemodialysis Adequacy measure, but are instead finalizing that this measure will be included in the PY 2014 ESRD QIP. The measure specifications for the URR measure can be found at: *http://www.dialysisreports.org/pdf/esrd/public-measures/DialysisAdequacy-URR65-2013-2014-FR.pdf.*

iii. Vascular Access Type (VAT) Measure

Section 1881(h)(2)(A)(iii) of the Act states, in part, that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures on vascular access, including for maximizing the placement of arterial venous fistula. For the PY 2014 ESRD QIP, we proposed to adopt a VAT measure. We noted that arteriovenous (AV) fistulae are the preferred type of vascular access for patients on maintenance hemodialysis. Because of the lower complication rates (including reduced infections), decreased risk of patient mortality, and greater cost efficiency associated with this type of vascular access for eligible patients,[4, 5] we proposed to adopt a VAT measure, based on two measures that are endorsed by the NQF. These measures assess (i) The percentage of a provider's/facility's patients on hemodialysis using an autogenous AV fistula with two needles during the last HD treatment of the month (NQF #0257); and (ii) the percentage of a provider's/facility's patients on hemodialysis using an intravenous catheter during the last HD treatment of the month that have had an intravenous catheter in use for 90 days or longer (NQF #0256).

While catheter reduction and increased use of AV fistula are both important steps to improve patient care, we recognized that these two events are tightly interrelated and do not want to penalize providers/facilities twice for related outcomes. We therefore proposed to combine these two separate measures into one measure to contribute jointly to the Total Performance Score. Because the rates and goals for each subcomponent measure are very different, we proposed to calculate separate measure rates for each measure, based on a provider's/facility's performance on each subcomponent measure and to adopt a different methodology (discussed below) for purposes of setting performance standards and scoring providers/facilities on this measure.

As explained above, section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We stated in the proposed rule that we believe that assessing the type of vascular access used in hemodialysis patients is important because clinical evidence has shown that proper vascular access reduces the risk of adverse outcomes such as infections. We also noted that we considered proposing to adopt the two NQF-endorsed measures noted above (#0256 and #0257); however, in order to ensure that these measures fit the purposes of the ESRD QIP, we made modifications to these NQF-endorsed measures. Accordingly, we proposed to adopt this measure under section 1881(h)(2)(B)(ii) of the Act.

We noted in the proposed rule that since July 1, 2010, we have asked dialysis providers/facilities to submit VAT data on ESRD claims (CR 6782). We also proposed that hemodialysis patients with acute renal failure, peritoneal dialysis patients, and patients under 18 years of age would be excluded from this proposed measure. Finally, we stated our belief that adoption of this measure would be consistent with the efforts of the Fistula First initiative, which advances the use of fistulas proven to reduce the risk of infection/morbidity and mortality.[6]

The comments we received on this proposed measure and our responses are set forth below.

*Comment:* Many commenters supported the proposed VAT measure, noting the benefits of AV fistulas and the problems with catheters. Many commenters also stated that they support CMS' decision to exclude hemodialysis patients with acute renal failure, PD patients, and patients under age 18 from this proposed measure.

*Response:* We thank commenters for their support.

*Comment:* Some commenters applauded CMS for proposing to adopt a VAT measure but noted certain ''flaws.'' Commenters noted that the measure (i) ignores grafts, which are preferable to catheters and are available to some patients who are not candidates for fistulas; (ii) is limited to Medicare beneficiaries; (iii) could prejudice facilities with new patient populations who do not yet have a permanent access type and those with patients who refuse or are not eligible for fistulas, causing an access to care issue; and (iv) because of the 90 day requirement for the catheter measure, will provide less than a year's worth of data on which facilities will be evaluated.

*Response:* We thank commenters for their insights and will address each issue in turn. As we have noted previously, VAT is critical to patient care. Catheters are undesirable due to their high rate of complications, such as infections, and we discourage their use through the proposed catheter submeasure. The preferred type of vascular access is an AV fistula due to lower rates of complications, which we promote through the fistula submeasure. Although grafts do decrease the risk of infections and complications when compared to catheters, grafts do not decrease these risks as much as fistulae. We, therefore, do not believe that grafts

[4] *http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/va_guide2.htm.*

[5] *http://www.fistulafirst.org/AboutAVFistulaFirst/History.aspx.*

[6] *See http://www.fistulafirst.org/* for further information regarding this initiative.

are either beneficial enough to be specifically rewarded or harmful enough to be specifically penalized.

We agree that it would be beneficial to measure vascular access type for all ESRD patients, but, at this time, we are unable to collect the needed data through Medicare claims. We believe that when CROWNWeb becomes available as a data collection vehicle for all providers/facilities, we will be able to collect data on all patients, and we anticipate proposing in future rulemaking to change this measure when these events occur. We are actively monitoring access to care and issues associated with ''cherry-picking,'' and it is our intent to engage the community as we monitor these issues.

Finally, we will be able to measure 1 year of catheter data despite the 90 day pre-requisite. The proposed measure specifications state that the catheter submeasure assesses the percentage of hemodialysis patients in whom (i) A catheter was in use at the last hemodialysis treatment of the month and for each of the prior 90 days; and (ii) a catheter was the *only* means of vascular access (that is, patient did not have an AV fistula or AV graft reported at any time during the 90 days).[7] The measure specifications state that patients with a catheter for at least 90 days will be counted in this measure. For example, if a patient was treated at a facility for all of October, November, and December of 2011 and has a catheter for these months, this catheter would be counted in January 2012.

*Comment:* One commenter recommended that CMS: (i) Consider developing adjusters for unusual patient factors, facility census, and overall case-mix to discourage ''cherry-picking''; and (ii) develop a mechanism to more effectively engage, and hold accountable, vascular surgeons in creating successful vascular access. Another commenter suggested that the measure be modified to only include patients with catheters for at least 6 months.

*Response:* We do not agree that only those patients who have catheters 6 months or longer should be included in the measure. We note that the proposed catheter submeasure is based on an NQF-endorsed measure (#0256) which includes patients with a catheter longer than 90 days.[8] It is important to allow facility's some flexibility without underplaying the risks associated with catheter infections. We believe that 90 days allows facilities a window of time to stabilize patients and obtain a functional arteriovenous fistula. We appreciate the role that vascular surgeons play in obtaining vascular access, and we would expect providers/facilities and their staff to work closely together to ensure that proper care is furnished. We note, however, that the ESRD QIP applies only to providers/facilities.

As we noted above, we are actively monitoring access to care and issues associated with ''cherry-picking,'' and will consider proposing additional policies in future rulemaking should we conclude that they would improve the overall quality of the ESRD QIP.

*Comment:* One commenter suggested that CMS develop a measure to monitor fistula flow.

*Response:* We thank the commenter for the suggestion. We continue to work on developing measures appropriate for the ESRD QIP.

*Comment:* One commenter asked for clarification of the VAT measure specifications, including the following: (i) What are the blood flow requirements through the AV fistula; (ii) when in the month is the access type to be reported; and (iii) are Medicare only patients counted? The commenter also asked for clarification of the following catheter submeasure specifications: (i) Are Medicare only patients counted; (ii) do facilities count catheters even if there is another access in place; and (iii) how should facilities report the ''90 day'' requirement if the V-codes do not match this criterion? Some commenters generally commented that the measure specifications are unclear and confusing and asked for clarification.

*Response:* The proposed VAT measure specifications for the AV fistula submeasure do not contain a blood flow requirement but rather require that the dialysis was performed with two needles. We do not require blood flow because we assume that, if a fistula is used for dialysis treatment, the blood flow achieved is adequate to meet treatment goals. Since July 1, 2010, providers/facilities have been asked to report the access that was used for dialysis during the last dialysis session of the month covered by the claim (CR 6782). These instructions were updated, effective January 1, 2012 (CR 7460), to state that, if an AV fistula/AV graft is used (both must be used with two needles to be reported), but the patient still has a catheter in use providers/facilities should report the presence of both the catheter and the AV fistula/AV graft. Accordingly, for purposes of the measure calculation during the performance period, in instances where an AV fistula or AV graft is reported along with a catheter, we will only count the AV fistula or AV graft as the patient's access type. For purposes of the measure calculation during the baseline period, we exclude any claims reporting more than one access type because we assume this was reported in error since the guidance did not indicate that more than one access type should be reported. Only Medicare patients are included in the proposed VAT measure because we will be calculating it using Medicare claims data. The specifications for the catheter submeasure exclude catheters present for less than 90 days during calculation of the catheter measure rate in order to allow time to establish another form of vascular access. All catheters must be reported regardless of duration of use, the 90 day exclusion will be applied at the time of measure rate calculations.

We thank commenters for requesting clarification, and we would clarify in this final rule that, for the catheter submeasure, a patient will only be attributed to a facility if he or she was at that facility for the 90 days during which he or she had a catheter so that providers/facilities have adequate time to facilitate placement of a permanent access and are not penalized for care provided prior to the patient receiving care at the facility. Because claims do not specify the access type for each patient at every dialysis session, we also clarify that, if the last session of a month indicates only a catheter, we consider that patient to have had the catheter for the entirety of that month.

We further clarify that we will use a patient-month methodology calculating the submeasure rates for the VAT measures (*i.e.* each patient's value for each month will be included in the measure rate [9]).The NQF measures which we referred to in the proposed rule are calculated for a one month time period; however, our measure specifications stated that the VAT measure can be calculated in a manner similar to the PY 2012 ESRD QIP measures which are calculated as a percent of patients (*i.e.* each patient's mean or median value is calculated for the year at the facility and then the patient is classified as meeting the

[7] *See http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2014-FR.pdf* and *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2014-FR.pdf.*

[8] *See http://www.kidney.org/professionals/kdoqi/pdf/12-50-0210_JAG_DCP_Guidelines-VA_Oct06_SectionC_ofC.pdf*; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id...67692.*

[9] For example, if one patient was treated every month, his/her claim inputs would account for twelve, individual inputs for calculating the measure rate. Whereas a patient that is only seen for four months would be counted as four inputs.

requirement or not). We believe that patient-months would provide a more accurate picture of the care provided to a patient by weighting the VAT by the number of months that access was present. For instance, if a patient had a catheter for seven months out of the year and an AV fistula for 5 months, the patient's ''average'' access would be a catheter and the facility would get no credit for the presence of an AV fistula. By using patient-months, we can more accurately assess these patients by counting seven of 12 months towards the catheter submeasure and five of 12 months towards the AV fistula submeasure. This would also weight each patient's contribution to the facility measure rate by the amount of time a patient received care in that facility.[10]

After considering the comments, we finalize the VAT measure for the PY 2014 ESRD QIP with the clarifications and changes discussed above. This measure is comprised of two submeasures, one of which measures catheters and one of which measures AV fistulas. The VAT measure specifications can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2014-FR.pdf* and *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2014-FR.pdf*.

iv. Vascular Access Infections (VAI) Measure

We proposed to measure dialysis access-related infection rates by assessing the number of months in which a monthly hemodialysis claim reports a dialysis access-related infection using HCPCS modifier V8, and we noted that since July 1, 2010, we have asked dialysis providers/facilities to code all Medicare claims for dialysis access-related infections using this modifier (CR 6782). As discussed more fully in the proposed rule, we proposed to adopt this measure under section 1881(h)(2)(B)(ii) of the Act.

The public comments we received on the VAI measure and our responses are set forth below.

*Comment:* Many commenters commended CMS for moving towards measuring infections. However, some commenters noted that infections should not be measured through claims because claims data are unable to provide precise identification of healthcare-associated infections (HAIs), nor do they provide information in a timely manner to effectively drive quality improvement. Additionally, several commenters noted or asked for clarification regarding whether claims can result in duplicative counting of a patient with a recurrent infection, penalizing a facility twice (or more) for the same event. Commenters also stated that CMS has not issued specific guidance for uniformity in reporting the V8/V9 modifiers and requested a workable definition of VAI to account for cases where it is difficult to accurately identify the source of infection. One commenter argued that infection measures should not be a composite so that facilities can individualize areas of concern. Some commenters noted the measure's lack of precedent and NQF endorsement, suggesting instead that CMS use the NHSN-endorsed measure (NQF #1460) (which would also prevent redundancy) or change the measure to a reporting measure only.

*Response:* We agree that reducing vascular access infections is critical to improving quality of care because infections are one of the leading causes of morbidity and mortality among the Medicare ESRD population. Furthermore, many of these infections can be prevented through evidence-based practices. However, in response to these comments, we reassessed our proposal and concluded that the claims-based data that we proposed to use to calculate this measure is not detailed enough and, as a result, could lead to inaccurate assessments and comparisons of quality. In addition, we are also proposing that providers/facilities begin reporting similar information via the CDC NHSN Dialysis Event reporting system and recognize the burden that may result from requiring reporting to two separate systems for purposes of the ESRD QIP. We note that commenters were much more supportive of the CDC infection tracking system and the associated NHSN-based blood stream infection measure which is NQF-endorsed (#1460) and upon which we based the NHSN Dialysis Event reporting measure. Given the overall quality of the data obtained through the NHSN system and the general support expressed by the ESRD community, we believe that patients' needs will be best served if providers/facilities focus efforts on reporting infection data via the CDC NHSN system. We recognize that the proposed PY 2014 NHSN Dialysis Event reporting measure would not be calculated using actual infection data, but we will consider incorporating a measure which is calculated based on the substance of the data collected through the NHSN Dialysis Event reporting system for future years if the data indicates a need for financial incentives to drive improvement.

*Comment:* One commenter argued that, because of the prevalence and costs associated with catheter related infections, catheter measures should be in the PY 2012 ESRD QIP and, because the ESRD QIP can only penalize a facility by up to two percent, a new program should be implemented to penalize facilities further for catheter infections. Additionally, this commenter stated that ESRD facilities should be required to educate patients on appropriate homecare and supplies to help prevent infection.

*Response:* We thank the commenter for the input and concern. CMS continues to consider programs within its statutory authority which will lead to an increase in the quality of care provided to Medicare ESRD beneficiaries. The PY 2012 ESRD QIP, however, has been finalized, and we have calculated and will shortly be implementing the resulting payment reductions. We note that the ESRD Conditions for Coverage require that the patient be included as a member of the dialysis multidisciplinary team, and that providers/facilities educate patients and promote appropriate patient care (for example 42 CFR 494.90(d)).[11]

For the reasons discussed above, we are not finalizing the VAI measure for use in the PY 2014 ESRD QIP. We will consider proposing in future rulemaking to adopt a CDC NHSN-based clinical measure that assesses infection rates related to dialysis.

v. Standardized Hospitalization Ratio (SHR)-Admissions Measure

In the proposed rule, we proposed to adopt the SHR-Admissions measure to measure hospitalizations for Medicare dialysis patients. We proposed to adopt this measure under section 1881(h)(2)(A)(iii) of the Act. The proposed SHR-Admissions measure is a risk-adjusted measure of hospitalizations for Medicare dialysis patients. The data needed to calculate the proposed SHR-Admissions measure is based on claims and has been regularly reported to DFR since 1995 (previously known as Unit-Specific Reports). We noted that the measure is an ''all-cause'' measure, meaning that

[10] For example, if one patient was treated every month, his/her claim inputs would account for twelve, individual inputs for calculating the measure rate. Whereas a patient that is only seen for four months would be counted as four inputs.

[11] We also encourage providers/facilities to utilize other clinical practice guidelines regarding patient education. *See,* for example, *http://www.kidney.org/professionals/kdoqi/pdf/12-50-0210_JAG_DCP_Guidelines-VA_Oct06_SectionC_ofC.pdf*.

hospitalizations related to other medical conditions outside of ESRD are included in the measure. We refer readers to the proposed rule for further information on this proposed measure (76 FR 40524).

The public comments we received on the SHR-Admissions measure and our responses are discussed below.

*Comment:* Many commenters voiced concern that the SHR-Admissions measure does not reflect issues that dialysis facilities can control, may lead to untimely or inappropriate care, and is not adequately transparent in its calculation. Commenters also stated that the measure may lead to ''cherry-picking'' of patients based on their risk of hospitalizations, causing access to care issues for patients with more severe illness. Commenters suggested that, instead, CMS measure hospitalizations resulting from the care, or lack of care, provided by ESRD facilities. Other commenters disapproved of the SHR-Admissions measure because there is currently no mechanism either for correcting or updating patient comorbidity data on CMS' Medical Evidence Reporting Form 2728, and these comorbidities affect the calculation of the measure. Another commenter stated that, because patients in nursing homes are more likely to have a greater number and severity of comorbidities, the metrics for independent living patients and nursing home patients should be compared to determine if the established goals place nursing homes at a disadvantage in achieving such goals. Another commenter suggested that, because of the issues mentioned above, if CMS retains the measure, it should weight it less than the other clinical measures. Some commenters suggested that CMS use a longer baseline period, such as four years.

*Response:* After reviewing these comments, we have decided, for the reasons articulated by commenters, to not finalize our proposal to adopt the SHR-Admissions measure for the PY 2014 ESRD QIP. We recognize concerns that this measure may not promote improved patient care and may not accurately reflect hospitalizations which can be controlled by dialysis facilities, and we are concerned about the potential for ''cherry-picking.'' We are additionally concerned that we do not yet have the necessary data to more accurately risk-adjust the measure. Therefore, after considering the comments, we agree that the measure as proposed should not be included in the PY 2014 ESRD QIP. We intend, however, to work to develop a measure for future years of the ESRD QIP that does not raise the issues identified by the commenters, and we welcome public input on the composition of such a measure.

*Comment:* One commenter supported tracking hospitalization rates among dialysis clinic patients. Another commenter suggested that the SHR-Admissions measure could be used as a balancing measure once CMS retires the Hemoglobin Less Than 10 g/dL measure to ensure that patients do not experience hospitalizations due to hemoglobin levels that are too low.

*Response:* We thank the commenters for their support, but, for the reasons stated above, we will not include this measure in the program at this time. While the SHR-Admissions measure would include hospitalizations due to anemia, the SHR-Admissions is an all-cause measure, and it is uncertain how sensitive it would be in detecting practice changes and patient outcomes related to anemia management alone. As we have stated, we will continue to work with the ESRD community to develop appropriate measures reflecting hospitalizations and will specifically consider measures which account for hospitalizations related to inappropriate anemia management.

For the reasons discussed above, we are not finalizing the SHR-Admissions measure for use in the PY 2014 ESRD QIP. We intend to work with the community to adopt a measure for future years of the program that more accurately measures quality of care in this area.

vi. Minimum Case Number for Clinical Measures and Other Considerations

We proposed that a provider/facility would need to report a minimum number of eleven cases for a proposed clinical performance measure in order to receive a score on that measure (76 FR 40533). As stated above, we believe that this minimum threshold will help reduce the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider's/facility's performance score.

The comments we received regarding this proposal and our responses are set forth below. We also address other comments regarding the measures we proposed to adopt for the PY 2014 ESRD QIP below.

*Comment:* Commenters voiced concerns about CMS' approach to including low-volume facilities in the program because one patient could significantly affect a score for reasons unrelated to quality of care, such as comorbidities. This scoring could, in turn, affect patient volume if patients and their care-givers judge facilities based on their scores. Commenters suggested different minimum case thresholds such as 20 cases or 25 cases, or that providers with fewer cases be scored differently; some commenters also noted that their studies showed that the sample size rather than overall performance is driving the results for facilities and requested that CMS raise the case minimum to 20. Another commenter urged CMS to research the reliability of a measure to set the minimum number of cases, publish minimum case reliability data, and use this data to set a minimum number of cases for all value-based purchasing programs. One commenter urged CMS to re-consider its scoring methodology to analyze for statistical significance. Another commenter stated the belief that the ESRD QIP methodology does not appropriately account for low patient census, unusual treatment setting, or patient case-mix, and recommended that CMS develop a mechanism to adjust for circumstances in which facilities with an unusual care setting, atypical case-mix, or small patient census may be at high risk of incurring penalties for failure to meet performance standards.

*Response:* We appreciate the commenters' concerns regarding the potential impact of patient case mix on smaller providers/facilities. One goal of the ESRD QIP is to accurately assess the quality of care provided by a provider/facility. However, we recognize that a quality measure score could be impacted by one or more factors unrelated to the care furnished by the provider/facility, and that the potential of such factors to greatly skew the calculation decreases as the number of cases included in the measure increases. Similarly, a provider/facility with a small number of patients could find that one patient's outcome determined its score on a quality measure. Thus we proposed that a provider/facility would need to have a minimum of eleven cases that meet the eligibility criteria for a measure in order to be scored on that measure. This eleven case minimum allows as many providers/facilities as possible to participate in the program. This minimum case number is also consistent with how we have traditionally reported measures on Dialysis Facility Compare. We will continue to closely monitor beneficiary access to care, including evaluating the rate of facility closures.

We recognize, however, that we are introducing new measures and scoring methodologies for the PY 2014 program. As additional data becomes available for these measures, we will conduct additional analysis to assess our case

minimum. If we determine that a different threshold is more appropriate, we will propose an alternative scoring approach in future rulemaking for the ESRD QIP to ensure that smaller or low-volume facilities are not unfairly penalized.

*Comment:* One commenter urged CMS to use only NQF-endorsed measures for the ESRD QIP because of the NQF's high level of review. Because none of the PY 2014 measures are NQF-endorsed, this commenter does not support their adoption.

*Response:* We believe that, when evaluating measures for the ESRD QIP, it is important to consider measures endorsed by NQF and other consensus-based entities and we have based our measures on available endorsed measures where possible. We note, however, that under Section 1881(h) of the Act, the Secretary has discretion to adopt measures that are not NQF-endorsed in certain circumstances. We refer readers to our discussions of our rationale for adopting the individual measures, above.

*Comment:* Commenters noted that the same data sent to multiple laboratories can yield different results from each laboratory. They noted that this variability, rather than the actual care delivered, may affect provider's/facility's rates and, ultimately, their Total Performance Scores. These commenters suggested that CMS incorporate an acceptable standard deviation value into the measure rate calculations in order to mitigate this variability. One commenter also stated that CMS should allow rounding to the tenth to address ''between instrument variability within a single laboratory.''

*Response:* The proposed PY 2014 scoring methodology allows providers/facilities some latitude to account for issues such as laboratory variability. For example, as further explained below, providers/facilities need not score at the performance standard for each measure in order to avoid a payment reduction. We believe that such flexibility mitigates concerns about details such as laboratory variability. We do agree that it is important to account for the precision of the data that we use to calculate rates and scores, and, as explained above with regard to the Hemoglobin Greater Than 12 g/dl measure, we will specify the number of decimal places for measure calculations to reflect the precision of the data submitted by providers/facilities.

*Comment:* One commenter requested clarification that the PY 2014 measures do not apply to providers/facilities that only treat patients receiving peritoneal dialysis (PD).

*Response:* Two of the measures apply to PD patients and, therefore, PD-only facilities will be evaluated on these measures. According to the specifications, adult PD patients would be included in the calculations for the following measures: Hemoglobin Greater Than 12 g/dL, and the Mineral Metabolism reporting measure. Pediatric PD patients qualify for the mineral metabolism reporting measure.

For the reasons stated above, we are finalizing our proposal that a provider/facility must have a minimum of eleven cases for a measure, each with four claims, in order to receive a score for that measure.

vii. National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

As we noted in the proposed rule, healthcare-associated infections (HAI) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. In a national effort to reduce this outcome, Department of Health and Human Services agencies, including CMS, are partnering with the Centers for Disease Control and Prevention (CDC) to encourage providers to report to the NHSN as a way to track and facilitate action for reducing HAIs.

The NHSN is currently a secure, Internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at the CDC. NHSN has been operational since 2008 with acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. We believe that reporting dialysis events to the NHSN by all providers/facilities would support national goals for patient safety, and particularly goals for the reduction of HAIs. Accordingly, for the PY 2014 ESRD QIP we proposed to adopt a measure that would assess whether providers/facilities enroll and report dialysis event data to the NHSN.

We stated our belief that, by measuring only whether providers/facilities report dialysis event data to the NHSN, providers/facilities would be given time to become familiar with the NHSN reporting process. We also noted our intention in the future to propose to adopt a measure that would score providers/facilities based on actual dialysis events reported to the NHSN if necessary. Specifically, we proposed that providers/facilities: (i) Enroll in the NHSN and complete any training required by the CDC; and (ii) submit three or more consecutive months of dialysis event data to the NHSN.

Section 1881(h)(2)(B)(i) of the Act requires that unless the exception set forth in section 1881(h)(2)(B)(ii) applies to the Act, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently the NQF). Section 1881(h)(2)(B)(ii) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although a measure calculated using NHSN Dialysis Event data is currently endorsed by the NQF, the measure for reporting purposes only has not been NQF-endorsed. We noted that because HAIs are a significant patient safety concern, we intend to propose to adopt one or more measures that assess actual dialysis event rates in the future if necessary.

The public comments we received on the proposed NHSN Dialysis Event reporting measure and our responses are discussed below.

*Comment:* Many of the commenters voiced general approval of the proposed NHSN reporting measure, but voiced concern that the required training, enrolling, and reporting will unduly burden many facilities, diminishing the amount of time staff can focus on patients. One commenter suggested that CMS more clearly study and define what is needed of staff before moving forward with the measure. Other commenters noted that CROWNWeb will be collecting similar data upon its implementation, leading to redundancy in reporting and further burdening providers/facilities, and requested that CMS delay an infection reporting measure until it can be recorded via CROWNWeb. Commenters also noted that this measure is redundant because it captures data already being captured by other measures. Other commenters expressed concern that the CDC does not have infrastructure to be able to support the high volume of new reports and facilities will not have the necessary reporting mechanisms in place to submit these reports. They suggested that providers/facilities only be scored on enrolling and training for PY 2014, delaying actual reporting of

data to allow providers/facilities to prepare to meet the NHSN requirements and the NHSN to prepare for receiving these reports. One commenter noted that the CDC reporting requires manual entry which can lead to data entry error and suggested the CMS arrange an alternative mechanism for collection; another commenter suggested that this mechanism be CROWNWeb.

*Response:* The CDC has informed us that it is preparing for the additional volume of new system enrollees and data reporting that will result from the ESRD QIP and is enhancing the NHSN's technical infrastructure. Additionally, our proposal that providers/facilities submit, at a minimum, only three consecutive months of data in CY 2012 is expected to lessen the demand on the NHSN's infrastructure. Thus, we believe that the CDC will be able to accommodate the additional data that will be reported to the NHSN as a result of this measure.

Furthermore, we do not believe that this reporting requirement will unduly burden providers/facilities. For facilities that are currently enrolled in the NHSN, CDC has studied what is required of staff in order to comply with this reporting. In addition, we believe that this reporting requirement will not be burdensome because, reporting this data will only take five to ten minutes per patient, or a total of two hours and ten minutes, of staff time per month for a facility of average size. Although we stated in the proposed rule that we believed that enrolling and training would take a total of 48 hours per facility (76 FR 40540), based on data we have since received from the CDC, we have revised that analysis in the final rule and now believe that both enrolling and training, each a one-time event, will take approximately 8 total hours, spread across a period of several weeks, to complete. Although the NHSN currently requires manual entry of data, CDC is moving towards an electronic system that will further reduce the time required for data entry and reduce the opportunity for error.

Finally, we, as we noted above, we agree with this measure's possible redundancy and we are no longer adopting the VAI measure for PY 2014. Thus, the NHSN measure will be the only measure related to infections. Furthermore, we do not intend to require reporting of the same data elements to both the NHSN and CROWNWeb. It is our intent to require providers/facilities to report dialysis event data to only one system.

Despite our belief that this measure will not unduly burden providers/facilities, to decrease any perceived burden and to further align our reporting requirements with those of NHSN, we will allow all facilities until March 31, 2013 at 11:59 EST to report these data as allowed by the NHSN system.

*Comment:* One commenter suggested that, if CMS requires this burdensome reporting, CMS should increase its base rate for dialysis care. Another commenter noted that this measure does not increase quality because it only requires reporting.

*Response:* Section 1881(h) of the Act does not authorize the Secretary to increase the base rate for dialysis care. Furthermore, we do not agree that this measure does not incentivize quality. In order for providers/facilities to successfully report at least 3-consecutive months of data to the NHSN, the provider/facility must either have or must implement processes to record dialysis infection events. This implementation will require providers/facilities to begin monitoring dialysis events and could draw their attention to areas in need of improvement. In future years of the ESRD QIP, we will consider incorporating a measure based on providers'/facilities' infection rates.

For the reasons stated above, we are adopting the NHSN reporting measure for the PY 2014 ESRD QIP.

viii. Patient Experience of Care Survey Usage Measure

Section 1881(h)(2)(A)(ii) of the Act states that the measures specified for the ESRD QIP shall include, to the extent feasible, a measure (or measures) of patient satisfaction as the Secretary shall specify. Information on patient experience with care at a facility is an important quality indicator to help providers/facilities improve services to their patients and to assist patients in choosing a provider/facility at which to seek care. We proposed to adopt a measure for the PY 2014 ESRD QIP that assesses provider/facility usage of the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey. The intent of including this reporting measure is to assess the degree to which providers/facilities are providing their patients with a voice in the quality of their hemodialysis care.

We proposed to measure whether a provider/facility administers the survey, but we did not propose to measure a provider's/facility's actual performance based on the survey results. We expect to adopt such a measure for the ESRD QIP in future rulemaking. For purposes of reporting this proposed measure for the ESRD QIP, we stated that we will consider the ICH CAHPS survey to have been administered if the provider/facility administered it in accordance with the current specifications for the survey. These specifications can be accessed at: *https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222*.[12]

We proposed to measure whether a provider/facility has attested that it successfully administered the ICH CAHPS survey during the performance period for the PY 2014 program. We proposed that providers/facilities would be required to submit this attestation through CROWNWeb (which will be implemented nationally in 2012) by January 30, 2013 at 11:59 p.m. EST.

The public comments we received regarding the proposed ICH CAHPS reporting measure and our responses are discussed below.

*Comment:* Many of the commenters were generally supportive of a patient experience measure, but stated that the ICH CAHPS survey is too burdensome for patients to complete and for providers/facilities to implement. Several of these commenters suggested that, instead, either providers/facilities be allowed to field any type of patient experience survey or CMS adopt a more simplistic patient experience measure. Other commenters suggested that the 57 question survey be split into three independently verified domains, each given to one-third of the patient population and each including a set of core questions, to lessen patient burden and prevent incomplete surveys. One commenter believes the survey should more adequately address the range of care a patient may receive and suggested that CMS develop a process measure to allow patients to voice individual dialysis experiences. Some commenters asked CMS to implement a survey that is validated across all treatment modalities and settings; another commenter asked CMS to clarify whether the survey applies to PD and HHD. One commenter also noted that this measure alone is not sufficient because it requires providers/facilities to attest to administration of the survey, but it does not base payment reductions upon the results of these surveys.

*Response:* We thank commenters for their support and suggestions. As we noted in the proposed rule (76 FR 40525), we believe empowering patients to voice their concerns is a critical part of quality improvement. Patient surveys can, and should, draw provider/facility

[12] In order to successfully field the survey, the facility/provider must follow the recommendations found at: *https://www.cahps.ahrq.gov/CAHPSkit/files/53_Fielding_the_ICH_Survey.pdf.*

attention to insights that can only be provided by those receiving care. Given the importance of this survey, we do not believe the burden to patients or providers/facilities outweighs the importance of this measure. Many of the concerns the commenters voiced can be mitigated without decreasing the number of questions on the survey or how the survey is administered. For example, as the specifications indicate,[13] patients may take a break during the administration of the survey or take the survey in multiple sittings if they feel that the number of questions is too great to answer at one time. Additionally, the survey requires third-party administration, taking no additional dialysis staff time.

We note that the ICH CAHPS survey was developed through the study of surveys used by dialysis providers. The CAHPS tool went through extensive testing during development including focus groups and one-on-one patient sessions. Thus, we believe that this survey is the best method available at this time to measure patient experience. We also note that we intend to develop a measure that evaluates providers/facilities based on patient responses to the ICH CAHPS survey and use of a uniform survey tool will allow us to more accurately compare providers/facilities in future years of the program.

Furthermore, we disagree that this reporting measure does not improve quality. In order to successfully report the measure, providers/facilities must attest that they have successfully administered the ICH CAHPS survey. The results of these surveys will be reported to the provider/facility by the third-party administrator, and these results can draw providers'/facilities' attention to areas in need of improvement.

Finally, we thank commenters for their suggestions in developing new measures. The ICH CAHPS survey was developed for adult in-center HD patients and this measure therefore does not apply to HHD, PD, or pediatric patients. Further, at this time, we are not aware of a tool which allows patients to rate their experiences for every dialysis experience. We continue to evaluate opportunities to accurately capture patient experience for all modalities.

*Comment:* Some commenters expressed concern that CROWNWeb will not be available or will be unreliable for submitting the ICH CAHPS survey attestations. These commenters, however, also thought that a paper attestation would be overly burdensome. They encouraged CMS to work with the community to offer an alternative solution.

*Response:* CROWNWeb is on schedule for national release in CY 2012 which will allow providers/facilities to report their attestations by the January 2013 deadline. We do recognize, however, that unanticipated delays may occur. Therefore, if CROWNWeb will not be available in time for the January 30, 2013 attestation deadline, we will adopt an alternative, electronic mode of attestation and notify providers/facilities of this method through the ESRD Networks.

*Comment:* One commenter noted discrepancies between the ICH CAHPS specifications and the proposed regulation, including (i) ICH CAHPS requires survey administration to all or a random sample of patients (depending on how many patients the facility serves), whereas the proposed regulation requires surveying in-center hemodialysis patients, and (ii) ICH CAHPS recommends using third-party survey administrators, whereas the proposed regulation seems to expect facilities to survey their own patients. This commenter noted concern that requiring a third-party survey administrator will unequally burden small clinics. Another commenter requested that facilities be allowed to administer their own surveys, provided that those fielding the surveys are not center staff.

*Response:* As outlined in the specifications,[14] the ICH CAHPS survey was developed for adult, in-center hemodialysis patients and, therefore, this is the population to which it must be administered. Specifically, it must be administered to all patients meeting these criteria or, if a facility cares for over 200 such patients, a random sample of 200. This administration must be completed by a third-party; *https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222.* Even if the surveys were not administered by staff with whom the patient had a direct relationship, a patient could still feel pressure to refrain from responding candidly. It is crucial that patients feel comfortable answering honestly and openly, and, therefore, it is vital that this survey be administered by a third-party. As we noted above, although we are aware of the burden associated with this administration, we do not believe it outweighs the importance of recognizing patients' experience of care. For the reasons discussed above, we are finalizing the use of the ICH CAHPS reporting measure in the PY 2014 ESRD QIP.

ix. Mineral Metabolism Reporting Measure

Section 1881(h)(2)(A)(iii) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced CKD. Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation, which is why we believe that routine blood testing of calcium and phosphorus is necessary to detect abnormalities.[15]

The Kidney Disease: Improving Global Outcomes (KDIGO) 2009 guideline recommends that the serum phosphorus level in a dialysis patient generally be lowered toward the normal range, but does not recommend a specific target level that would apply to all patients.[16] The guideline also recommends that therapy to correct for abnormal levels be administered based on the health needs of the individual patient. Accordingly, we noted in the proposed rule that we do not feel it is appropriate at this time to propose to adopt a measure that would penalize providers/facilities if they did not achieve a specific target serum phosphorus level in all patients. We also noted that there is currently no NQF-endorsed measure dealing with the achievement of specific target phosphorus levels. In the time since this rule was proposed, the NQF has endorsed a mineral metabolism measure based on calcium levels (NQF #1454) which we will consider proposing for

[13] *See https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222.*

[14] *https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222.*

[15] Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney International* 2009; 76 (Suppl 113): S1–S130.

[16] Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney International* 2009; 76 (Suppl 113): S1–S130.)

future years of the ESRD QIP.[17] We also noted that the NQF has previously endorsed phosphorus and calcium monitoring measures (NQF #0261 and NQF #0255) and, in 2008, we adopted serum calcium and serum phosphorus monitoring as CPMs (*http://www.dialysisreports.org/ESRDMeasures.aspx*). Despite the current lack of consensus on specific target ranges for both phosphorus and calcium levels in dialysis patients, we stated our belief that there is consensus that monthly monitoring of calcium and phosphorus is important for early detection of abnormalities.

Section 1881(h)(2)(B)(i) of the Act requires that unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Although we gave due consideration to the NQF-endorsed measures on phosphorus and calcium level monitoring in dialysis patients, we noted that it is not feasible for us to propose to adopt either of them at this time as we do not currently collect data on whether these levels are checked for each patient each month to allow calculation of the measure rates. We are also not aware that any other consensus building entity has endorsed or adopted measures on this topic. Therefore, we proposed to adopt a Mineral Metabolism reporting measure that is based on the two NQF-endorsed measures, but requires providers/facilities to attest to compliance with monthly monitoring, and we proposed to adopt it under section 1881(h)(2)(B)(ii) of the Act.

We proposed that providers/facilities would be required to submit an attestation through CROWNWeb that they have conducted the appropriate monitoring. We further proposed that this reporting must be electronically submitted by January 30, 2013 at 11:59 p.m. E.S.T.

We also noted that we anticipate adopting, for future years of the ESRD QIP, one or more mineral metabolism clinical measures in addition to or in replacement of the proposed Mineral Metabolism reporting measure.

The public comments regarding the proposed Mineral Metabolism reporting measure and our responses are discussed below.

*Comment:* Several commenters expressed support for this measure, but requested that CMS also develop an outcomes measure for phosphorus for submission to the NQF for endorsement as soon as feasible. Several commenters urged CMS to also adopt a parathyroid hormone (PTH) measure in order to encompass all areas of bone mineral metabolism. One commenter noted the morbidity and mortality risks associated with extreme PTH values and stated that it is important to monitor the number of patients with PTH below 100 pg/mL and above 400 pg/mL who are not on therapy. Another commenter suggested that CMS consider the addition of a statement in the attestation to indicate that a treatment plan is in place for any abnormalities in bone mineral metabolism; one commenter also expressed concern that the reporting measure alone would not improve quality.

*Response:* We do not agree that this measure does not incentivize quality. In order to successfully report the measure, providers/facilities must attest that they have monitored calcium serum and phosphorous serum at least once a month for each Medicare ESRD patient, and to do that, the provider/facility must either have or implement processes to collect and monitor this data. This monitoring could draw provider/facility attention to areas in need of improvement and mineral metabolism concerns for individual patients.

We continue to explore new measures in the area of bone mineral metabolism; we will consider commenters' suggestions for additional measures for future years of the ESRD QIP, including outcomes-based bone mineral metabolism measures and measures that indicate whether a treatment plan is in place for identified abnormalities.

*Comment:* One commenter agreed that the Mineral Metabolism measure should be a reporting measure only and discouraged CMS from instituting a clinical measure unless and until studies prove a causal relationship between certain values and morbidity and mortality.

*Response:* We thank this commenter for the support. We will consider commenters' suggestion as we develop a mineral metabolism measure for future years of the ESRD QIP.

*Comment:* Some commenters expressed concern that CROWNWeb will not be available or will be unreliable for submitting the Mineral Metabolism attestations. These commenters, however, also thought that a paper attestation would be overly burdensome. They encouraged CMS to work with the community to offer an alternative solution.

*Response:* CROWNWeb is on schedule for national release in CY 2012 which will allow providers/facilities to report their attestations by the January 2013 deadline. We do recognize, however, that unanticipated delays may occur. Therefore, if CROWNWeb will not be available in time for the January 30, 2013 attestation deadline, we will provide an alternative, electronic mode of attestation and notify providers/facilities of this method through the ESRD Networks.

For the reasons discussed above, we are finalizing the Mineral Metabolism reporting measure for the PY 2014 ESRD QIP. We note that, as we proposed, a provider/facility must attest that it measured the calcium and phosphorous of each Medicare ESRD patient at least once per month.

3. Performance Period for the PY 2014 ESRD QIP

Having decided to propose to adopt all of CY 2011 as the performance period for the PY 2013 ESRD QIP, we examined what performance period would be most appropriate for the PY 2014 ESRD QIP. We noted that we believe that a 12-month performance period is most appropriate for the ESRD QIP at this point in the program. We also noted that a period of a year accounts for seasonal variations, but also provides a timely incentive and feedback for providers/facilities, as well as timely performance information for Medicare beneficiaries. We have also determined that CY 2012 is the first feasible period during which we can collect sufficient performance period data for all of the proposed measures. Therefore, we proposed to select all of CY 2012 as the performance period for the PY 2014 ESRD QIP.

The comments we received on the proposed selection of CY 2012 as the performance period and on the use of shorter performance periods in future years, and our responses are set forth below.

*Comment:* Commenters applauded CMS for adopting a prospective

[17] *See http://www.qualityforum.org/Projects/e-g/End_Stage_Renal_Disease_2010/End_Stage_Renal_Disease_2010.aspx* for more information regarding the National Voluntary Consensus Standards for ESRD.

performance period of CY 2012 for the PY 2014 ESRD QIP and noted their disapproval of any performance period of less than a full year.

*Response:* We thank commenters for their support of the proposed PY 2014 performance period. We also believe that it is most appropriate and helpful for providers/facilities to be scored on a full year of data at this point in the program.

For the reasons stated above, we are finalizing CY 2012 as the performance period for all of the finalized measures for the PY 2014 ESRD QIP.

4. Performance Standards and the Methodology for Calculating the Total Performance Score for the PY 2014 ESRD QIP

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for the performance period.

The final rule entitled, ''Medicare Programs; Hospital Inpatient Value-Based Purchasing Program,'' appeared in the **Federal Register** on May 6, 2011 (76 FR 26490) and set forth our view that value-based purchasing represents an important step in revamping how we pay for care and services, allowing CMS to move increasingly toward rewarding better value, outcomes, and innovations instead of merely paying for volume (76 FR 26491). The final rule also set forth principles guiding the development of performance scoring methodologies, including:

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience, and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

For the PY 2014 ESRD QIP, we proposed to adopt a new performance scoring methodology to replace the methodology we are using for the PY 2012 and are finalizing in this final rule for the PY 2013 ESRD QIP. We believe that this scoring methodology will more accurately reflect a provider's/facility's performance on the measures proposed for the PY 2014 ESRD QIP because it will enable us to differentiate between providers/facilities that simply meet the performance standards, those that exceed the performance standards by varying amounts, and those that fall short of the performance standards. We further believe that the proposed methodology will better incentivize providers and facilities to both achieve high Total Performance Scores and improve the quality of care they provide.

i. Performance Standards for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we proposed to establish performance standards under section 1881(h)(4)(A) of the Act. This section of the Act generally provides that, subject to subparagraph (E), the Secretary shall establish performance standards with respect to measures selected for the ESRD QIP for a performance period with respect to a year. Furthermore, under section 1881(h)(4)(B) of the Act, the performance standards established under subparagraph (A) must include levels of achievement and improvement, as determined appropriate by the Secretary. To establish performance standards under section 1881(h)(4)(A) of the Act, the Secretary must also comply with section 1881(h)(4)(C) of the Act, which requires the Secretary to establish performance standards prior to the beginning of the performance period for the year involved.

With respect to the anemia management and dialysis adequacy measures, we proposed to set the achievement performance standard under section 1881(h)(4)(A) of the Act as the national performance rate on each measure during a proposed baseline period. We proposed that the national performance rate for each measure would be calculated at the national aggregate level as the number of Medicare patients for whom the measure was achieved divided by the total number of Medicare patients eligible for inclusion in the measure. We also proposed to set the improvement performance standard as the national performance rate on each measure during the same proposed baseline period. We noted that our goal is to incentivize providers/facilities to achieve these national performance rates, whether they do so by attaining achievement points or improvement points under our proposed scoring methodology (76 FR 40527). We proposed to use a baseline period from July 1, 2010 to June 30, 2011 to calculate the national performance rate. We stated our belief that this baseline period would enable us to calculate national performance rate values for these proposed clinical measures before the beginning of the performance period. We indicated that we would specify these values in the final rule.

With respect to the proposed VAT measure, we proposed to set performance standards using the same methodology and baseline period that we proposed to use for the other proposed clinical measures; however, we proposed to set performance standards for each of the subcomponent measures rather than for the overall combined measure.

We proposed to establish the achievement performance standard for the proposed NHSN Dialysis Event reporting measure as the successful completion by providers/facilities of: (i) Enrollment in the NHSN and completion of the required training during the performance period (as verified by a digital certificate obtained from CDC), or, in the case of providers/facilities that have previously enrolled, continued enrollment throughout the entirety of the performance period; and (ii) submission to the NHSN of at least three-consecutive months of dialysis event data gathered during the performance period.

We proposed to establish the achievement performance standard for the ICH CAHPS reporting measure as an attestation by the provider/facility that it successfully administered the ICH CHAPS survey during the performance period.

We proposed to establish the achievement performance standard for the proposed Mineral Metabolism reporting measure as whether a provider/facility submitted an attestation stating that it measured the serum calcium and serum phosphorus levels of Medicare patients treated by the provider/facility at least once within the month throughout the duration of the performance period.

As noted above, section 1881(h)(4)(B) of the Act provides that the performance standards established under section 1881(4)(A) of the Act must include levels of achievement and improvement, as determined appropriate by the Secretary. We determined that an improvement performance standard is not appropriate for the proposed reporting measures because it is not feasible to measure improvement on these measures at this time because we do not have any existing data we can use to compare provider/facility performance.

We also noted that we do not interpret section 1881(h)(1)(B) of the Act to require that providers/facilities meet or

exceed the performance standards we establish with respect to each individual ESRD QIP measure. Rather, we proposed to implement a scoring methodology that enables a provider/facility to avoid a payment reduction as long as it achieves a minimum Total Performance Score that, as discussed more fully below, is equal to the Total Performance Score it would have received if it had met the performance standards for all of the proposed measures.

Additionally, we noted that, beginning in PY 2015, we intend to propose to establish floors for performance such that performance standards would never be lower than those set for the previous year, even if provider/facility performance fails to improve, or even declines, over time. We also noted that, although we would consider continuing to set the national performance rate as the achievement and/or improvement performance standard, we would also consider establishing future performance standards that reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients, should such a consensus be reached.

ii. Setting Performance Benchmarks and Thresholds

Under the proposed scoring methodology for the PY 2014 ESRD QIP, a provider's/facility's performance on each of the finalized clinical measures would be determined based on the higher of (i) an achievement score or (ii) an improvement score. In determining the achievement score, we proposed that providers/facilities would receive points along an achievement range, defined as a scale that runs from the achievement threshold to the benchmark. We proposed to define the achievement threshold for each of these proposed measures as one standard deviation below the achievement performance standard for the measure (which we proposed to set as the national performance rate on the measure during the baseline period). We stated our belief that this achievement threshold will provide an incentive for providers/facilities to continuously improve their performance while not reducing the payments made to providers/facilities that score at or above the national performance rate. We proposed to define the benchmark as the mean of the top decile of provider/facility performance during the baseline period because it represents a demonstrably high but achievable standard of excellence that the best performing providers/facilities reached during the baseline period.

In determining an improvement score for the clinical measures, we proposed that providers/facilities would receive points along an improvement range, defined as a scale running between the provider's/facility's performance on the measure (the improvement threshold) during the twelve-month baseline period and the benchmark. The provider/facility's improvement score would be calculated by comparing its performance on the measure during the performance period (CY 2012) to its performance on the measure during the baseline period (July 1, 2010–June 30, 2011).

iii. Scoring Provider and Facility Performance on Clinical Measures Based on Achievement

We proposed to award between 0 and 10 points for achievement for all of the clinical measures except the VAT measure based on where a provider's/facility's performance falls relative to the achievement threshold and the benchmark for that measure. The following formula is used when the provider's/facility's performance rate is equal to or greater than the achievement threshold (but below the benchmark). Using this formula, a provider/facility would receive a score of 1 to 9 points based on a linear scale disturbing all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark.

[9* ((Provider's performance period rate—achievement threshold)/(benchmark—achievement threshold))] + .5.

We proposed that all achievement points would be rounded to the nearest integer, with 0.5 rounded up). If a provider's/facility's score was:

- Equal to or greater than the benchmark, the provider/facility would receive 10 points for achievement
- Less than the achievement threshold (that is, the lower bound of the achievement range), the provider/facility would receive 0 points for achievement.

iv. Scoring Provider/Facility Performance on Clinical Measures Based on Improvement

We proposed that providers/facilities would earn between 0 and 9 points for all of the clinical measures except the VAT measure based on how much their performance on the measure during the performance period improved from their performance on the measure during the proposed individual facility baseline period. A unique improvement range for each measure would be established for each provider/facility. The following formula is used when the provider's/facility's performance rate is equal to or greater than the improvement threshold (but below the benchmark). Using this formula, the provider/facility would receive a score of 0 to 9 improvement points based on equally spaced intervals between the improvement threshold and the benchmark.

[10 * ((Provider performance period rate—provider baseline period rate)/(Benchmark—provider baseline period rate))]—.5, where the provider performance score falls in the range from the provider's baseline period score to the benchmark.

We proposed that all improvement points be rounded to the nearest integer, with 0.5 rounded up). If a provider's/facility's score on the measure during the performance period was equal to or lower than its baseline period score on the measure, the provider/facility would receive 0 points for improvement.

v. Calculating the VAT Measure Score

We proposed to calculate the VAT measure score by first calculating the measure rate according to measure specifications for each of the two measure subcomponents. We proposed that these two rates would then be converted into separate achievement and improvement scores, using the above methodology, for each subcomponent using achievement and improvement ranges specific to each subcomponent measure. The higher of the achievement or improvement score for each measure component would then be averaged to produce one overall score for the VAT measure. We believe that this method of calculating this measure stresses the importance of both vascular access sub-measures without penalizing providers/facilities for two similar measures or unduly weighting a provider's/facility's Total Performance Score in favor of VAT measures.

vi. Calculating the NHSN Dialysis Event Reporting Measure, Patient Experience Survey Usage Reporting Measure and Mineral Metabolism Reporting Measure Scores

We proposed to adopt a different scoring methodology for the proposed NHSN Dialysis Event reporting measure,

Patient Experience Survey Usage reporting measure, and Mineral Metabolism reporting measure.

With respect to the proposed NHSN Dialysis Event Reporting measure, we proposed to assign providers/facilities a score of 0, 5, or 10 points as follows:

- Providers/facilities that enrolled in the NHSN during or before the performance period, completed the required training, and successfully reported at least three-consecutive months of dialysis event data to the NHSN before January 30, 2013, for the period of January 1, 2012–December 31, 2012 would receive 10 points.
- Providers/facilities that enrolled in the NHSN and completed the required training during or before the performance period, but did not report at least 3-consecutive months of dialysis event data to the NHSN before January 30, 2013, for the period January 1, 2012 through December 31, 2012, would receive 5 points.
- Providers/facilities that failed to enroll in the NHSN and/or complete the required training during or before the proposed performance period would receive 0 points.

We proposed to assign providers/facilities a score of 10 points if they attest that they successfully administered the ICH CAHPS survey during the performance period according to the specifications referenced above. Providers/facilities that did not provide such an attestation would receive 0 points.

We proposed to assign providers/facilities that measured the serum calcium and serum phosphorus levels of all Medicare ESRD patients treated by the provider/facility at least once within the month throughout the duration of the proposed performance period a score of 10 points, while providers/facilities that did not do so would receive 0 points. We will measure this by requiring a facility to furnish an attestation at the end of the performance period. Those facilities that do not provide this attestation will receive 0 points.

vii. Weighting of the PY 2014 ESRD QIP Measures and Calculation of the PY 2014 ESRD QIP Total Performance Score

Section 1881(h)(3)(A)(iii) of the Act provides that the methodology for assessing provider/facility total performance must include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers and facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

In determining how to appropriately weight the PY 2014 ESRD QIP measures for purposes of calculating Total Performance Scores, we considered a number of criteria. Specifically, we considered the number of measures we have proposed to include in the PY 2014 ESRD QIP as well as CMS and HHS quality improvement priorities. We stated our belief that weighting the finalized clinical measures equally will incentivize providers/facilities to improve and achieve high levels of performance across all of the measures, resulting in overall improvement in the quality of care provided to ESRD patients. For these reasons, we proposed to assign equal weight to the five proposed clinical measures, with those equal weights adding up to 90 percent of the Total Performance Score. We stated our belief that, while the reporting measures are valuable, the clinical measures measure actual patient outcomes and therefore, justify a combined weight of 90 percent. We proposed that the remaining 10 percent of the Total Performance Score would be comprised of the proposed reporting measures, with each measure weighted equally. We recognize that reporting is an important component in quality improvement, and that this type of measure should also be included in the ESRD QIP, although at a substantially lower weight.

We also considered whether and how we could award a Total Performance Score to providers/facilities that do not report data on at least eleven cases with respect to one or more of the finalized clinical measures. As we stated above, we proposed that this minimum number of cases must be reported with respect to each clinical measure in order for the provider/facility to receive a score on that measure. We stated that because we are proposing to adopt additional measures, we believe that it is appropriate to calculate Total Performance Scores for all providers/facilities. In the case of a provider/facility that has sufficient data from the performance period, but lacks sufficient data from the baseline period, we proposed to only calculate its achievement score, because it would not be possible to calculate its improvement score. We believe that this approach is necessary to ensure that as many providers/facilities receive a score as possible. We proposed that the combined weight of the clinical measures that are scored would still be equal to 90 percent of the Total Performance Score, but only those measures for which providers/facilities report a minimum of eleven cases or more would be included in determining this score, with each such measure being weighted equally. We stated our belief that this approach achieves that goal of including as many providers/facilities as possible, while ensuring the reliability of the measure scores.

Similarly, we proposed to assign equal weight to the proposed NHSN Dialysis Event reporting measure, Patient Experience Survey reporting measure, and Mineral Metabolism reporting measure, with those equal weights adding up to 10 percent of the Total Performance Score. Applying the proposed weighting criteria to a provider/facility that receives a score on all of the proposed measures, we proposed to calculate the provider/facility Total Performance Score using the following formula:

Total Performance Score = [(.18 * Hemoglobin Greater Than 12g/dL Measure) + (.18 * Kt/V Dialysis Adequacy Measure) + (.18 * Vascular Access Type Measure) + (.18 * Vascular Access Infection Measure) + (.18 * SHR–Admissions Measure) + (.0333 * NHSN Reporting Measure) + (.0333 * Patient Experience Survey Reporting Measure) + (.0333 * Mineral Metabolism Reporting Measure)] * 10.

We proposed that the Total Performance Score be rounded-up to the nearest integer (and any individual measure values ending in .5 would be rounded-up).

We solicited public comment on the proposed performance scoring methodology as detailed above. The comments we received and our responses are summarized below.

*Comment:* One commenter urged that CMS should give greater weight to those measures over which facilities have the greatest control and asked for clarification of the process that will be used to weight measures in future years of the ESRD QIP. Another commenter suggested that CMS weight measures that detect underutilization of services more than those that detect overutilization. Another commenter suggested that CMS weight each measure based on its potential to improve quality.

*Response:* We believe, at this time, that it is appropriate to weight all of the clinical measures equally and all of the reporting measures equally in order to equally incentivize quality in all of these areas of care. Additionally, we believe that providers/facilities can, overall, impact the outcomes of these measures by providing high-quality,

patient-centered care in accordance with the specified measures. Finally, we do not believe it is appropriate to penalize underutilization more than overutilization. Whether care is substandard due to underutilization or overutilization, it is still substandard care and should be recognized as such. We seek to be as transparent as possible in all aspects of the ESRD QIP, and we will outline the weighting methodology for future years of the program through rulemaking.

*Comment:* Several commenters argued that the clinical measures should not be weighted equally. Some commenters suggested that the VAT catheter submeasure comprise a larger weight in the final VAT measure score because of the literature suggesting that a reduction in catheters will also reduce infections and mortality. One commenter voiced support for CMS' proposal that the clinical measures compose 90 percent of the Total Performance Score, but argued that, because of the importance of vascular access to overall health and cost reduction, the VAT measure should be weighted at 50 percent with the other clinical measures comprising the equally weighted remainder of the clinical measure score. One commenter suggested that CMS weight the VAT measure less than the other clinical measures. Other commenters suggested that, if CMS retains the VAT measure, the catheter submeasure be weighted greater than the fistula submeasure, perhaps at a 2:1 ratio. Some commenters also suggested that the Patient Experience Survey measure be weighted half as much as the other reporting measures because of the greater clinical impact of the Mineral Metabolism and NHSN reporting measures.

*Response:* We believe that all of the clinical measures improve care and are important to the program. For the measures finalized for PY 2014, we do not believe any one area of care should be promoted over another, and we believe that providers/facilities should be equally incentivized to achieve high standards in all of the areas evaluated by the clinical measures. Thus, although we have finalized only three of the five proposed clinical measures, we still believe that is appropriate to evenly weight the clinical measures. Additionally, we continue to believe that the clinical measures are vital to improving care and should be weighted more substantially than those measures which to not score providers/facilities based upon actual outcomes. We also believe that appropriate VAT is critical to ensuring optimal patient outcomes. Thus, we do not agree that we should weight this measure less than the other clinical measures. Furthermore, we do not believe it is in the best interest of patients to weight the fistula VAT submeasure more than the catheter VAT submeasure because of our goal to promote fistula use. Although we agree that catheters pose a greater risk to patients, we do not believe this necessitates weighting the catheter subcomponent measure twice as much as the AV fistula subcomponent measure as both are equally important in promoting the best clinical practices with respect to VAT. Therefore, as stated below, we finalize that the three clinical measures will be weighted equally to comprise 90 percent of a providers/facilities Total Performance Score.

As we have also stated, we believe that the Patient Experience Survey is one of the most important tools in impacting clinical practices because it is the only measure that gives patients a voice that may otherwise go unrecognized. Therefore, we do not believe the ICH CAHPS measure should have a lesser weight than the other reporting measures.

*Comment:* One commenter expressed concern that new facilities without a complete data set available for the measures will be unfairly penalized.

*Response:* Like all ESRD QIP providers/facilities, new facilities will only be included in the program if they have the requisite amount of data. For each of the clinical measures, there must be at least eleven cases each with four claims, regardless of whether the facility is new or established, in order for such measure to be included in the Total Performance Score. For the reporting measures, however, we acknowledge that we did not specify any data requirements, and we recognize that new facilities may be unfairly penalized if they do not have a sufficient amount of time to fulfill the requirements for the reporting measure.

Accordingly, we finalize that a provider/facility that receives a new CCN on or after July 1, 2012 will have the option to not be scored on the reporting measures. We believe that these new providers/facilities need a reasonable amount of time to put the necessary infrastrucure into place in order to be able to satisfy these measures. For example, with respect to the ICH CAHPS patient survey experience measure, a new facility would need to, at a minimum, hire a third party vendor, treat at least one in-center hemodialysis patient for 3 months, and field the survey (which, depending on the responsiveness of the patient, could take an additional period of months). For these new providers/facilities, that do not successfully satisfy the requirements for the reporting measures, their Total Performance Score will be calculated based solely on the applicable clinical measures that apply to them.

However, we also recognize that under our scoring methodology, a provider/facility's score on a reporting measure could help it achieve the minimum Total Performance Score needed to avoid a payment reduction that it would otherwise receive based solely on its clinical measure score(s). In order to balance these competing concerns, we will allow a new provider/facility (defined above as one that receives a new CCN on or after July 1, 2012) the option to report one or more of the reporting measures. If the new provider/facility chooses to take advantage of this option by successfully satisfying the reporting requirement for one or more of these measures, we will score the new provider/facility on those measures and include those scores in the calculation of that provider/facility's Total Performance Score.

We believe that we should include as many providers/facilities in the program as possible. In the proposed rule, we proposed to calculate Total Performance Scores for all providers/facilities and did not specifically state any minimum number of clinical and reporting measures a provider/facility would need to receive a Total Performance Score. Thus, we clarify in this final rule that a provider/facility will receive a Total Performance Score for PY 2014 if it is eligible for at least one measure. We finalize that, if a provider/facility is eligible for at least one clinical measure and at least one reporting measure, the clinical measures will be equally weighted to sum 90 percent of the Total Performance Score, and the reporting measures will be equally weighted to sum 10 percent of the Total Performance Score. If a provider/facility is only eligible for clinical but not reporting measures or vice versa, we will compute its Total Performance Score based solely on the measures for which it is eligible.

*Comment:* Some commenters commended CMS for proposing measures, proposing timeframes, and proposing the weight each measure would have in the PY 2014 program within one regulation.

*Response:* We thank commenters for their support.

*Comment:* Commenters noted that establishing the achievement threshold as one standard deviation below the national performance rate might lead to inappropriate achievement thresholds as a result of skewed performance distributions. Some commenters

suggested that, instead, CMS base performance standards on the median performance of providers/facilities, with the achievement threshold being at the 15th percentile. Other commenters urged CMS to establish the achievement threshold as the mean performance of facilities performing in the lowest third.

*Response:* In the proposed rule, we defined the performance standards as the national performance rate, the achievement threshold as one standard deviation below the achievement threshold, and the benchmark as the mean of the top decile of providers/facilities. After receiving public comment, we have found that the distribution of facility performance on several measures is skewed, we have determined that the median is a better measure of central tendency, which was our original intent for these standards. If the measures had had a more even distribution, one standard deviation below the mean would have been calculated to be at approximately 35 percentage points below the mean or the 15th percentile. Thus, we agree with the commenters who suggested that the performance standard should be set at the median performance of providers/facilities during the baseline period. In order to more accurately access the achievement threshold, we will set the performance standards (both achievement and improvement) as the median of facility/provider performance and establish the achievement threshold at the 15th percentile because the 15th percentile represents approximately one standard deviation below the median had the distributions been even.

*Comment:* Several commenters argued that the performance standards must be published and commenters must be allowed to comment on these standards and the related scoring methodology before the beginning of the performance period.

*Response:* Our proposal set forth the performance standards that would apply to the PY 2014 clinical measures and assigned example numerical values to each of those proposed measures using data from July 1, 2010 through November 30, 2010, which was the most current data that was available at the time that overlapped with the proposed performance period. Because of data limitations related to the claims verification process which allows providers/facilities a period of time to review and contest claims, we are able in this final rule to finalize the performance standards that will apply to the PY 2014 ESRD QIP but cannot yet assign actual numbers to those finalized standards based on a full year of data. However, we will post these numbers on the following Web site: *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014-FR.pdf*. We are publishing in this final rule numbers based on data from July 1, 2010 through March 30, 2011, or nine of the 12 months of baseline data. We will publish numbers based on 12 months, July 1, 2010 through June 30, 2011, on or before January 31, 2012 at the following Web site: *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014-FR.pdf*. We do not anticipate that the final numbers will differ substantially from these numbers.

We believe that this approach complies with section 1881(h)(4) of the Act, including the requirement in subparagraph (C) that the Secretary establish performance standards under subparagraph (A) prior to the beginning of the performance period. However, we recognize that providers/facilities are very interested in these numbers and have a legitimate need to learn what they will be with respect to a payment year as soon as possible. Although we are not able to provide them in this final rule for the reasons discussed above, we anticipate that beginning with the PY 2015 ESRD QIP, we will be able to select a baseline period that ends early enough to make these numbers available in the final rule that applies to that program. The estimated actual values that apply to the PY 2014 performance standards, based on nine of the twelve months of baseline data, are shown in Table 5 below.

*Comment:* One commenter suggested that CMS modify the payment reduction scale to encourage providers to perform well on all of the measures.

*Response:* As we noted in the proposed rule, we do not interpret section 1881(h)(1)(B) of the Act to require that providers/facilities meet or exceed the performance standards we establish with respect to each individual ESRD QIP measure. Rather, we believe that our proposed approach best balances the goal of incentivizing providers/facilities to provide quality care across all of the measures while still recognizing the higher quality of care provided by those providers/facilities that exceed the performance standards on certain measures. Additionally, we believe that this approach will give providers/facilities the flexibility they need to become familiar with the new scoring methodology.

*Comment:* Several commenters commended CMS for recognizing both achievement and improvement in its scoring methodology. Some commenters suggested that CMS implement a methodology to ensure that improvement standards do not diminish incentives for achievement (for example, facilities should be required to meet minimum thresholds prior to having improvement rewarded). Commenters noted that CMS should adjust its scoring methodology to ensure that facilities performing consistently above the achievement threshold are not penalized. Under the proposed scoring system, these facilities would not be eligible for improvement points and could perform worse in the long run than those who performed less well in baseline years. These commenters suggested that CMS establish a consistency multiplier. Another commenter proposed that CMS set a fixed achievement threshold in order to prevent penalizing facilities that have improved (that is, improvement will raise the standard which will cause the achievement threshold to rise which will cause the provider to have to improve more). One commenter stated that the performance standards for both PY 2013 and PY 2014 should be less stringent to decrease the incentive to game the system.

*Response:* We believe that the scoring methodology we are finalizing for the PY 2014 ESRD QIP provides appropriate incentives to providers/facilities to both achieve and improve. We acknowledge that under the methodology, it might be possible for a provider/facility to attain a lower measure rate on one or more measures than the measure rate attained by other providers/facilities but receive more points overall in the form of improvement points. However, we believe it is appropriate to incentivize lower-achieving facilities to continue to improve, even if their measure rates do not meet the achievement threshold and even if their improvement points would be higher than their achievement points. For these providers/facilities, our scoring methodology allows us to reduce the amount of a payment reduction that they might otherwise receive because they have improved over their baseline rates. Additionally, because providers/facilities can score 1–10 points for achievement and only 0–9 points for improvement, providers/facilities can always be rewarded more for achieving at higher levels. We agree with the commenters that the performance standard will likely continue to rise if we continue to utilize this scoring methodology in future years, and we will take these comments into consideration as we gain experience with the ESRD QIP.

Additionally, we do not believe that the performance standards for PY 2013 or PY 2014 are too stringent. For PY

2014, the performance standard is at the midpoint of providers'/facilities' performance. Thus, this standard has been achieved by half of all facilities. To begin scoring achievement points, providers/facilities need only be at or above the 15th percentile. Thus, we believe that the performance standards have been and will continue to be attainable. We will be monitoring outcomes and practice patterns in the ESRD setting to determine whether any ESRD QIP policies might be encouraging activities that could be described as ''gaming,'' and, to the extent necessary, we will make changes to the ESRD QIP to lessen the potential that such activities occur.

*Comment:* Some commenters suggested that there was an error in CMS' proposed scoring methodology because, if a facility does not improve at all, it is possible for that facility to receive a negative improvement score; these commenters asked CMS to clarify that facilities with the same or lower improvement score compared to their baseline score will have an improvement score of zero.

*Response:* Under the proposed scoring methodology, scores would be rounded to the nearest integer, with a score of 0.5 rounded up to the next highest integer. Accordingly, the lowest improvement score a provider/facility could receive is (−) 0.5, and this score would be rounded to zero. The commenter is correct in that the lowest score a facility can receive for both improvement or achievement is zero.

*Comment:* One commenter expressed concern that, by setting the benchmark score at the mean of the top decile of provider/facility performance, many facilities will be unfairly penalized and requested that CMS set a benchmark closer to the national performance rate.

*Response:* As noted, one of the goals of the ESRD QIP is to incentivize the highest quality care. However, we agree that the benchmark should be lowered to reflect a more attainable standard, and because we are changing the achievement threshold to a fixed point, we also believe it is appropriate to modify our methodology for calculating the benchmark. To more accurately represent the top of all performers, we will calculate the benchmark at the 90th percentile instead of as the mean of the top decile of performers; while the mean of the top decile will vary depending upon the rates of the top ten percent of performers for each measure, the 90th percentile is a fixed place on all measure performance distributions, thus allowing a more consistent calculation throughout various distributions for all measures. We believe that this change conforms the benchmark to the new performance standards and achievement threshold while still accomplishing the benchmark's intent to incentivize providers/facilities to provide the highest achievable level of care.

For the reasons discussed above, we are finalizing the PY 2014 ESRD QIP scoring methodology to score each clinical measure rate as the higher of the measure's achievement or improvement score, as explained above. We are also finalizing the proposed scoring methodology for calculating the reporting measure scores and the requirement that a provider/facility must have received a CCN on or before July 1, 2012 in order to automatically be scored on the reporting measures. We note that, as discussed above, for the NHSN Dialysis Event measure, we will now allow providers/facilities until March 31, 2013 at 11:59 EST to report the required three consecutive months of data from the performance period. We are also finalizing our proposal to calculate the VAT measure score as the average of the submeasure scores.

Based on public comments, we are not finalizing the proposed definition of performance standards, achievement thresholds, or benchmarks which were based on means and standard deviations. Due to skewed distributions of facility performance, we are finalizing the performance standards (both achievement and improvement) as the median (50th percentile), the achievement threshold as the 15th percentile, and the benchmark as the 90th percentile. We agree with commenters that this better reflects the central tendency and spread of these performance distributions.

We are finalizing the proposed baseline period of July 1, 2010–June 30, 2011. We are also finalizing our proposal that providers/facilities that do not have enough data in the baseline period to calculate a rate for a measure but do have enough data to calculate a measure rate in the performance period will receive a score on that measure based solely on achievement. We also finalize that the clinical measures for which a provider/facility is eligible will be equally weighted to comprise 90 percent of its Total Performance Score, and the reporting measures for which a provider/facility is eligible will be equally weighted to comprise 10 percent of its Total Performance Score. If a provider/facility is only eligible for one type of measure, the provider's/facility's Total Performance Score will be calculated based on that measure(s) alone.

Because of the data limitations explained above, we are unable at this time to assign final numbers to the performance standards, achievement thresholds, and benchmarks. We will publish these numbers at the following Web site: *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014-FR.pdf* on or before January 31, 2012. Below, in Table 4 and 5, we have provided estimates based upon data from July 1, 2010 through March 30, 2011. We do not believe that these estimates will vary significantly from our finalized numbers.

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**Table 4. Estimated Achievement Thresholds and Benchmarks for the PY 2014 ESRD QIP.**

| Quality Measure | Measure Description/Definition | Achievement Threshold (15th Percentile) | Benchmark (90th Percentile) |
|---|---|---|---|
| Hemoglobin Greater Than 12 g/dL Measure | % of patients with hemoglobin greater than 12 g/dL | **14%** | **0%** |
| Dialysis Adequacy Measure (URR) | % of hemodialysis (HD) patients with URR ≥ 65 | **91%** | **100%** |
| Vascular Access Type Measure | Average of the two sub-measures | | |
| (Fistula) | *% of patients receiving treatment with fistulae* | **44%** | **73%** |
| (Catheter) | *% of patients receiving treatment with catheters* | **24%** | **5%** |
| NHSN Dialysis Event Reporting Measure | Enroll and report at least 3 months of dialysis event data | N/A | N/A |
| Patient Experience of Care Survey Usage Reporting Measure | Providers/facilities must attest that they successfully fielded survey during the performance period | N/A | N/A |
| Mineral Metabolism Reporting Measure | Measure serum calcium and serum phosphorus levels of Medicare patients | N/A | N/A |

**Table 5. Estimated Numerical Values for the Finalized Achievement and Improvement Performance Standards for the PY 2014 ESRD QIP Clinical Measures Using July 1, 2010 to March 30, 2011 Data**

| Measure | Achievement/Performance Standard |
|---|---|
| Hemoglobin > 12 g/dL | 5% |
| Vascular Access Type | |
| %Fistula | 57% |
| %Catheter | 13% |
| URR | 97% |

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vii. Examples for 2014 ESRD QIP Performance Scoring Model

Below, we provide examples to illustrate the performance scoring model. Figures 1–4 illustrate the scoring for a clinical measure. Figure 1 shows Facility A's performance on the URR measure. The example benchmark (90th percentile) calculated for this measure in this case is 100 percent, while the example achievement threshold (15th percentile) is 91 percent. Facility A's performance rate of 100 percent during the performance period meets or exceeds the benchmark, so Facility A would earn 10 points (the maximum) for achievement for this measure. (Because, in this example, Facility A has earned the maximum number of points possible for this measure, its improvement score is irrelevant.)

**Figure 1. Example of Dialysis Facility Earning Points by Achievement or Improvement:**

**Facility A**

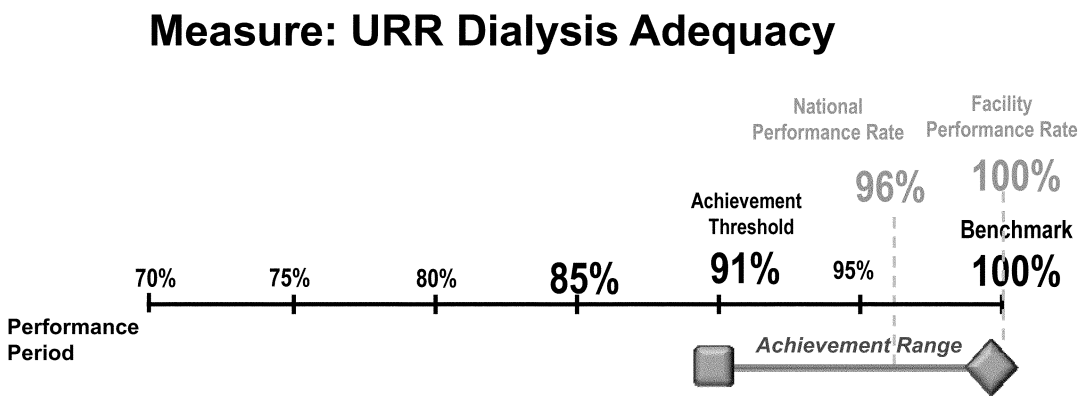
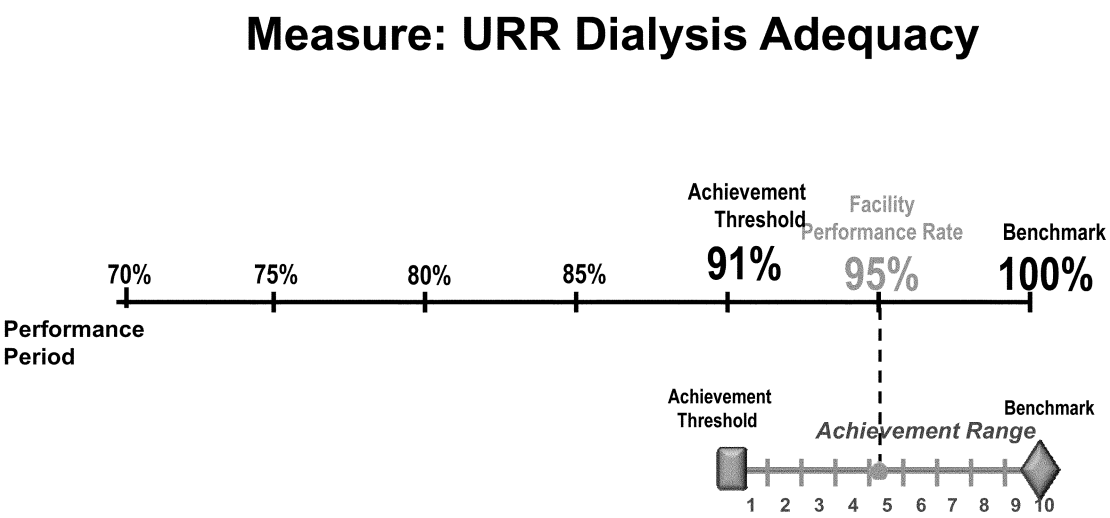



Figure 2 and 3 show the scoring for another facility, Facility B. As illustrated below, the facility's performance on the URR measure went from 80 percent in the baseline period to 95 percent during the performance period.

**Figure 2. Example of Dialysis Facility Earning Points by Achievement or Improvement:**

**Facility B**



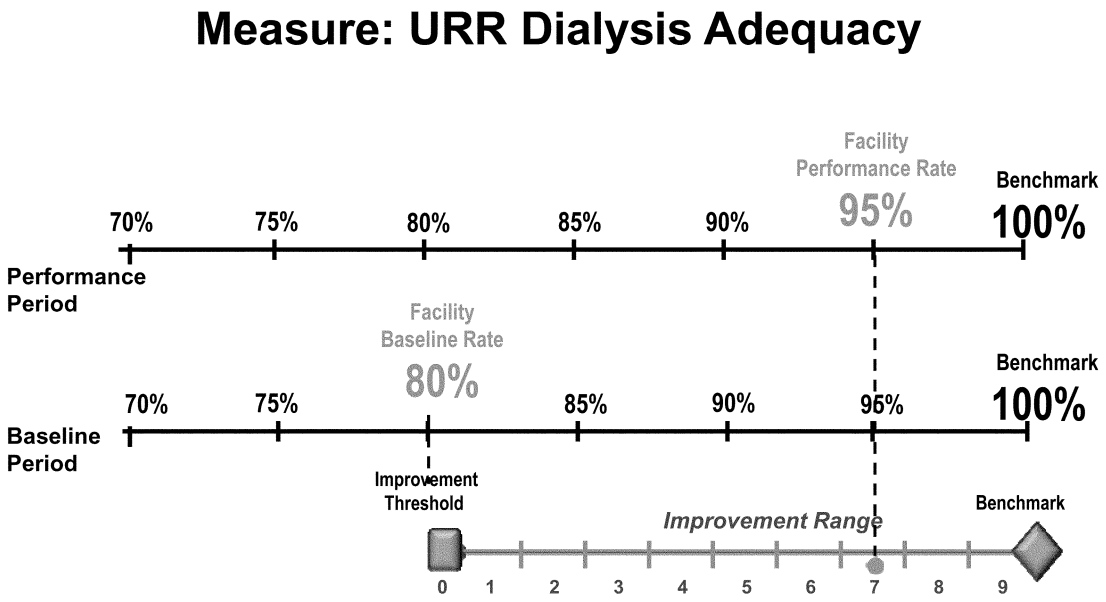

Applying the achievement scale, Facility B would earn 5 points for achievement, calculated as follows:

$9 * [(95 - 91)/(100 - 91)] + .5 = 4.5$, which is rounded to 5 points.

However, because Facility B's performance during the performance period is also greater than its baseline period performance (but Facility B's performance period score is less than the benchmark), it would be scored based on improvement as well, as shown by Figure 3, below.

**Figure 3. Example of Dialysis Facility Earning Points by Achievement or Improvement:**

**Facility B**




Applying the improvement scale, based on Facility B's period-to-period improvement, from 80 percent to 95 percent, Facility B would earn 7 improvement points, calculated as follows:

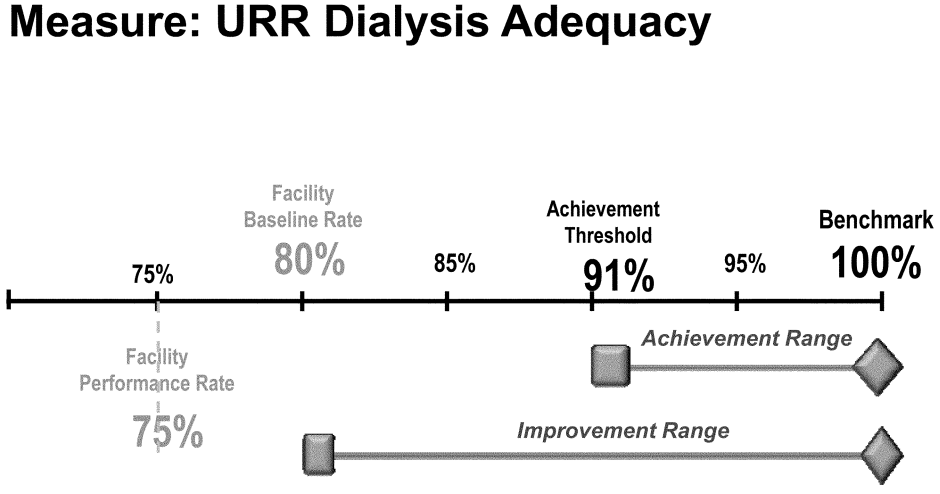
10 * [(95 − 80)/(100 − 80)] − .5 = 7.5 − .5 = 7.0, which would be rounded to 7 points.

Because the higher of the two scores is used for determining the measure score, Facility B would receive 7 points for this measure.

In Figure 4 below, Facility C's performance on the URR measure drops from 80 percent in the baseline period to 75 percent in the performance period, a decline of 5 percent.

**Figure 4. Example of Dialysis Facility Earning Points by Achievement or Improvement:**

**Facility C**



Because Facility C's performance during the performance period falls below the achievement threshold of 91 percent, it would receive zero points for achievement. Facility C would also receive zero points for improvement because its performance during the performance period was lower than its performance during the baseline period. In this example, Facility C would receive zero points for the URR Measure.

The method illustrated above would be applied to each clinical measure in order to obtain a score for each measure. Scores for reporting measures are calculated based upon the methodology as proposed.

Applying the weighting criteria to a provider/facility that receives a score on all finalized measures, we calculate the provider's/facility's Total Performance Score using the following formula:

Total Performance Score = [(.300 * Hemoglobin Greater Than 12g/dL Measure) + (.300 * URR Hemodialysis Adequacy Measure) + (.300 * Vascular Access Type Measure) + (.0333 * NHSN Reporting Measure) + (.0333 * Patient Experience Survey Reporting Measure) + (.0333 * Mineral Metabolism Reporting Measure)] * 10.

The Total Performance Score be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer)).

However, if, for example, a provider/facility did not receive a score on the proposed VAT measure, the provider's/facility's Total Performance Score would be calculated as follows:

Total Performance Score = [(.4500 * Hemoglobin Greater Than 12g/dL Measure) + (.4500 * URR Hemodialysis Adequacy Measure) + (.0333 * NHSN Reporting Measure) + (.0333 * Patient Experience Survey Reporting Measure) + (.0333 * Mineral Metabolism Reporting Measure)] * 10, (the Total Performance Score will be rounded to the nearest integer (and any values ending in .5 would be rounded to the next higher integer)).

Finally, if, for example, a provider/facility qualified for two of the reporting measures,[18] the provider's/facility's Total Performance Score would be calculated as follows:

Total Performance Score = [(.300 * Hemoglobin Greater Than 12g/dL Measure) + (.300 * URR Hemodialysis Adequacy Measure) + (.300 * Vascular Access Type Measure) + (.05 * NHSN Reporting Measure) + (.05 * Mineral Metabolism Reporting Measure)] * 10.

6. Payment Reductions for the PY 2014 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across providers and facilities such that providers and facilities achieving the lowest Total Performance Scores receive the largest payment reductions. We have adopted a sliding scale of payment reductions for the PY 2012 ESRD QIP (76 FR 634) and have finalized a sliding scale in this final rule for PY 2013 ESRD QIP. In developing a payment reduction scale for the PY 2014 ESRD QIP, we sought to create an approach that would retain aspects of the tiered sliding scale selected for the PY 2012 ESRD QIP, but also reflect the change in provider/facility scores under the new scoring methodology. Under the proposed approach, a provider/facility would not be required to meet or exceed the performance standards with respect to each of the finalized measures in order to avoid receiving a payment reduction under the ESRD QIP. Rather, even if a provider/facility failed to meet or exceed the performance standards with respect to one or more of these measures, the provider/facility could avoid a payment reduction if it achieved a minimum Total Performance Score that is equal to or greater than the minimum Total Performance Score it would receive if it had met the performance standards for each finalized measure, or, in the case of the VAT measure, for the two subcomponent measures. At the time we issued the proposed rule, we were unable to calculate the minimum Total Performance Score because we did not have the data for the baseline period. We estimated, however, that the minimum Total Performance Score that a provider/facility would have to achieve to avoid a payment reduction would be 60 points, and we stated that we would specify the exact number in the final rule. We proposed to implement at least a 1.0 percent payment reduction for all providers/facilities that fail to meet or exceed this minimum Total Performance Score.

To ensure that the proposed payment reduction methodology complies with the section 1881(h)(3)(A)(ii) requirement that providers and facilities achieving the lowest Total Performance Scores receive the largest payment reductions, we proposed to increase the payment reduction from 1.0 percent to 1.5 percent for all providers/facilities that fail to achieve a Total Performance Score that is 10 points below the minimum Total Performance Score (described above). Additionally, we proposed to increase the payment reduction to 2.0 percent for all providers/facilities that fail to achieve a Total Performance Score that is 20 points below the minimum Total Performance Score (described above). We stated our belief that such a sliding scale will incentivize providers/facilities to meet the performance standards and continue to improve their performance because even if a provider/facility fails to achieve the minimum Total Performance Score, such provider/facility will still be incentivized to strive for, and attain, better performance in order to reduce the amount of its payment reduction.

The comments we received on the proposed payment reductions are set forth below.

*Comment:* One commenter opposed the elimination of the 0.5% payment reduction level and suggested that there be at least five tiers in the payment reduction scale because, in addition to allowing comparisons between years, five-tiers in the payment reduction scale is more consistent with the literature supporting value-based purchasing programs.

*Response:* We agree with the commenter's concern and will include the 0.5 percent payment reduction level as an additional level in the PY 2014 ESRD QIP payment reduction scale. Thus, the payment reductions for PY 2014 will range on a sliding scale from 0.5 percent to 2.0 percent with the provider/facility moving down a tier for every ten points its Total Performance Score falls below the minimum Total Performance Score. We are finalizing new measures, a new scoring methodology, and rigorous performance standards which are not familiar to the community. We believe that including this additional payment reduction level will allow time for us as well as providers/facilities to become familiar with this new structure.

*Comment:* One commenter disapproved of setting 10 points as a threshold for each reduction in payment for PY 2014 when CMS cannot yet estimate the minimum Total Performance Score because the distribution in payment reductions is not yet known and will not be known until the performance period has ended. Instead, the commenter suggested that CMS allow for a sufficient period of

[18] This could occur, for example, if a provider/facility is a pediatric and/or peritoneal facility only.

time for the quality measure scores to be made publicly available and data to be collected to assess the potential impact of the QIP on the facilities. Another commenter suggested that CMS score the PY 2014 measures on a 30 point scale consistent with PY 2012 so that facilities and consumers can meaningfully compare performance from year to year.

*Response:* We appreciate the commenter's concern regarding how we establish the minimum Total Performance Score and each successive payment reduction level. Although we will not know the distribution of payment reductions based on the minimum Total Performance Score until we have the data at the end of the performance period, given our current estimates of the data, we believe that, the payment reductions will be appropriate to incentivize providers/facilities to improve patient care. We have calculated these estimates based on the data currently available to us, as further explained in the Regulatory Impact Statement, and they are similar to the reductions for PY 2012 and our estimates for PY 2013. However, in light of the commenter's concern, we will further adjust how we set the minimum Total Performance Score. Rather than set the minimum Total Performance Score as the score a provider/facility would receive if it had met the performance standards for each finalized measure, we will define the minimum Total Performance Score as the score a provider/facility would receive if it had met the performance standards for each of the finalized clinical measures. Recognizing many commenters' concerns regarding the new reporting measures, and our lack of data on which to approximate likely provider/facility performance, we will exclude them from the calculation of the minimum Total Performance Score. We believe this policy will balance our desire to appropriately incentivize improvements in clinical quality while ensuring that providers/facilities are not unduly penalized.

Based on our analysis of the data from July 1, 2010 through March 30, 2011, we estimate that the PY 2014 minimum Total Performance Score will be 56 points. We will publish the final minimum Total Performance Score at the following Web site: *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014–FR.pdf* on or before January 31, 2012.

Additionally, although we generally believe that the ESRD QIP should provide a means for patients to evaluate their providers/facilities over time, we do not believe that, even if we set performance on a 30 point scale, PY 2014 would be comparable to previous years of the ESRD QIP because of the significant changes to scoring methodology and measures. We believe a 100 point scale will accommodate a growing number of measures that may be adopted in future years of the QIP and plan to consistently use the 100 point scale going forward.

Based on the public comments we received, we are finalizing most of the payment reduction methodology that we proposed; however, we are adding an additional payment reduction level of 0.5 percent, with the scale now ranging from 0.5 percent to 2.0 percent. For every ten points a provider/facility's Total Performance Score falls below the minimum Total Performance Score, it will receive an additional 0.5 percent reduction. We are modifying our definition of the minimum Total Performance Score to be equal to the score a provider/facility would receive if it performed at the performance standards for each of the clinical measures.

As noted above, we are unable to publish a finalized minimum Total Performance Score until we assign a final number to each finalized performance standard. We will publish a finalized minimum Total Performance Score at the following Web site: *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014–FR.pdf* on or before January 31, 2012. Based upon the performance standard examples we provided above, we estimate that the minimum Total Performance Score will be 56. We do not anticipate that this estimate will substantially change. Using this estimation, the payment reduction scale would be as detailed below in

**Table 6. Estimated Payment Reduction Scale for PY 2014.**

| Score | Reduction |
|---|---|
| 100 to 56 | 0% |
| 55 to 46 | 0.5% |
| 45 to 36 | 1.0% |
| 35 to 26 | 1.5% |
| 25 or below | 2.0% |

7. Public Reporting Requirements

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information regarding performance under the ESRD QIP available to the public, including information on the Total Performance Score (as well as appropriate comparisons of providers and facilities to the national average with respect to such scores) and performance scores for individual measures achieved by each provider and facility. Section 1881(h)(6)(B) of the Act further requires that a provider or facility have an opportunity to review the information to be made public with respect to that provider/facility prior to such information's publication.

In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each provider and facility with a certificate containing its Total Performance Score to post in patient areas within the facility. Finally, section 1881(h)(6)(D) of the Act requires the Secretary to post a list of providers/facilities and performance-score data on a CMS-maintained Web site.

For both the PY 2013 and PY 2014 ESRD QIP, we proposed no change in the implementation of these statutory provisions (section 1881(h)(6)(A) through section 1881(h)(6)(D) of the Act) from the proposals finalized in the 2012 ESRD QIP final rule (76 FR 636 through 639), wherein we finalized the establishment of procedures for providers/facilities to review the information to be made public and the procedures for informing the public through facility-posted certificates.

The comments we received on the public reporting proposals are set forth below.

*Comment:* Some commenters noted that information reported to the public should be meaningful and requested that CMS include language on the ESRD QIP certificates stating (i) The date range of the performance period; (ii) the date ranges used to compute the performance standards; and (iii) a statement that the data may not reflect current medical standards or facility/provider performance.

*Response:* The certificates for PY 2012 will indicate the year of the performance period. We will monitor whether beneficiaries find the certificates to be effective in conveying performance, and we will continue to evaluate the information they should include for PY 2013 and PY 2014. We believe that the intent of the certificates is to convey information about facility performance in an understandable, clear, and concise manner. We do not believe that details about the baseline data used to compute the performance standards, or disclaimers about the limitations of the data, are required to convey this basic message, but we encourage providers/facilities to discuss these certificates with their patients and provide any further explanatory information they feel is necessary.

*Comment:* Several comments requested that CMS address procedural issues related to facility Performance Score Reports.

*Response:* Performance Score Reports (PSRs) are distributed to providers/facilities for their review after the end of the performance period but before payment reductions are assessed. For PY 2012, PSRs were sent to providers/facilities in July 2011, and provider/facilities were permitted to preview the reports and ask us any questions. We are currently reviewing our PSR process, and we will consider commenters' suggestions as we develop the PSRs for PY 2013 and PY 2014.

For the reasons set forth above, we are finalizing the public reporting requirements as proposed.

8. Future QIP Measures

As part of our effort to continuously improve the ESRD QIP, we are working to adopt additional robust measures that provide valid assessments of the quality of care delivered to ESRD beneficiaries. To that end, we are developing measures that apply to all modalities (including home and in-center dialysis) and the pediatric population. We also sought public comment on the inclusion of iron management measures, serum calcium management measures, and serum phosphorus management measures for future years of the ESRD QIP. Specifically, we sought public comment on:

- Measurement of Serum Calcium Concentration.
- Measurement of Serum Phosphorus Concentration.
- Assessment of Iron Stores.

These measures are currently collected through CROWNWeb as part of the CPM set. The full specifications for these measures may be accessed at: *http://www.dialysisreports.org/ESRDMeasures.aspx*.

The comments we received on future measures are set forth below.

*Comment:* Many commenters suggested measures and/or domains for future ESRD QIP payment years. These suggestions included (i) Iron measures, perhaps measuring trends in ferritin; (ii) upper serum phosphorus limit measures; (iii) hypercalcemia measures (*e.g.* NQF #1454); (iv) PTH measures; (iv) albumin measures; (v) immunization measures; (vi) fluid management measures; (vii) quality of life measures; (x) measures focusing upon the nurse-patient relationship; (viii) measures assessing the number of HHD and PD patients; (ix) blood pressure measures; and (x) standardized mortality rate measures. Other commenters suggested that we make the reporting measures clinical measures as soon as feasible. Commenters also encouraged us to consider domains and measures in which the pediatric community, HHD patients, and PD patients can more actively participate.

*Response:* We thank commenters for these suggestions. We continue to monitor measure development and valid and available data sources and look forward to working with the ESRD community to choose future measures which drive quality of care.

*Comment:* One commenter stated a belief that that CMS should not adopt any current or future measures that do not indicate a causal relationship between the measure and morbidity and mortality and requested that CMS conduct more scientific tests on these measures. Therefore, this commenter believes that an iron stores measure should be a reporting measure only until further scientific evidence can be obtained. This commenter also expressed concern that a ''one size fits all'' system will lead to ''cherry-picking.''

*Response:* We thank the commenter for the input. We continue to analyze and develop measures that we believe best reflect quality in care. We also continue to monitor access to care issues and will adjust the ESRD QIP to address these issues in future rulemaking, as needed.

*Comment:* One commenter suggested that the ESRD QIP should focus more on mitigating patient non-compliance.

*Response:* We thank the commenter for the suggestion and will consider it as we further develop measures and policies for the ESRD QIP. We also note that there are mechanisms currently in place under the ESRD Conditions for Coverage that require that providers/facilities educate patients and promote appropriate patient care (*e.g.* 42 CFR 494.90(d)).

*Comment:* Some commenters urged CMS to require reporting of the ESRD QIP measures for all applicable patient populations, including both Medicare and non-Medicare populations, because providers will then have a better understanding of their overall performance.

*Response:* We intend to propose to require reporting of measure data on all ESRD patient populations after the launch of CROWNWeb. We have thus far not required reporting on all patient populations because our measures have been claims-based and have thus been restricted to Medicare patients. We adopted claims-based measures to reduce the burden of reporting for providers/facilities in the initial years of the program.

*Comment:* Some commenters requested that we clearly provide the criteria which we will use to select future measures and their weight and suggested that measures be ''phased-in.'' Commenters also suggested the CMS use criteria similar to that used by the NQF to adopt measures and employ the feedback of the Measure Applications Partnership in selecting measures appropriate for the program.

*Response:* We believe that we have outlined the criteria we used to select measures and their weights for the ESRD QIP, and we will continue to do so in the future. We will also consider NQF criteria, as well as feedback of other consensus-based entities, such as the Measures Application Partnership, as we select measures for the ESRD QIP. We also believe that, in some cases, it might be appropriate to ''phase-in'' measures, and we will continue to consider the best methods of introducing measures to the program.

*Comment:* One commenter suggested that CMS impose a method for ensuring that the data provided by facilities/providers is accurate.

*Response:* We currently have the ability to cross check the accuracy of some of the data reported via CROWNWeb. If a provider/facility reports information via CROWNWeb,

we can see if this information reflects that submitted for the ESRD QIP. We will continue to monitor provider/facility compliance with the ESRD QIP reporting requirements, and we will propose to implement a validation methodology in future rulemaking if we conclude that this would be appropriate for the program.

*Comment:* Some commenters encouraged CMS to implement a program or conduct demonstration programs for incentive bonus payments rather than payment reductions. These commenters suggested that these bonuses could be funded by the money saved in payment reductions under the ESRD QIP. Another commenter suggested that CMS make more of the payment amount contingent upon quality, and one commenter urged CMS to encourage innovation in the ESRD field.

*Response:* Section 1881(h) does not provide us with the authority to issue bonus payments to providers/facilities based on their performance under the ESRD QIP or to make reductions of more than 2.0 percent. We have conducted quality incentive ESRD demonstration projects in the past, and we intend to do so in the future; we will consider commenters' suggestions as we develop future projects. We believe that the ESRD QIP will encourage innovation in the ESRD field as providers/facilities seek to reach the highest quality standards through better and more efficient methods of care.

9. Process of Updating Measures

Section 1881(h)(2)(C) of the Act enables the Secretary to establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties. Occasionally there are changes in science or new issues arise related to patient safety that may impact the measures that have been adopted through the rulemaking process. Therefore, for such cases where new information is available that specifically relates to patient safety concerns, we proposed that we would post a notice of the updates we intend to make to the measure(s) in the **Federal Register**. We proposed to specify in the notice a time period during which we would accept comments from the public. We also proposed to consider these comments and post a notice in the **Federal Register** finalizing any updates that we make to the measure(s). We stated our belief that this process will enable us to make necessary updates to the ESRD QIP measures to ensure that the measures are based on the best available scientific data.

*Comment:* Some commenters requested that CMS use the rulemaking process to update and/or modify measures.

*Response:* We believe that the measure updating process that the Secretary establishes under section 1881(h)(2)(B) can be a subregulatory process, as long as it is established in consultation with interested parties. We also believe that we have met this statutory requirement by proposing in rulemaking to implement a process to update measures. Generally, we will use the rulemaking process as often as possible to updated and/or modify measures. But the process we proposed to adopt balances our need, in some circumstances, to expeditiously update measures to address changes in science or issues related to patient safety while still allowing the public to express its critiques, concerns, and approval of such updates.

After considering the comments, we are finalizing our process for updating measures as proposed.

## III. Ambulance Fee Schedule

### *A. Summary of Proposed Provisions*

In the CY 2012 ESRD PPS proposed rule (76 FR 40535 through 40536), we proposed to revise the regulations at § 414.610 to conform with section 106 of the Medicare and Medicaid Extenders Act of 2010 (MMEA), and to incorporate a technical correction.

1. Section 106 of the Medicare and Medicaid Extenders Act of 2010 (MMEA)

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

For covered ground ambulance transports which originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.

For covered ground ambulance transports which do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. In the CY 2011 physician fee schedule final rule (75 FR 73385 and 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 106(a) of the MMEA again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2011 and before January 1, 2012. In the CY 2012 ESRD PPS proposed rule (76 FR 40535), we proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of these payment add-ons, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

b. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. This section specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, shall continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 physician fee schedule final rule (75 FR 73385 through 86, 73625 through 26), we revised § 414.610(h) to conform the regulations to this statutory requirement. Subsequently, section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. Therefore, in the CY 2012 ESRD PPS proposed rule (76 FR 40536), we

proposed to revise § 414.610(h) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through December 31, 2011.

For further information regarding the extension of this MIPPA provision, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

c. Amendment to Section 1834(l)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added paragraph (12) to section 1834(l) of the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area''; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 physician fee schedule final rule (75 FR 73385 through 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 106(c) of the MMEA again amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, as directed by the MMEA, we are continuing to apply the rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2011 and before January 1, 2012 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS supplied ZIP Code File.

In the CY 2012 ESRD PPS proposed rule (76 FR 40536), we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to the statutory requirement set forth at section 106(c) of the MMEA. This statutory requirement is self-implementing. The statute requires a one-year extension of the rural bonus (which was previously established by the Secretary), and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this rural bonus, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

2. Technical Correction

In the CY 2011 physician fee schedule final rule (75 FR 73386, 73625), CMS made technical changes to reformat § 414.610(c)(1). However, in making these revisions, language related to the ambulance fee schedule conversion factor (CF) was inadvertently left out of this regulation. Specifically, the following sentence was inadvertently omitted from revised § 414.610(c)(l): ''The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.'' Prior to the changes made in the CY 2011 physician fee schedule final rule, this was the first sentence under § 414.610(c)(l)(i). We did not intend to delete this language in making the CY 2011 formatting changes. Therefore, in the CY 2012 ESRD PPS proposed rule (76 FR 40536), we proposed to revise § 414.610(c)(1) to reinstate this sentence which was inadvertently deleted in the CY 2011 physician fee schedule final rule.

*B. Response to Comments*

We did not receive any comments regarding the proposed revisions to § 414.610 discussed above. (We received one ambulance-related comment during the comment period which was beyond the scope of the proposed rule, and thus, it is not addressed in the final rule). Therefore, we are finalizing the revisions to § 414.610 as proposed.

## IV. Durable Medical Equipment and Supplies

*A. Background for Durable Medical Equipment (DME) and Supplies*

Title XVIII of the Social Security Act (the Act) governs the administration of the Medicare Program. The statute provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility care, home health care, physician services, and durable medical equipment (DME). DME is covered by Medicare based, in part, upon section 1832(a) of the Act, which describes the scope of benefits under the supplementary medical insurance program (Medicare Part B). Section 1861(s)(6) of the Act defines ''medical and other health services'' to include DME as a separate benefit for which payment is authorized by section 1832 of the Act. Section 1861(m)(5) of the Act specifically includes DME in the definition of the term ''home health services.''

In accordance with section 1861(n) of the Act, the term ''durable medical equipment'' includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home whether furnished on a rental basis or purchased. The patient's home includes an institution used as his or her home other than an institution that meets the requirements of section 1861(e)(1) or section 1819(a)(1) of the Act. Besides being subject to this provision, the coverage of DME must also meet the requirements of section 1862(a)(1)(A) of the Act, which in general excludes from payment any items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which (except for certain specified exceptions) precludes payment for personal comfort items.

Section 1834(a) of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, sets forth the payment rules for most DME furnished on or after January 1, 1989. Historically, the Medicare payment amount for a DME item is generally equal to 80

percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met. The fee schedule amounts are generally calculated using average allowed charges from a base period and then updated by annual update factors. Sections 1834(a)(2) through (a)(7) of the Act set forth six separate classes of DME and separate payment rules for each class. The six classes of items are: inexpensive and other routinely purchased DME; items requiring frequent and substantial servicing; customized items; oxygen and oxygen equipment; other covered items (other than DME); and capped rental items. For DME in general, § 414.210(f) specifies that payment can be made for replacement of DME that is lost, stolen, irreparably damaged, or has been in continuous use for the equipment's reasonable useful lifetime (RUL). In general, the RUL for DME is established as 5 years. Computation of the RUL is based on when the equipment is delivered to the beneficiary, not the age of the equipment. The 5-year standard is set forth in section 1834(a)(7)(C)(iii) of the Act for capped rental DME, but was applied to all DME through the regulations. The RUL is used to determine how often it is reasonable to pay for replacement of DME under the program and is not specifically set forth as a minimum lifetime standard. Therefore, we are using our discretion to establish a rule regarding how long equipment must withstand repeated use to be considered DME.

Payment for inexpensive or routinely purchased DME is made on a purchase or rental basis, with total payments being limited to the purchase fee schedule amount for the item. The regulation at 42 CFR 414.220 provides that inexpensive DME have an average purchase price of $150 or less and routinely purchased DME are items that have historically been acquired on a purchase basis 75 percent of the time or more. Accessories used with DME are also included in the inexpensive or routinely purchased DME class. Payment is generally made on a monthly rental basis with no cap on the number of rental payments made for items such as ventilators that require frequent and substantial servicing. Payment for items meeting the definition of customized DME set forth at § 414.224 is made on a lump sum purchase basis in an amount established based on the Medicare claims processing contractor's individual consideration and judgment of a reasonable payment amount for each item. Payment for oxygen equipment set forth at § 414.226 is made on a monthly basis for up to 36 months of continuous use. The supplier retains ownership of the oxygen equipment following the 36-month cap, but must continue to furnish the equipment for the remainder of the equipment's 5-year RUL, at which point the beneficiary can elect to obtain new equipment. Payment for capped rental items set forth at § 414.229(f) is made on a monthly rental basis for up to 13 months of continuous use. The supplier must transfer title to the equipment to the beneficiary on the first day following the 13th month of continuous use.

In establishing regulations for the purpose of implementing the payment rules mandated by OBRA 87, 42 CFR 414.202 sets forth the basic definition of DME that was originally established and elaborated upon in program instructions discussed below. Section 414.202 defines DME as equipment furnished by a supplier or a home health agency that—

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- Is appropriate for use in the home.

The benefit for DME as it was initially defined at section 1861(s)(6) of the Act was a benefit for ''rental of durable medical equipment.'' The owner of rented equipment is paid for the use of the equipment. When the equipment is no longer needed, it is returned to the owner and can then be rented by another customer. Items that are disposable cannot be rented and items that last for short periods of time are not likely to be items that would be rented. The Act was amended by section 16 of the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 (Pub. L. 95–142) to allow for purchase of DME in cases where purchase is less costly or more practical than rental. In 1978, program instructions were added to the Medicare Part B Carriers Manual (HCFA–Pub. 14–3, Rev. 3–669) to further define DME and durability of an item, that is, when an item is considered durable. The instructions are now included in section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (CMS–Pub. 100–02). In specifying which items satisfy the durability criteria, these program instructions provide that ''an item is considered durable if it can withstand repeated use, that is, the type of item which could normally be rented'' and excludes items that are ''of an expendable nature.'' The instructions do not specify exactly how long an item must last to be considered a durable item that would normally be rented as opposed to a disposable item or an item that would not normally be rented.

CMS has provided program instructions for coverage of supplies and accessories at Section 110.3 in Chapter 15 of the Medicare Benefit Policy Manual. The instructions provide that payment may be made for supplies that are necessary for the effective use of DME, such as lancets used to draw blood for use with a home blood glucose monitor. The lancet itself is disposable and would not be covered as DME, but it is a covered item that falls under the general DME benefit because it is necessary for the effective use of DME—the home blood glucose monitor. Supplies necessary for the effective use of DME also include oxygen and those drugs and biologicals which must be inserted directly into the equipment for the effective use of DME.

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs by providers, physicians, and other suppliers. The HCPCS Code Set is divided into two principal subsystems, referred to as level I and level II of the HCPCS:

Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes, which are copyrighted by the American Medical Association (AMA), and are used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals that are billed to public or private health insurance programs.

Level II of HCPCS is a standardized coding system used primarily to identify products and supplies that are not included in the CPT codes, such as DME, orthotics, prosthetics, and supplies when used outside a physician's office. Assignment of a HCPCS code is not a coverage determination and does not imply that any payer will cover the items in the code category. In October 2003, the Secretary delegated authority under the Health Insurance and Portability Act of 1996 to CMS to maintain and distribute HCPCS Level II codes.

*B. Current Issues*

The regulation and program instructions do not lend guidance regarding the specific period of time that equipment must function in order

to be considered ''durable.'' In addition, the regulation does not provide specific guidance or criteria regarding how to determine if new devices consisting of a system of durable and non durable components that together serve a medical purpose fall within the DME benefit category. Therefore, we believe it is necessary to revise the regulation at this time to include a definition of DME that uses more specific language to define the term ''durable'' for the purpose of determining whether equipment is DME. The issue of linking durability to the lifetime of equipment and where to draw the line has come to our attention in light of the recent technology and engineering in the field of medical devices and equipment. Establishing a minimum lifetime requirement (MLR) would help facilitate the benefit category determination process for items that clearly last longer or shorter than the minimum lifetime threshold.

In cases where it is not clear that the equipment can function for the specified minimum period of time, we proposed that reviewing additional information and evidence consistent with the present benefit category determination process would be necessary to determine the expected life of the equipment. CMS and CMS contractors would base the decision on various sources of information including but not limited to the HCPCS request form, pre-market clearance documents from the Food and Drug Administration (FDA), product warranty documents, product Web site, product marketing materials, product user guides, product operating manuals, consumer product reviews, subject matter expert reviews, industry product standards data, and product data created as a result of clinical studies or standardized test results. A minimum lifetime standard for DME may also help facilitate the HCPCS process. The current application form used to request new HCPCS codes for items includes the question regarding whether equipment is durable and, if so, instructs the applicant to provide an explanation of how the item can withstand repeated use. We have received requests from several entities including DME stakeholders for additional clarification regarding the durability standard for DME. Comments from some of these entities indicate that there is limited direction on what is required for an item to be considered ''durable'' in the current regulation. Additional clarification of the term ''durable'' would be helpful to industry stakeholders such as manufacturers in anticipating how their products would be treated under coding classification and benefit category determinations.

*C. Overview of the Provisions of the Proposed Durable Medical Equipment (DME) Regulation*

On July 8, 2011, we published in the **Federal Register** a proposed rule entitled, ''Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment'' (76 FR 40498). In that rule, we proposed revising the definition of DME by adding a 3-year MLR that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME.

*D. Summary of the Proposed Provisions and Responses to Comments on the Definition of Durable Medical Equipment (DME) 3-Year Minimum Lifetime Requirement (MLR)*

We received approximately 35 comments on our proposal. Interested parties that submitted comments included several medical device and equipment manufacturers, a healthcare provider, RESNA (Rehabilitation Assistive Technology Standards Board) and national organizations for HCPCS coding, disability, medical technology innovators and beneficiaries. In this final rule we provide a summary of each proposed provision, a summary of the public comments received, and our responses to them.

We proposed making changes to the definition of DME at 42 CFR 414.202 in order to clarify the meaning of the term ''durable'' in order to reflect our current interpretation of the statutory provisions discussed above consistent with the DME payment provisions. Specifically, we proposed establishing a 3-year MLR that equipment will be expected to meet in order to be considered DME. Based upon the statute and current regulations, equipment would not qualify as DME if it could not withstand repeated use. Although the capacity for reuse is in itself a fundamental characteristic of durability, it is not clear how many months or years an item must withstand repeated use in order to be considered durable.

The Merriam Webster dictionary defines ''durable'' as the ability to exist for a long time without significant deterioration. The United States Department of Commerce uses a durability standard of 3 years for consumer durable goods for National Income and Accounts estimates.[19] Furthermore, economics dictionaries,[20] various encyclopedias,[21] and economics textbooks [22] define durable goods as goods that are expected to last longer than 3 years.

In addition, information gathered from various sources such as Rehabilitative Engineering and Assistive Technology Society of North America (RESNA),[23] product catalogs, product warranty documents, and consumer product reviews indicate that conventional DME items such as wheelchairs, hospital beds, and ventilators specified in section 1861(n) of the Act typically have a useful life of 3 or more years before they need to be replaced or need major repairs. Therefore, we proposed establishing a 3-year MLR for items to meet the durability criterion for DME.

The 3-year MLR was proposed to increase the clarity of the current definition and give regulatory weight to a reasonable benchmark for a minimum period of durability or repeated use that an item would be expected to meet in order for the equipment to be considered DME. In addition, the rule was proposed to provide clear guidance to CMS and other stakeholders for making consistent informal benefit category determinations and national coverage determinations for DME. It was also proposed to assist manufacturers in designing and developing new medical equipment to have a better understanding of how long an item must be able to withstand repeated use in order to be considered DME for Medicare purposes. It is important to note that the 3-year MLR does not replace the RUL standard established by section 1834(a)(7)(C) of the Act for payment purposes. The RUL rules are used to determine how often payment can be made for replacement items and is not a MLR for DME. Although the proposed 3-year MLR is a requirement for determining whether an item will be considered durable, it is not an indication of the typical or average lifespan of DME, which in many cases may last for much longer than 3 years.

[19] The NIPA Handbook (Concepts and Methods of the U.S National Income and Product Accounts, Chapter 5–Personal Care Expenditures. The handbook is available at *http://www.bea.gov/national/pdf/NIPAhandbookch5.pdf.*

[20] The McGraw Hill Dictionary of Modern Economics by Douglas Greenwald & Associates, Economics dictionary by Donald Moffat, Dictionary of Business and Economics by Christine Ammer and Dean Ammer.

[21] Encyclopedia of Business, Britannica Encyclopedia and Gale Encyclopedia.

[22] A Lexicon of Economics by Kenyon A. Knopf.

[23] *http://resna.org/.*

1. Application of the 3-Year MLR to Items Currently Covered as DME and to Supplies and Accessories of Covered DME

We proposed that the 3-year MLR be prospective only and not apply to equipment classified as DME before the proposed rule is implemented. Based on our experience with the program, we believe that most items that are currently classified as DME function for 3 or more years. We also proposed not to apply the standard to supplies and accessories used with DME that are paid for under the DME benefit or blood glucose monitors and blood testing strips to allow for continued coverage of such items, supplies and accessories that are necessary for the effective use of DME. In the proposed rule we also solicited public comments on methods for determining when multi-component devices are durable. We requested comments only and did not propose any regulation changes regarding this issue. The comments received on this issue will be taken into consideration in determining whether changes on this issue should be proposed in future rulemaking.

*Comment:* Several commenters acknowledged that it is necessary to establish a MLR for use in determining if medical equipment is durable for purposes of Medicare payment.

*Response:* We agree and thank the commenters for their support and feedback that it is necessary to establish a MLR for use in determining if medical equipment is durable.

*Comment:* Several commenters argued that the proposed rule is unnecessary and the current criteria for determining whether equipment is durable are clear, with one commenter stating that Medicare payment rules and manufacturer warranties already provide beneficiaries with appropriate protection. Two commenters suggested that CMS should publish a MLR for DME through subregulatory guidance.

*Response:* We appreciate the comments; however, we believe there is a need to make changes to the definition of DME at 42 CFR 414.202 to clarify the meaning of the term ''durable'' to reflect our current interpretation of the statute, consistent with the DME payment rules previously discussed. Manufacturers of new technology medical devices have specifically asked how long an item must withstand repeated use in order to be considered durable equipment, and therefore our objective is to establish a clear expected MLR for equipment in order to facilitate consistent benefit category determinations. We also wanted to publish the 3-year MLR through rule making rather than providing this clarification through Manual provisions and program instructions to provide an opportunity for input given that the definition of DME is set forth in regulations.

*Comment:* Several commenters stated that the proposed 3-year MLR was arbitrary and inappropriate.

*Response:* We disagree. As discussed previously, the 3-year MLR for durability reflects the standard used by various Federal agencies to define durable consumer goods such as cars, refrigerators, air conditioning units, as well as hospital beds, walkers, crutches, scooters, wheelchairs, oxygen equipment, *etc.* Federal agencies such as the Department of Commerce and the Department of Labor have been applying this standard to durable goods including DME. Furthermore, the 3-year durability standard is widely supported in the industry. See for example, Simon Kuznet's ''National Income and Capital Formation'' published by the National Bureau of Economic Research (1937), defining durable commodities as those whose period of utilization is more than 3 years, and references in a wide variety of more recent literature, textbooks, dictionaries and encyclopedias, which specifically reference a 3-year period of time in defining or classifying items as durable.[24] We see no reason why a different standard for durability should be used for the equipment covered as DME under the Medicare program. Therefore, we believe it is reasonable for the Department of Health and Human Services to apply this 3-year standard to DME.

Additionally, in light of the statutory 5-year RUL requirement and the DME payment rules, which support the fact that equipment paid for under the DME benefit is intended to be used over many years, we believe that it is reasonable to require that such equipment be functional or capable of withstanding repeated use for at least 3 years. As we discussed in our equipment replacement payment rule, we expect that equipment furnished by suppliers will function for a reasonable period of time. See 71 FR 65884, 65920 (Nov. 9, 2006). We believe that a 3-year MLR would provide sufficient flexibility to cover new technology items that could be considered durable, but that may not last for 5 years before having to be replaced. As noted previously, the Congress, in drafting section 4152(c)(2)(F) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508), selected 5 years as the default RUL for capped rental DME. The RUL was specified to be 5 years for each capped rental DME item unless prior experience in making payment for the item resulted in the establishment of an alternative RUL for the item. As part of the interim final rule (57 FR 57675) implementing this provision on December 7, 1992, we extended the RUL provision to other items of DME and specified that, in the absence of program instructions, the carrier may determine that the RUL of equipment is greater than, but not less than, 5 years. See 57 FR 57675, 57686 (Dec. 7, 1992). Furthermore, such standards are consistent with the DME payment methodology, mandated by Section 4062(b) of the Omnibus Budget Reconciliation Act of 1987, Public Law 100–203, and section 5101(b) of the Deficit Reduction Act of 2005, Public Law 109–171, which authorized the changes in the payment for oxygen equipment and mandated a cap on payments for all rented equipment other than a few frequently serviced items such as ventilators. The following are some examples of changes in payment rules that were made to avoid excessive payments for durable items needed and used by patients for extended periods of time lasting for several years.

- The rental payments for inexpensive equipment such as canes and crutches that the beneficiary elects to rent rather than purchase is capped at the purchase fee for the equipment.
- The payment for oxygen equipment is currently capped at 3 years and suppliers are mandated to continue furnishing the equipment after the cap for up to 2 additional years.
- Title to other expensive equipment such as wheelchairs and hospital beds is transferred to the beneficiary after 13 continuous rental payments.

The 5-year RUL and payment rules apply to durable equipment that can be used for many years. See 71 FR at 65920, (regarding the expectation that suppliers furnish a quality item that will last over a 5-year period). CMS continues to expect that in light of these

[24] The NIPA Handbook (Concepts and Methods of the U.S National Income and Product Accounts, Chapter 5—Personal Care Expenditures,The handbook is available at *http://www.bea.gov/national/pdf/NIPAhandbookch5.pdf*, U.S. Department of Labor/Bureau of Labor Statistics. *http://www.bls.gov/ppi/ppiwholesale.htm*, The McGraw Hill Dictionary of Modern Economics by Douglas Greenwald & Associates, Economics dictionary by Donald Moffat, Dictionary of Business and Economics by Christine Ammer and Dean Ammer, Encyclopedia of Business, Britannica Encyclopedia and Gale Encyclopedia, Lexicon of Economics by Kenyon A. Knopf, Fiscal Policy and Business Cycles by Alvin H. Hansen, Economics: Principles in Action by Steven M. Sheffrin, Durability of Output and Expected Stock Returns by Joao F. Gomes, Leonid Kogan, & Motohiro Yogo, Economics Fluctuations and Forecasting by Vincent Su, Macroeconomics by Roger A. Arnold, and National Income and Capital Formation by Simon Kuznet.

RUL provisions, equipment covered under the DME benefit should be capable of withstanding repeated use for a minimum time period. Consistent with these standards, we believe that a 3-year durability threshold is reasonable, especially given our history with the program and the vast majority of categories of DME that already last for at least a 3-year period.

*Comment:* One commenter suggested that CMS should refrain from adding a 3-year MLR and instead define what is meant by repeated use.

*Response:* We appreciate the comment; however, we believe it is necessary to establish a reasonable expectation regarding durability by adding a 3-year MLR to the definition of DME. Manufacturers of new technology medical devices have specifically asked how long an item must withstand repeated use in order to be considered durable equipment, and therefore we believe it is necessary to establish a clear expected MLR for equipment in order to assure payment for quality items of DME, and facilitate consistent benefit category and national coverage determinations.

*Comment:* One commenter suggested establishing 6 months as the MLR for DME.

*Response:* We appreciate the comment, however, as discussed earlier, 3 years is a standard used by Federal agencies and the industry for classifying durable goods, which include equipment typically covered under the DME benefit. Therefore, we believe that adopting a standard of 3 years for purposes of the Medicare program would be reasonable and assure payment for equipment consistent with industry standards. Furthermore, as noted previously, in light of the statutory 5-year RUL requirement we do not believe it is reasonable to establish a 6-month standard. As discussed earlier, consistent with the statute, the payment rules support the fact that equipment included in the DME benefit is intended to be used over many years. For all the reasons stated above, we do not believe that a 6-month MLR for DME is a reasonable option.

*Comment:* Several commenters added that using a universal 3-year MLR for all types of products is inflexible and nonfeasible. One commentator indicated that engineering a device for a guaranteed lifetime is virtually impossible.

*Response:* We do not believe that establishing an expected 3-year MLR is inflexible and nonfeasible. As noted earlier, the regulations already provide a requirement for repeated use and a 5-year RUL standard. We proposed to establish an expected 3-year threshold standard consistent with these requirements and other Federal agencies and industry standards. In addition, while we understand that exact periods of longevity will vary, the purpose of the rule is to establish a MLR in order for the equipment to be considered durable for purposes of Medicare payment determinations. The 3-year MLR is intended to be a minimum threshold that equipment will be expected to meet in order to be considered durable under Medicare regulations We expect that equipment furnished under the benefit will be quality items that will function consistent with industry standards for a 3 year threshold period.

Furthermore, a vast majority of the categories of DME last for 3 years or longer. Therefore, consistent with these RUL and payment provisions, we believe that a 3-year MLR would continue to provide the flexibility to cover new technology items.

We also appreciate the comment that engineering a device for a guaranteed lifetime is virtually impossible; however, given the industry standards, we expect that equipment should function for a minimum threshold period of time. Based on our experience in making benefit category determinations and analyzing the types of equipment that are covered under the DME benefit over the years; we believe that the 3-year MLR is a reasonable threshold standard for the types of equipment paid for under the DME benefit. Therefore, we believe that for purposes of Medicare payment, it is reasonable to establish a threshold of 3 years which is consistent with other Federal agencies and industry standards.

*Comment:* Two commenters suggested that the MLR should be based upon a specific code set, natural therapeutic requirements, and normal length of needs and medical necessity as dictated by the prescriber, rather than a universally applied standard.

*Response:* We thank the commenters for their input that the MLR should be based upon a specific code set, natural therapeutic requirements, and normal length of needs and medical necessity as dictated by the prescriber, rather than a universally applied standard. However, we have established a standard applicable to the Medicare benefit that is designed to be consistent with criteria established in the statute and payment provisions. We have interpreted the benefit consistent with the standards in the statute, Medicare payment regulations, industry standards, and Federal agency standards. Furthermore, based on our experience in making benefit category determinations and analyzing the types of equipment that are covered under the DME benefit over the years, the majority of the categories of DME items already last for 3 years or longer. As noted earlier, we already expect items will function consistent with the 5-year RUL and DME payment rules. For all the reasons discussed, we believe that it is appropriate to apply the 3-year MLR as a threshold for defining durability for equipment under the program.

*Comment:* One commenter recommended that CMS create a rebuttable presumption that a DME item should last for 3 years but provide that a manufacturer can rebut that presumption with convincing evidence that the 3-year MLR should not be applied automatically in a particular instance.

*Response:* We disagree with the commenter's recommendation for creating a rebuttable presumption that a DME item should last for 3 years. As stated earlier, manufacturers of new technology medical devices have specifically asked how long an item must withstand repeated use in order to be considered durable equipment, and therefore our objective is to establish an expected MLR for equipment in order to assure payment for quality items and facilitate consistent benefit category and national coverage determinations. The issue of linking durability to the lifetime of equipment and where to draw the line has come to our attention in light of the recent technology and engineering in the field of medical devices and equipment. We are establishing a MLR for DME to clarify our expectation regarding durability. An option to rebut the 3-year MLR in some instances would undermine this objective.

*Comment:* Several commenters recommended that CMS collaborate with industry stakeholders to develop additional requirements related to determining durability of items.

*Response:* We appreciate the comment. The current processes including Benefit Category Determination (BCD), National Coverage Determination (NCD), Local Coverage Determinations (LCD), and Healthcare Common Procedure Coding System (HCPCS) include meetings with manufacturers in addition to the public where we seek input from the stakeholders. We will continue to receive input from stakeholders consistent with the BCD and NCD process when determining whether an item is durable. See 68 FR 55634, (September 26, 2003); and *http://www.*

*cms.gov/DeterminationProcess/Downloads/FR09262003.pdf.*

See also, information on the HCPCS Level II coding process at: *http://www.cms.gov/MedHCPCSGenInfo/Downloads/2013_HCPCS_Application.pdf. http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage.*

*Comment:* Several commenters stated that the rule would create burdensome testing requirements to verify the 3-year MLR for a device. One commenter stated that testing standards cannot validate the lifetime of a device and it is unclear how a manufacturer would prove an item meets the 3-year MLR. One commenter noted that added testing for durability will increase the cost for manufacturers in addition to designing new 3-year versions of DME products that currently function for a shorter period of time.

*Response:* We did not intend to create burdensome testing requirements. As noted previously, our objective is to establish a reasonable minimum lifetime standard for DME for purposes of Medicare payment, consistent with other Federal agencies and industry practice. As stated in the proposed regulation, in cases where it is not clear that the equipment can function for the specified minimum period of time, we will review information and evidence consistent with the current benefit category determination process to determine the expected life of the equipment. As discussed previously, the benefit category determination process typically involves reviewing information from various sources including but not limited to information related to Food and Drug Administration (FDA) pre-market clearance, product manuals, operating guides, warranty documents, and standardized test results. The NCD process is available at *http://www.cms.gov/DeterminationProcess/Downloads/FR09262003.pdf.* See also, 68 FR 55638 (September 23, 2003).

Additionally, we routinely collect information regarding durability of new products as part of the HCPCS editorial process in order to identify categories of new DME subject to the procedures established in accordance with the mandate of section 531(b) of the Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA 2000), Public Law 106–554. Based on our experience with the program, this information has been readily available from the manufacturers of these items and other entities submitting requests for changes to the HCPCS. Information on the HCPCS Level II coding process is available at: *http://www.cms.gov/MedHCPCSGenInfo/Downloads/2013_HCPCS_Application.pdf* and *http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage.*

Furthermore, the 3-year MLR will be prospective and will not be applied on a retroactive basis; it will be used for making benefit category decisions for new items. As noted previously, we believe that a vast majority of the categories of DME already last for at least 3 years, consistent with the RUL and payment provisions. The 3-year MLR is designed to be a minimum threshold for determining if an item is considered durable and we expect that new DME products in general will continue to meet or exceed this MLR. For reasons discussed above, we have no reason to believe that the 3-year MLR will increase the cost for manufacturers.

*Comment:* One commenter supported the grandfathering provision.

*Response:* We thank the commenter for the input and support.

*Comment:* Several commenters voiced concerns that the new requirement will stifle innovation and prevent the entry of new devices in the market. Several commenters stated that the grandfathering provision would create disparities among manufacturers and be disadvantageous to new product manufacturers and advantageous to existing DME product manufacturers. Some commenters stated that applying the rule prospectively and not applying the rule to items currently classified as DME makes the rule unclear and nontransparent.

*Response:* We did not intend to create disparities. As noted in the proposed regulation and a response to an earlier comment, we are making changes to the definition of DME to reflect our current interpretation of the statute consistent with the RUL and general DME payment provisions. The 3-year MLR is designed to be applied on a prospective basis and would represent a minimum threshold for determinations regarding equipment durability. As noted earlier, in light of the statutory 5-year RUL requirement and DME payment rules which support the fact that DME items should be able to withstand repeated use for many years; we believe that it is reasonable to require that equipment be capable of withstanding repeated use consistent with the industry 3 year standard. We believe that a 3-year MLR would provide the flexibility to cover new technology items that can be considered durable, but may not last for 5 years before having to be replaced.

We also believe that the 3-year MLR is reasonable given the general payment and RUL requirements. As discussed previously, the 5-year RUL is well established since 1992 and we have not found that the RUL standard has stifled innovation or prevented entry of new devices in the market. Therefore, in light of these provisions, we believe that 3 years is a reasonable threshold consistent with Medicare payment rules, industry standards and Federal agency standards. However, while we expect that equipment will meet our 3 year standard, we will continue to monitor the issue and undertake additional rulemaking if necessary.

*Comment:* One commenter requested clarification on the applicability and scope of the rule. Some commenters requested clarification on how the MLR would be applied to new generations of products that are currently classified as DME or how the standard would apply to an existing DME item that is modified in the future to improve functionality. One commenter recommended that the new rule not apply if an existing DME item is just upgraded. Some commenters questioned if the rule would be applicable to only products that apply for a new HCPCS code. Some commenters questioned if the new rule would apply to items that are billed using existing HCPCS codes or any item that fits into an existing product category or existing HCPCS codes and how miscellaneous codes would be handled.

*Response:* We will apply the revised definition for DME on a prospective basis. That is, we will not redetermine for payment as DME any product that is currently paid under the DME benefit. The revised definition would only apply to new products. To the extent that a modified product is not a new product (including an item that has been upgraded), the 3-year MLR will not be applicable. We will consider issuing additional guidance to provide further clarification if necessary.

*Comment:* One commenter questioned how CMS would validate that a device lasts fewer than 3 years. One commenter requested clarification on whether the MLR would be calculated from the date the manufacturer sells the item to the provider or date first provided to the patient.

*Response:* We are not proposing a new process and as noted previously, we will continue to follow the current benefit category determination process to determine whether a product meets the standards for DME set forth in the rule. As noted earlier, the expected life of an item will be estimated based upon information gathered from various sources consistent with the current benefit category determination process

and will be calculated based upon use, not when it is sold to a supplier.

*Comment:* One commenter voiced concern that there would be no process for appealing decisions that items are not durable.

*Response:* A manufacturer or supplier can request a reconsideration of an informal BCD determination or a reconsideration of a formal NCD consistent with the statute. See (68FR 55638, September 26, 2003) available at: *http://www.cms.gov/DeterminationProcess/Downloads/FR09262003.pdf*.

*Comment:* One commenter stated that the current testing standards for certain types of equipment that are currently classified as DME require a much shorter lifespan than 3 years.

*Response:* We appreciate the comment; however, as stated previously, the 3-year MLR would not apply to any items currently classified as DME. In addition, the 3-year MLR would not apply to blood testing strips, accessories and supplies used with DME that are necessary for the effective use of the DME item. For example: A blood glucose monitor and lancets used to obtain blood samples for use in a blood glucose monitor are covered under the DME benefit. The blood glucose monitor is covered as DME and the lancets are covered as supplies necessary for the effective use of the DME item.

After reviewing all the comments, we are finalizing the regulation to revise the definition of durable medical equipment at § 414.202 by adding a 3-year MLR that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. This will be effective with respect to items classified as DME after January 1, 2012.

2. Application of the 3-Year MLR to Multi-Component Devices

In some cases, a device may be a system consisting of durable and non-durable components that together serve a medical purpose. Currently, a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components that are part of the device are durable. Therefore, if the proposed regulation to establish a minimum 3-year MLR for DME is applied to these devices, the component(s) of a multi-component device that performs the medically necessary function of the device would need to meet the 3-year MLR. Although, we did not propose to change our policy with regard to these types of systems at this point, we solicited public comments on this topic. Specifically, we solicited public comments on various ways we might consider applying the 3-year MLR to multi-component devices consisting of both durable and non-durable components. Various options might include the following:

1. Apply the 3-year MLR to the component(s) that performs the entire medically necessary function of the device.

2. Apply the 3-year MLR to the component(s) that performs a vital part of the medically necessary function of the device.

3. Consider a device/system to be durable only if the cost of the durable component(s) over a period of time (for example, 5 years) makes up greater than 50 percent of the overall cost of the device/system over the same period.

In the proposed rule we solicited public comments on the application of various options to multi-component devices to determine whether the device is durable. We received approximately 20 comments pertaining to the topic of applying the 3-year MLR to multi-component devices consisting of both durable and non-durable components. One commenter disagreed with option one because this option requires that the whole device meet the MLR as many devices will not be able to function without even minor elements, such as accessories and supplies. This commenter noted that for the option two, it is not clear what is meant by ''performs a vital part of the medically necessary function.'' This commenter further stated that for option three it is unclear what is meant by ''cost.'' The commenter noted that option 3 could be considered if the Medicare reimbursement rate for the durable and non-durable components is used as the ''cost'' for calculating the ratio of the cost for durable and non-durable components. One commenter supported the 3-year MLR and endorsed option 2 which applies the 3-year MLR to the component(s) that performs a vital part of the medically necessary function for multi-component devices.

Several commenters endorsed the coverage of a specific multi-component device for Medicare beneficiaries. One commenter stated that medical equipment comprised of durable and non-durable components should be considered durable if any one component of the equipment is able to meet the MLR as determined in the HCPCS application process and CMS should evaluate the medically necessary function performed by the device in its totality rather than basing durability on the component that performs the medically necessary function of the device.

We requested comments only and did not propose any regulation changes. Therefore, the comments received will be taken into consideration for future proposed rulemaking.

## V. Interim Final Rule Regarding the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

*A. Background*

1. Legislative and Regulatory History of the DMEPOS Competitive Bidding Program

Section 1847 of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)(Pub. L. 108–173), requires the Secretary to establish and implement a Medicare DMEPOS Competitive Acquisition Program (''competitive bidding program'' or ''program''). Under the competitive bidding program, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas (CBAs) based on bids submitted by qualified suppliers and accepted by Medicare. For competitively bid items, the payment amounts, referred to as ''single payment amounts'', replace the fee schedule payment methodology set forth in section 1834 of the Social Security Act (the Act) and 42 CFR part 414, Subpart D of our regulations.

The competitive bidding program guarantees savings to both the Medicare program and beneficiaries under the program. The program also includes provisions to ensure beneficiary access to quality DMEPOS items and services. Section 1847 of the Act limits participation in the program to suppliers who have met applicable quality and financial standards and requires the Secretary to maintain beneficiary access to multiple suppliers.

On May 1, 2006, we issued a proposed rule (72 FR 25654) in the **Federal Register** that would implement the competitive bidding program for certain DMEPOS items and services and solicited public comment on our proposals. On April 10, 2007, we issued a final rule (72 FR 17992) in the **Federal Register** addressing the comments on the proposed rule and establishing the regulatory framework for the Medicare DMEPOS competitive bidding program in accordance with section 1847 of the Act.

Consistent with the requirements of section 1847 of the Act and the

competitive bidding regulations, we began implementing the program by conducting the first Round of competition in 2007 in 10 of the largest metropolitan statistical areas (MSAs) for 10 product categories and implemented the competitive bidding program on July 1, 2008.

2. The MIPPA and the Medicare DMEPOS Competitive Bidding Program

On July 15, 2008, section 154 of the Medicare Improvements for Patients and Providers Act (MIPPA) amended section 1847 of the Act to make certain limited changes to the Medicare DMEPOS competitive bidding program. Section 154(a) of the MIPPA delayed competition under the program and terminated the competitive bidding contracts effective June 30, 2008.

The MIPPA required the Secretary to conduct a second competition for Round 1 in 2009 (''Round 1 rebid'') that included the ''same items and services'' in the ''same areas'' as the 2007 Round 1 competition, with certain limited exceptions. Specifically, the Round 1 rebid excluded negative pressure wound therapy (NPWT) items and services and excluded Puerto Rico. In addition, section 154(a) of the MIPPA permanently excluded group 3 complex rehabilitative wheelchairs from the competitive bidding program by amending the definition of ''items and services'' in section 1847(a)(2) of the Act. Suppliers, including suppliers that previously were awarded a competitive bidding contract, had to resubmit bids to be considered for a contract under the Round 1 rebid.

Section 154(a) of the MIPPA also delayed competition for Round 2 of the competitive bidding program from 2009 to 2011 and subsequent competition under the program from 2009 until after 2011. A competition for a national mail order competitive bidding program may occur after 2010 as a result of the MIPPA.

The MIPPA mandated certain changes to the bidding process, starting with the Round 1 rebid. Section 154(a) of the MIPPA added a new paragraph (F) to section 1847(a)(1) of the Act, which sets forth a process for supplier feedback on missing financial documents. Pursuant to this requirement, we notify suppliers that submit their bids within a specific time period if their bid submission is missing any of the required financial documents. We allow suppliers to submit missing financial documents within 10 business days after this notice.

Section 154(b) of the MIPPA amended section 1847(b)(3) of the Act to require contract suppliers to notify us of subcontracting relationships they have entered into for the purpose of furnishing items and services under the competitive bidding program. Contract suppliers must also inform CMS whether each subcontractor meets the accreditation requirement set forth in section 1834(a)(20)(F)(i) of the Act, if applicable to the subcontractor.

Section 154(d) of the MIPPA excludes from the competitive bidding program certain DME furnished by a hospital to the hospital's patients during an admission or on the date of discharge.

On January 16, 2009, we published in the **Federal Register** (74 FR 2873) an interim final rule with comment period to incorporate into regulations at 42 CFR 414 Subpart F the MIPPA provisions discussed above.

In addition to the changes implemented through the interim final rule, section 154 of the MIPPA made other changes to the competitive bidding program which included:

- Exclusions of certain areas in subsequent rounds that are not already selected under Rounds 1 and 2;
- Extension of the Program Advisory and Oversight Committee;
- Exemption for Off-the-Shelf Orthotics from Competitive Bidding when provided by Certain Providers; and
- Evaluation of certain Healthcare Common Procedure Coding System (HCPCS) codes.

These provisions have been addressed through subsequent rulemaking or subregulatory guidance, as appropriate. For additional information about exclusions of certain areas in subsequent rounds that are not already selected under Rounds 1 and 2 and the exemption for off-the-shelf orthotics from competitive bidding when provided by certain providers, please refer to the November 29, 2010, **Federal Register** (75 FR 73574).

The following administrative requirements were also not addressed in the interim final rule:

- A post-award audit by the Office of Inspector General;
- Establishment of a Competitive Acquisition Ombudsman; and
- A Government Accountability Office report on the results of the competitive bidding program.

The MIPPA mandated a nationwide 9.5 percent reduction in the fee schedule payment amounts for all items and services that were competitively bid during the prior round of competition regardless of any exclusion such as group 3 complex rehabilitative wheelchairs. This provision was not addressed in the interim final rule because it was administered through the standard process for updating fee schedule amounts.

On February 10, 2009, we published a notice (74 FR 6557) in the **Federal Register** proposing to delay the effective date of the interim final rule by 60 days to allow Department officials the opportunity for further review of the issues of law and policy raised by the interim final rule. On February 19, 2009, we published another notice (74 FR 7653) in the **Federal Register** that implemented the temporary delay proposed on February 10, 2009. As specified by the February 19, 2009 notice, the interim final rule became effective on April 18, 2009.

*B. Overview of the Interim Final Rule*

On January 16, 2009, we published in the **Federal Register** an interim final rule (74 FR 2873 through 2881) entitled ''Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)''. In the interim final rule, we revised current provisions at 42 CFR part 414, Subpart F, to incorporate certain self-implementing MIPPA provisions. The interim final rule addressed the following changes made by the MIPPA:

General Changes to the DMEPOS Competitive Bidding Program:

- Temporary Delay of the Medicare DMEPOS Competitive Bidding Program.
- Supplier Feedback on Missing Covered Documents.
- Disclosure of Subcontractors and their Accreditation Status under the Competitive Bidding Program.
- Exemption from Competitive Bidding for Certain DMEPOS.
- Exclusion of Group 3 Complex Rehabilitative Wheelchairs.

Round 1 Changes of the Competitive Bidding Program:

- Rebidding of the ''same areas'' as the previous Round 1, unless otherwise specified.
- Rebidding of the ''same items and services'' as the previous Round 1, unless otherwise specified.

*C. Summary of the Interim Final Rule Provisions and Response to Comments on Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)*

The interim final rule was published in the **Federal Register** on January 16, 2009 with a comment period that ended

on March 17, 2009. We received approximately 793 timely pieces of comments from the interim final rule. Various parties submitted comments including DMEPOS manufacturers, suppliers, national associations representing the supplier community, and pharmacies.

We note that we received many comments on a wide range of issues that were not addressed in the interim final rule. We thank commenters for sharing their views on these issues; however, because these comments were outside the scope of the interim final rule, we do not address those comments in this final rule. In this final rule we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and any changes to the interim final rule we are implementing in this final rule as a result of comments received.

1. General Changes to the DMEPOS Competitive Bidding Program

a. Temporary Delay of the Medicare DMEPOS Competitive Bidding Program

Section 154(a) of the MIPPA amended section 1847(a)(1) of the Act to delay competition under Rounds 1 and 2 of the Competitive Bidding Program from 2007 and 2009 to 2009 and 2011, respectively. It also delayed competition for a national mail order program until after 2010 and competition in additional areas, other than mail order, until after 2011.

We revised § 414.410(a)(1) and (2) to indicate that competition under Round 1 of the competitive bidding program occurred in 2009 and competition under Round 2 of the program would occur in 2011. In addition, we have revised § 414.410(a)(3) to indicate that competition in additional MSAs will occur after 2011 (or, in the case of national mail order for items and services, after 2010).

The comments we received on Temporary Delay of the Medicare DMEPOS Competitive Bidding Program and our responses are set forth below.

*Comment:* Several commenters disagreed with starting competition for the Round 1 rebid in 2009 and wanted CMS to delay the program further. Some commenters suggested that CMS spend more time determining the impact and improving the quality of the DMEPOS Competitive Bidding Program for suppliers and beneficiaries by considering comments received on the interim final rule and evaluating the effects from Round 1 of the competitive bidding program before starting the Round 1 rebid.

*Response:* Section 154(a) of the MIPPA 2009 required the supplier competition for the Round 1 rebid to occur in 2009; therefore, we could not delay the program further. We note that we made numerous process improvements to the competitive bidding program for the Round 1 rebid. For example, we implemented an upgraded on-line bid submission system, early bidder education, and increased oversight of bidders that are new to product categories or competitive bidding areas to ensure they meet our requirements. These improvements, combined with the MIPPA reforms discussed in this final rule, resulted in a smoother experience for bidders and contributed to the successful implementation of the Round 1 rebid contracts and prices on January 1, 2011.

Consistent with our expectations, the Round 1 rebid results so far have been very positive. The program is fulfilling its promise as an effective tool to help Medicare set appropriate payment rates for DMEPOS items and services: payment amounts from the supplier competition for the Round 1 rebid of the program resulted in average savings of 35 percent as compared to the current fee schedule prices. The program is expected to save more than $17 billion in Medicare expenditures over 10 years. In addition to this positive impact on the Medicare Part B trust fund balance, the program is expected to save beneficiaries more than $11 billion over the next ten years as a result of lower coinsurance payments and the downward effect on monthly premium payments. The overall combined savings to Medicare and beneficiaries is therefore expected to total more than $28 billion over the first ten years of the program.

As anticipated, beneficiaries are receiving quality products from contract suppliers in their CBAs. 76 percent of contracts were awarded to suppliers already furnishing contract items in the local area. Additional contract suppliers have furnished other items in the local area or furnished contract items in other areas: fully 97 percent of contracts were awarded to suppliers already established in the competitive bidding area, the product category, or both. Also, CMS exceeded the the 30 percent small supplier target. For the Round 1 rebid, small suppliers, those with gross revenues of $3.5 million or less as defined for the program, make up about 51 percent of the contract suppliers. As discussed later in this preamble, our comprehensive monitoring program has shown a very smooth effective implementation with few inquiries and complaints and no changes in beneficiary health status outcomes.

After consideration of the public comments received, we are finalizing this provision without modification.

b. Supplier Feedback on Missing Covered Documents

Section 1847(b)(2)(A) of the Act prohibits the Secretary from awarding a contract under the program to a supplier unless the supplier meets applicable financial standards specified by the Secretary, taking into account the needs of small providers. We have implemented this requirement at § 414.414(d) of the competitive bidding regulations, which requires suppliers to submit, as part of their bids, financial documents specified in the request for bids (RFB).

The RFB issued for the Round 1 rebid required suppliers to submit the same categories of financial documents as we requested for the previous Round 1 competition. In the previous round of competition, we required suppliers to submit financial documents from the most recent 3 years. As stated in 42 CFR 414.414(d), the required financial documents have been specified in the RFB. Based on experience from the previous round of competition, we modified the required financial documents to lessen the burden on suppliers; instead of 3 years of documentation, we required only 1 year. We believe that we can determine whether a supplier demonstrates financial soundness by reviewing one year of documentation.

Section 154(a) of the MIPPA added a new paragraph (F) to section 1847(a)(1) of the Act, which established a detailed process by which we must notify suppliers of missing ''covered documents''—defined by MIPPA as financial, tax or other documents required to be submitted by a bidder as part of an original bid submission in order to meet required financial standards—if such documents are submitted within a specified time period. The MIPPA details the specific steps of this process and provides a timeline for each stage of this covered document submission review. We have implemented this provision of the MIPPA consistent with its detailed requirements.

Consistent with section 1847(a)(1)(F) of the Act, in the case of a bid in which one or more covered documents in connection with such a bid has been submitted not later than the covered document review date, we would notify suppliers of each covered document that is missing from the bidder's submission as of the covered document review date. As set out in the Act the ''covered document review date'' is the later of—

(1) The date that is 30 days before the final date specified by the Secretary for submission of bids; or (2) the date that is 30 days after the first date specified by the Secretary for submission of bids. For example, if a bid window opens on January 1st and closes on April 30th, the ''covered document review date'' would be the later of: (1) March 31st (30 days before the final date specified by the Secretary); or (2) January 31st (30 days after the first date specified by the Secretary). Therefore, in this case, the ''covered document review date'' would be March 31st. Suppliers that submit their financial documents after the covered document review date would not receive notice of any missing financial documents.

Section 1847(a)(1)(F)(i) of the Act requires that we notify bidders of any missing covered documents within 45 days after the covered document review date for the Round 1 rebid. In subsequent rounds of competition, we have 90 days after the covered document review date to provide such notice. For all rounds of competition, bidders that are notified of the missing covered document(s) have 10 business days after the date of notice to submit the missing covered document(s). If a supplier submits the missing covered document(s) within this time period, we may not reject the supplier's bid on the basis that any covered document is missing or has not been submitted on a timely basis.

Section 1847(a)(1)(F)(iii) of the Act places certain limitations on the covered document review process. First, the covered document review process applies only to the timely submission (prior to the covered document review date) of covered documents. Second, the process does not apply to any determination as to the accuracy or completeness of the covered documents submitted or whether such documents meet applicable financial requirements. Third, the process does not prevent us from rejecting a bid for reasons other than those not described in section 1847(a)(1)(F)(i)(II) of the Act. Fourth, the covered document review process shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

We have amended § 414.414 by adding paragraphs (d)(2)(i) through (iii) to set forth the required covered document review process. These paragraphs identify the timeframes established by the MIPPA for—

- Suppliers to submit covered documents in order to be eligible to receive notice of any missing covered documents;
- CMS to review the submitted covered documents and notify bidders of any missing covered documents; and
- Suppliers to submit the missing covered documents.

We also added a definition for ''covered document'' and ''covered document review date'' to § 414.402.

*Comment:* Several commenters suggested that the decision to change financial document requirements from 3 years to 1 year should have been subjected to notice and comment rulemaking. Commenters believed that this would ensure that quality suppliers are selected as contract suppliers, taking into consideration historical demonstrated financial stability. Some commenters also believed that it would be easier to falsify 1 year worth of financial documents as opposed to 3 years.

*Response:* As noted in the interim final rule, regulations at 42 CFR 414.414(d) state that required financial documents will be specified in the RFB. Based on our experience from the initial Round 1 competition, we determined that one year of financial documents provides sufficient information for determining whether suppliers meet the required financial standards. In the interest of lessoning the burden on suppliers and ensuring compliance with program requirements, we therefore decided to revise the financial documentation requirements from three years to one year. We also sought public comment on the RFB for the Round 1 rebid through the Paperwork Reduction Act (PRA) process, and the Office of Management and Budget (OMB) approved the RFB (OMB Control Number 0938–1016).

*Comment:* One commenter reflected that, in Round 1 of the competitive bidding program, many bidders lost because they did not have the required documents and CMS did not allow suppliers to resend the documents after the close of the bid window.

*Response:* The MIPPA-mandated covered document review process was incorporated into our regulations through the interim final rule addressed this issue. Many Round 1 rebid bidders took advantage of this process, and we believe it greatly helped these bidders ensure that they submitted all required financial documents.

*Comment:* One commenter suggested that the rule needs to address not only missing documents but missing and incorrect contents in documents.

*Response:* We appreciate this comment; however, the statute specifically indicates that the covered document review process does not apply to the accuracy or completeness of individual documents.

After consideration of the public comments received, we are finalizing this provision without modification.

c. Disclosure of Subcontractors and Their Accreditation Status Under the Competitive Bidding Program

Section 154(b)(2) of the MIPPA added a new paragraph (C) to section 1847 (b)(3) of the Act. This new paragraph requires contract suppliers to disclose information on: (1) Each subcontracting arrangement the supplier has in furnishing items and services under the contract; and (2) whether each such subcontractor meets the accreditation requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor. The contract supplier must make this disclosure not later than 10 days after the date a supplier enters into a contract with CMS. If the contract supplier subsequently enters into a subcontracting relationship, the supplier must disclose this information to CMS no later than 10 days after entering into the subcontracting relationship.

Section 154(b) of the MIPPA added section 1834(a)(20)(F)(i) to the Act, which mandates that the Secretary require suppliers furnishing items and services under a competitive bidding program on or after October 1, 2009, directly or as a subcontractor for another entity, to submit evidence of accreditation by a CMS-designated accreditation organization. Both contract suppliers and their subcontractors that furnish items and services under the competitive bidding program must do so in accordance with the applicable supplier standards found in Part 424, subpart D and other Federal regulations.

We have amended § 414.422, by revising paragraph (f) to set forth these requirements for disclosing subcontracting arrangements. We have also addressed subcontracting relationships and the method for disclosure of the subcontracting relationships in subregulatory guidance.

*Comment:* Some commenters stated that subcontracting relationships should not be allowed after contract suppliers have been selected. Commenters believed that companies that did not win a contract would contact the contract supplier and form an arrangement in which the contract supplier would bill for an item furnished by a non-contract supplier. Several commenters also mentioned that adding subcontractors after contract suppliers have been selected could mean that the contract suppliers are not

able to furnish items to beneficiaries in the CBA and that they need subcontractors to provide items for the contract supplier.

*Response:* The MIPPA specifically indicates that contract suppliers must disclose subcontracting relationships they establish after contract award; therefore, we do not have discretion to prohibit subcontracting after contract suppliers have been selected. Under the competitive bidding program, contract suppliers are permitted to subcontract under the same rules that apply to all DMEPOS suppliers. Thus, the extent to which contract suppliers subcontract is not a valid measure of contract suppliers' ability to furnish items.

We note that we have implemented a robust monitoring program to track and resolve any issues that might occur with program implementation and have not identified any concerns about contract suppliers' ability to furnish items. To date, the data show that Round 1 rebid implementation is going very smoothly with very few inquiries or complaints. For example, the competitive bidding call volume at the 1–800–MEDICARE call center for the first calendar quarter of 2011was less than 0.9 percent of 1–800–MEDICARE's total call volume. Most inquiries were about routine matters like selecting a contract supplier. Also, no changes in beneficiary health outcomes resulting from the competitive bidding program have been observed to date. The monitoring program includes:

- Local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen;
- A complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues;
- Contract supplier quarterly reports identifying the brands of products they furnish;
- Real-time claims analysis to identify utilization trends, monitor health outcomes and beneficiary access, address aberrancies in services, and target potential fraud and abuse;
- A CMS Competitive Acquisition Ombudsman who will respond to complaints and inquiries from beneficiaries and suppliers about the application of the program and will issue an annual Report to Congress;
- Secret shopping; and
- Beneficiary surveys.

*Comment:* Some commenters recommended that CMS obtain and verify disclosures of both accreditation and licensing status of contract suppliers and subcontractors prior to awarding contracts.

*Response:* Regulations at § 414.414 specify that suppliers must be licensed and accredited to be selected for contract award. We carefully check all bidders during bid evaluation and reject any bidders that are not fully licensed and accredited. As specified by MIPPA, contract suppliers must disclose any subcontractors within set time frames after contract award; disclosures must indicate if the subcontractors meet applicable accreditation requirements. We check all subcontractor disclosures and verify that all applicable accreditation requirements have been met. If we find that a contract supplier has subcontracted with an entity that does not meet applicable accreditation requirements, we will take appropriate action to ensure that the contract supplier stops using the subcontractor until the subcontractor becomes properly accredited. Although MIPPA does not require specific disclosure of subcontractors' licensure status, contract suppliers, like all suppliers, must comply with all State regulatory and licensure requirements (see § 424.57(c)(1)((ii)). This would include any State regulatory requirements regarding applicable subcontractor licensure.

*Comment:* Many commenters wanted CMS to clarify what is considered to be a subcontracting relationship between the contract supplier and a subcontractor with respect to accreditation. One commenter wanted CMS to provide the industry with a framework for entering into subcontracts.

*Response:* Contract suppliers may subcontract to the same extent as any other DMEPOS suppliers. The supplier standards at § 424.57 set forth requirements regarding subcontracting arrangements for purchase of inventory, delivery and instruction on the use of Medicare-covered items, and maintenance and repair of rented equipment. The quality standards are a helpful reference tool in distinguishing the role of a primary supplier versus the role of a subcontractor as described in the supplier standards. We note that guidance about subcontracting, including guidance about accreditation of subcontractors, may be found on the National Supplier Clearinghouse Web site, *http://www.palmettogba.com/nsc* and the Competitive Bidding Implementation Contractor Web site at *http://www.dmecompetitivebid.com.*

*Comment:* One commenter believed that the accreditation status of a subcontractor is irrelevant to the contract supplier's relationship with the subcontractor. One commenter did not believe that disclosing the subcontractor was a part of the MIPPA statute.

*Response:* MIPPA sections 154(b)(1) and (2) explicitly require subcontractors to meet applicable accreditation requirements and require contract suppliers to disclose their subcontracting arrangements within specific time frames. We do not have the authority to eliminate this requirement.

After consideration of the public comments received, we are finalizing this provision without modification.

d. Exemption From Competitive Bidding for Certain DMEPOS

Section 414.404(b) previously exempted from competitive bidding certain DME items when furnished by a physician or treating practitioner to his or her own patients as part of his or her professional services. This exception is limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are considered DME. Section 154(d) of MIPPA amended section 1847(a) of the Act to exclude from the competitive bidding program these same items when they are furnished by hospitals to the hospital's own patients during an admission or on the date of discharge. We interpreted this exclusion to include only DMEPOS paid for under Part B of the Medicare program because section 1847 does not apply to items that are paid for under Part A. As discussed in the April 10, 2007 final rule, in accordance with § 414.404(b)(3) payment for items furnished under the exceptions in § 414.404(b) will be made in accordance with § 414.408(a).

We have revised § 414.402 to include a definition for hospitals and have revised § 414.404(b)(1) to incorporate the mandated exemption from the competitive bidding program for hospitals that furnish certain types of competitively bid DME to their own patients during an admission or on the date of discharge. In addition, we amended subparagraph (b)(1)(iii) to address the billing requirements for hospitals under this exemption.

*Comment:* Some commenters expressed concern that the MIPPA hospital exemption was not more expansive. Several commenters suggested that CMS reconsider including hospital-based suppliers in the competitive bidding program. One commenter suggested that although there is a hospital exemption, hospitals may have trouble finding DME equipment, such as oxygen, for snowbird beneficiaries. A few commenters believed that quality of care and efficient operations of hospitals

would be impacted if they were allowed to furnish some items directly to their patients while having to arrange with contract suppliers for furnishing other items not covered by the exemption. One commenter suggested that a separate competitive bidding process should be established for hospital-based DME suppliers.

*Response:* Section 154(d) of MIPPA explicitly described the scope of the hospital exemption, so we do not believe we have discretion to provide a broader exemption. We do not believe that separate competitions for suppliers that only furnish items to patients in hospitals is necessary or would result in efficient implementation of the requirements of section 1847 of the Act.

After consideration of the public comments received, we are finalizing this provision without modification.

e. Exclusion of Group 3 Complex Rehabilitative Power Wheelchairs

Section 1847(a)(2) of the Act defines the items and services subject to competitive bidding. Section 1847(a)(2)(A) of the Act includes DME and supplies as items and services subject to competitive bidding. Section 154(a) of the MIPPA amended this definition to exclude group 3 complex rehabilitative power wheelchairs (and related accessories when furnished in connection with such wheelchairs) from competitive bidding. For Medicare coding, coverage, and payment purposes, power wheelchairs are classified under several groups based on performance and durability test results, patient weight capacity, and equipment handling capabilities. For a description of the components, performance requirements and coding guidelines for group 3 power wheelchairs, see *https://www.dmepdac.com/resources/articles/2006/08_14_06.pdf.* Group 2 complex rehabilitative power wheelchairs were included in Round 1 rebid of the competitive bidding program because they were not excluded by the MIPPA.

We amended § 414.402 to revise the definition of ''item'' to exclude group 3 complex rehabilitative wheelchairs from the competitive bidding program.

*Comment:* One commenter agreed that the exclusion was good policy because the equipment needs to be properly designed or it would result in additional costs for the government. Another commenter believed that the exclusion should not be implemented because having some power wheelchair equipment options subject to competitive bidding while others are not would promote Medicare fraud.

*Response:* The statute explicitly excludes Group 3 complex rehabilitative power wheelchairs from the competitive bidding program, and therefore, we do not believe we have any discretion to include these items in the program.

*Comment:* Some commenters suggest that Group 2 complex rehabilitative power wheelchairs be excluded from the competitive bidding program for several reasons. One commenter suggested that, if the Group 2 complex rehabilitative power wheelchairs are not excluded, suppliers should be able to bid above the fee schedule amount. Another commenter stated that the inclusion of Group 2 complex rehabilitative power wheelchairs in the Round 1 rebid is not envisioned by the statute; this commenter did not believe that this product category has the potential for significant savings.

*Response:* The MIPPA excludes Group 3 complex rehabilitative power wheelchairs from the competitive bidding program but also mandates rebidding of the ''same items and services'' as the previous Round 1. Therefore, we had no discretion to exclude 2 complex rehabilitative power wheelchairs from the Round 1 rebid because these wheelchairs were included in the Round 1 competition.

After consideration of the public comments received, we are finalizing this provision without modification.

2. Round 1 Changes to the Competitive Bidding Program

a. Rebidding of the ''Same Areas'' as the Previous Round 1, Unless Otherwise Specified

Section 1847(a)(1)(D)(i)(II) of the Act, as amended by section 154(a) of the MIPPA, required us to conduct the supplier competition for the Round 1 rebid in 2009. Pursuant to section 1847(a)(1)(D)(i)(II) of the Act, we conducted the competition for the Round 1 rebid in a manner ''so that it occurs in 2009 with respect to the same items and services and the same areas'' as the first Round 1 competition, except as provided by section 1847(a)(1)(D)(i)(III) and (IV) of the Act. Under section 1847(a)(1)(D)(i)(III), as amended by the MIPPA, we excluded Puerto Rico so that the Round 1 rebid of the competitive bidding program occurred in 9 of the largest MSAs. Therefore, the Round 1 rebid occurred in the following MSAs:

- Cincinnati—Middletown (Ohio, Kentucky and Indiana)
- Cleveland—Elyria—Mentor (Ohio)
- Charlotte—Gastonia—Concord (North Carolina and South Carolina)
- Dallas—Fort Worth—Arlington (Texas)
- Kansas City (Missouri and Kansas)
- Miami—Fort Lauderdale—Miami Beach (Florida)
- Orlando (Florida)
- Pittsburgh (Pennsylvania)
- Riverside—San Bernardino—Ontario (California)

Section 154(a) of MIPPA mandated that we conduct the Round 1 ''rebid'' in the ''same areas''—except for Puerto Rico—as the previous competition in 2007. As stated in the **Federal Register** (72 FR 18016), we identified CBAs in the 2007 Round 1 competition by counties and zip codes to clearly identify the boundaries of a CBA. Therefore, we believe it is reasonable to implement the ''same areas'' mandate by conducting the Round 1 rebid in those same zip codes. Certain zip codes changed since the first competition. We therefore reviewed zip code changes made since 2007 and incorporated applicable updates to the zip codes for the Round 1 rebid. For example, if a particular zip code had been split into two new zip codes, we included the new zip codes in the CBA. We did not add any new zip codes that expanded the geographic area of the CBAs.

Accordingly, we have amended § 414.410(a)(1) to reflect the areas for competition set forth in section 1847(a)(1) of the Act, as amended by the MIPPA.

*Comment:* Several commenters recommended various changes to the areas for the Round 1 rebid competition. For example, several commenters suggested that a few MSAs have rural areas and should be excluded from the program to prevent patient access and quality issues. Some also felt that small suppliers would not be able to provide items to the rural parts of the MSAs, especially with lower reimbursements. One commenter suggested that the Dallas MSA is too large and should be split into two separate CBAs. One commenter recommended that CBAs should be limited to large cities and not divided at a county level. One commenter suggested that CMS choose different MSAs for the Round 1 rebid competition because the original MSAs' suppliers have been affected financially from Round 1 and because the suppliers that bid in the first round know the single payment amounts that were selected for those areas and may cause bids to be skewed.

*Response:* MIPPA explicitly required the Round 1 rebid competition to occur in the same areas as in the initial Round 1 competition except for Puerto Rico, therefore we do not have any discretion to change the areas for the Round 1 rebid.

After consideration of the public comments received, we are finalizing this provision without modification.

b. Rebidding of the ''Same Items and Services'' as the Previous Round 1, Unless Otherwise Specified

Section 1847(a)(1)(D)(i)(II) of the Act, as amended by the MIPPA, required that we conduct the Round 1 rebid competitive bidding program with respect to the ''same items and services'' as were previously bid in Round 1 except as provided in section 1847(a)(1)(D)(i)(IV) of the Act, which excludes negative pressure wound therapy. The Round 1 rebid also excludes group 3 complex rehabilitative power wheelchairs as noted previously. Therefore, the Round 1 rebid included the following categories of items and services:

- Oxygen Supplies and Equipment.
- Standard Power Wheelchairs, Scooters, and Related Accessories.
- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2).
- Mail-Order Diabetic Supplies.
- Enteral Nutrients, Equipment and Supplies.
- Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Related Supplies and Accessories.
- Hospital Beds and Related Accessories.
- Walkers and Related Accessories.
- Support Surfaces (Group 2 mattresses and overlays) in Miami.

In the April 10, 2007 **Federal Register** (72 FR 18084), we define an item, in part, as a product included in a competitive bidding program that is identified by a HCPCS code.

Therefore, consistent with our understanding of the MIPPA and the mandate that bidding in the Round 1 rebid occur with respect to the ''same items and services'' as the previous round of competition, we conducted the competition for the Round 1 rebid for essentially the same codes for which we bid in 2007. We have made certain adjustments to reflect changes in the HCPCS codes consistent with 42 CFR 414.426. We excluded obsolete codes and codes which, in light of the MIPPA amendments, are no longer separately payable. For example, under the MIPPA, the transfer of title provision was deleted, thus oxygen accessories are no longer separately payable because the supplier maintains ownership of the equipment. The final list of HCPCS codes for the Round 1 rebid was published on the Competitive Bidding Implementation Contractor (CBIC) Web site at *http://www.dmecompetitivebidcom.* prior to opening of the bid window.

*Comment:* Some commenters suggested that several items should be excluded from competitive bidding for a variety of reasons.

*Response:* The MIPPA specifically required us to conduct the Round 1 rebid competitive bidding program for the ''same items and services'' as were previously bid in Round 1 except negative pressure wound therapy and group 3 complex rehabilitative power wheelchairs, and therefore, we had no discretion to exclude these items from the Round 1 rebid.

*Comment:* One commenter agreed with the statutory exclusion of negative pressure wound therapy (NPWT) for the Round 1 rebid and suggested that it be excluded entirely from competitive bidding.

*Response:* Although MIPPA excluded NPWT from the Round 1 rebid, it did not provide a permanent exclusion from the competitive bidding program. The statute mandates competitive bidding for most items of DME, including NPWT equipment and supplies. CMS has decided to utilize the flexibility provided by the statute to phase in items under the program beginning with high cost or high volume items. The average monthly rental fee schedule amount for the NPWT pump is currently $1,558, meaning the beneficiary pays at least $312 per month on average for rental of this device. By comparison, the average monthly fee and corresponding coinsurance amount for a respiratory suction pump is $46 (monthly fee) and $9 (monthly coinsurance). A study conducted in 2009 by the Office of Inspector General for the Department of Health and Human Services found that suppliers purchase these pumps for significantly less, $3,604 on average, than Medicare pays over 13 months, currently $16,359. The savings potential for the Medicare program and beneficiary for this item is therefore very significant. Medicare allowed charges for NPWT equipment and supplies were approximately $178 million in 2010, making this a high volume and high cost item as well.

We note that section 154 (c) (3) of MIPPA required the Secretary of the Department of Health and Human Services (DHHS) to perform an evaluation of the Healthcare Common Procedure Coding System (HCPCS) coding decisions for NPWT devices. CMS requested this report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). AHRQ determined that there are no significant therapeutic distinctions among NPWT devices. Because there are no significant differences among NPWT products, the current HCPCS codes are adequate and do not need to be updated or changed. The study results are available on the AHRQ Web site at: *http://www.ahrq.gov/clinic/ta/negpresswtd/npwtd01.htm*.

After consideration of the public comments received, we are finalizing this provision without modification.

*D. Other Public Comments Received on the January 16, 2009 Interim Final Rule*

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. This process may be waived, however, if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest. We found good cause to waive notice and comment rulemaking because we simply conformed the competitive bidding regulations to specific, detailed, and proscriptive statutory provisions.

The comments we received on the waiver of proposed rulemaking and our responses are set forth below.

*Comment:* Several commenters believed that CMS should have engaged in notice and comment rulemaking to implement MIPPA provisions rather than issuing an interim final rule with comment period for several reasons. One reason was so that stakeholders would have sufficient time and opportunity to give input on the program. The second reason was because commenters wanted to ensure that comments received during the comment period would be taken into account before any final rule was published. The third reason commenters wanted CMS to conduct a notice and comment rulemaking was because commenters felt that important issues were left unaddressed in the interim final rule such as how the program would be impacted by the changes that were made by MIPPA, lessons learned from Round 1, and supplier and beneficiary concerns and suggestions from Round 1. Commenters felt that CMS should address major issues in notice and comment rulemaking instead of using of subregulatory guidance and Web site postings.

*Response:* As we explained in the interim final rule, under the waiver of proposed rulemaking, we ordinarily publish a notice of proposed rulemaking to provide for public comment before provisions of a rule take effect, but the

process may be waived if the agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to public interest. Because CMS issued the rule to conform to the specific statutory requirements contained in section 154 of the MIPPA it was impractical, unnecessary, and contrary to public interest to use notice and comment rulemaking to incorporate these provisions into regulations. As indicated earlier in this preamble, we also made process improvements to ensure compliance with the statute that did not require notice and comment rulemaking before we conducted the Round 1 rebid. Finally, we agree that substantive issues should be addressed through notice and comment rulemaking consistent with the Administrative Procedure Act and note that we used notice and comment rulemaking to implement non-self-implementing provisions of MIPPA (see 75 FR 73170 (November 29, 2010).

*Comment:* A few commenters disagreed with the statement in the interim final rule that MIPPA ''did not alter fundamental requirements * * * used by us in * * * selecting suppliers under the program''. Some of the commenters believed that the interim final rule is not self-implementing and was not clear or understandable.

*Response:* We continue to believe as discussed in the interim final rule that the provisions of MIPPA included in the interim final rule were self-implementing. The language in these provisions was highly detailed and proscriptive and did not provide options for discretionary revisions.

## V. Collection of Information Requirements

### *A. Legislative Requirement for Solicitation of Comments*

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

Because we did not receive any comments for the ESRD PPS, we are finalizing the collection of information section as proposed.

### *B. Requirements in Regulation Text*

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

As discussed in section I.B.3 of this final rule, to receive the low-volume adjustment, an ESRD facility would need to provide an attestation to their Fiscal Intermediary or Medicare Administrative Contractor (FI/MAC) that it has met the criteria to qualify as a low-volume facility no later than November 1st of each year preceding the applicable low-volume adjustment payment year (except for the 2012 low-volume payment year, which has an attestation submission deadline of January 3, 2012). The FI/MAC would verify the ESRD facility's attestation of their low-volume status for the 3-consecutive years immediately preceding the payment year, using the ESRD facility's most recent final-settled or as-filed 12-month cost reports.

The burden associated with the requirement is the time and effort necessary for an ESRD facility attesting as a low-volume facility to develop an attestation and submit it to their FI/MAC. In the proposed rule, we estimated that it would require an administrative staff member from each low-volume facility 10 minutes to obtain the total number of treatments in the cost reports necessary for eligibility determination, develop the attestation, and submit it to their FI/MAC. For this final rule, using 2010 claims our contractor, UM–KECC, identified 963 ESRD facilities as providing treatments below the low-volume threshold of 4,000 treatments in 2010. Of these 963 facilities, we estimated that 378 met the additional low-volume criteria as specified in § 413.232. Further, due to the historical trend of increase in the number of small dialysis facilities, we believe that several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to the CY 2012 payment year. To take these facilities into account, we have rounded the total number of estimated low-volume facilities to 400. Therefore, for CY 2012, we estimate that the total initial ESRD facility burden would be 67 hours. The estimated cost associated with compliance with this requirement is $2.61 per ESRD facility and a total of $1,044 for all 400 facilities. These costs are estimated using the 2010 estimate for the occupational code 43–0000 Office and Administrative Support Occupation mean hourly wage of $15.66 as stated by the U.S. Bureau of Labor Statistics.

### *C. Additional Information Collection Requirements*

This final rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this final rule also makes reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

#### 1. Display of Certificates for the PY 2013 and PY 2014 ESRD QIP

Section II.B of this rule discusses a disclosure requirement for both the PY 2013 and the PY 2014 ESRD QIP. As stated earlier in this final rule, section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities about their total performance scores under the ESRD QIP. This section also requires each provider and facility that receives a QIP certificate to display it prominently in patient areas.

To comply with this requirement, we proposed to issue a PY 2013 and PY 2014 ESRD QIP certificate to providers and facilities via a generally accessible electronic file format. We proposed that each provider and facility would be required to prominently display the applicable ESRD QIP certificate in patient areas. In addition, we proposed that each provider and facility would take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we proposed that each provider/facility would be required to have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency. These proposals represent no change from the policy finalized for the PY 2012 ESRD QIP, and we are finalizing them in this final rule.

The burden associated with the aforementioned requirements is the time and effort necessary for providers and facilities to print the applicable ESRD QIP certificate, display the certificate prominently in patient areas, ensure the safety of the certificate, and respond to patient inquiries in reference to the certificates. We estimate that

approximately 5,503 providers and facilities will receive an ESRD QIP certificate in PY 2013 and PY 2014 and will be required to display it. We also estimate that it will take each provider/facility 10 minutes per year to print, prominently display, and secure the ESRD QIP certificate, for a total estimated annual burden of 917 hours [(10/60) hours × 5503 facilities] at a cost of $31, 755 [917 hours × $34.63 per hour]. We estimate that approximately one-third of ESRD patients (estimated to be 119,686 out of 395,058) will ask a question about the ESRD QIP certificate. We further estimate that it will take each provider/facility approximately 5 minutes to answer each patient question about the applicable ESRD QIP certificate, or 1.8 hours per provider or facility each year. The total estimated annual burden associated with this requirement is 9,905 hours [1.8 hours × 5503 providers]. The total estimated annual burden for both displaying the ESRD QIP certificates and answering patient questions about the certificates is 10,822 hours [10,822 hours + 9,905 hours] (for each of PY 2013 and PY 2014). While the total estimated annual burden associated with both of these requirements as discussed is 10,822 hours, we do not believe that there will be a significant cost associated with these requirements because we are not proposing to require providers/facilities to complete new forms. As discussed in section A.1.3 of this final rule, we estimate that the total cost for all ESRD providers/facilities to comply with the collection of information requirements associated with the certificate each year would be less than $400,000.

We did not receive any public comments regarding our analysis of the economic impact of the collection of information requirement for this proposal.

2. NHSN Reporting Requirement for the PY 2014 ESRD QIP

As stated above in section II.B.2.b.vi of this final rule, we are finalizing a proposal to include reporting dialysis events to the National Healthcare Safety Network (NHSN) as a reporting measure for the PY 2014 ESRD QIP. Specifically, we are requiring providers/facilities to: (1) Enroll in the NHSN and complete required training as verified by a digital certificate obtained from CDC; and (2) submit at least 3-consecutive months of dialysis event data to the NHSN.

The burden associated with these requirements is the time and effort necessary for providers and facilities to enroll in the NHSN and conduct the required training and submit 3 months of data. We estimated in the proposed rule that approximately 5,503 providers and facilities will enroll in the NHSN and submit the necessary data. We also estimated that it would take each provider or facility 48 hours per year to enroll in the NHSN and complete the required training, for a total estimated annual burden of 264,144 hours [5,503 providers × 48 hours]. Upon further consultation with the CDC, we have now revised this estimate. We now believe that it will take each provider/facility approximately 8 hours to enroll in the NHSN and complete the required training, for a total estimated burden of 44,024 hours (8 hours × 5,503 facilities). Based on the Bureau of Labor Statistics we estimate the average salary to be $34.63 per hour. Thus, average cost for each provider/facility will be $277.04 (8 hours × $34.63 per hour). Across all 5,503 providers/facilities, this will equal approximately $1.5 million ($277.04 × 5,503 facilities). However, we further estimate that the number of dialysis events in a 3-month period will be 125,680 for the 2014 ESRD population. We estimate it will require 2 hours of staff time per month to collect and submit data on these events and the estimated burden for submitting 3 months of data will be 33,018 hours (6 hours times 5,503 facilities). If the dialysis events are distributed evenly across all 5,503 providers/facilities, that will result in an additional 6-hour burden ($218.58 (6 hours times $36.43)) for each provider/facility. Based upon our updated analysis, the total estimated annual burden for enrolling in the NHSN, conducting the required training, and submitting 3-consecutive months of data is 77,042 hours (44,024 + 33,018). We estimate that the total cost for all ESRD providers/facilities to comply with the collection of information requirements associated with NHSN reporting requirement each year will be less than $2.8 million (77,042 × $36.43), with the total average cost per provider/facility approximately $508.80 ($2.8 million/5,503 facilities).

We did not receive any public comments regarding our proposed analysis of the economic impact of the collection of information requirements related to the adoption of an NHSN reporting measure for the PY 2014 ESRD QIP.

3. Patient Experience Survey Usage Requirement for the PY 2014 ESRD QIP

As stated above in section B.A.2. of this final rule, we are finalizing our proposal to include a measure that assesses provider/facility usage of the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey as a reporting measure for the PY 2014 ESRD QIP. The burden associated with this requirement is the time and effort necessary for providers and facilities to administer the ICH CAHPS survey and submit an attestation to CMS that they successfully administered the survey.

We estimate that approximately 5,503 providers and facilities will administer the ICH CAHPS survey and submit an attestation to that affect. We estimate that it will take each provider or facility 16 hours per year to be trained on the survey features. We further estimate that it will take each provider/facility approximately 5 minutes to submit the attestation each year. The estimated total annual burden on providers/facilities is estimated to be 88,507 hours [(5,503 providers × 16 hours) + (5,503 providers × (5/60) hours)] which is valued at $3 million [88,507 hours × $34.63 per hour], or $556.97 per provider/facility [$3 million/5,503 providers]. We estimate that administering the survey would take a third-party entity 45 minutes per patient (to account for variability in education levels) and 200 surveys per year which equals 150 hours [(45/60) hours × 200 surveys] or $2,707.32 [150 hours × $17.58 per hour] per facility-year to administer the ICH CAHPS survey for an estimated annual burden of 825,450 hours (150 hours × 5,503 providers) which is valued at $14.5 million ($2,637.00 × 5,503 providers). As discussed in section A. of this final rule, we estimate that the total cost for ESRD providers/facilities to comply with the collection of information requirements associated with administering the ICH CAHPS survey each year will be approximately $3,193.97 [$556.97 + $2,637.00] or $17.5 million [$3 million + $14.5 million] across all ESRD providers/facilities.

We did not receive any public comments regarding the proposed collection of information requirements associated with our adoption of this measure for the PY 2014 ESRD QIP.

4. Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP

As stated above in section B.A.2 of this final rule, we are finalizing our proposal to include a Mineral Metabolism reporting measure as part of the PY 2014 ESRD QIP. The burden associated with this requirement is the time and effort necessary for providers and facilities to review their records and submit an attestation to CMS that they had monitored on a monthly basis the serum calcium and serum phosphorus levels of all patients each month.

We estimate that approximately 5,503 providers and facilities will submit the

attestation. We estimate that it will take each provider or facility approximately 18 hours to review its records and submit the attestation each year. The estimated total annual burden on providers/facilities is estimated to be 99,054 hours [18 hours × 5,503 providers] which is valued at $3.43 million [99,054 hours × $34.63 per hour], or $623 per provider/facility [$3.43 million/5,503 providers].

We did not receive any public comments regarding our proposed collection of information requirements associated with the adoption of a mineral metabolism reporting measure for the PY 2014 ESRD QIP.

5. Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Collection of Information Requirements

We solicited public comment on the following information collection requirements (ICRs):

i. ICRs Regarding Round 1 Rebid

We previously estimated that the burden associated with Round 1 would be 1,086,164 hours (68 hours × 15,973 bids). Our estimate was that on average it would take a supplier 68 hours to complete and submit a bid and that we would receive 15,973 bids. Although we expect the amount of hours to generally remain the same (68 hours) for the Round 1 rebid, based on our Round 1 experience we anticipated fewer bids. For the 2007 Round 1 of the competitive bidding program, we received approximately 6,500 bids. Therefore, the total estimated burden associated with the Round 1 rebid was approximately 442,000 hours (68 hours × 6,500).

ii. ICRs Regarding Disclosure of Subcontracting Arrangements

Section 414.422(f) states that suppliers entering into a contract with CMS must disclose information on each subcontracting arrangement that the supplier has to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in section 424.57, if applicable. Section 414.422(f) also requires that the required disclosure be made no later than 10 days after the date a supplier enters into a contract with CMS or 10 days after a supplier enters into a subcontracting arrangement after entering into a contract with CMS.

The burden associated with the requirements in § 414.422(f) is the time and effort necessary to disclose the information to CMS. In the 2007 Round 1 competition, there were 329 winning suppliers. Therefore, we approximated fewer than 400 winning suppliers for the Round 1 rebid. Also, we estimated it will take each of the winning suppliers that use subcontractors on average approximately 1.5 hours to submit information on each subcontracting arrangement to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in § 424.57, if applicable. Those that do not use subcontractors will not have a reporting burden. The total estimated burden associated with these requirements is approximately 600 hours (1.5 hours × 400 winning suppliers).

We did not receive any comments on the information collection requirements of the interim final rule. We sought comments on these information collection requirements again in the May 19, 2009 **Federal Register** (74 FR 23415), and the Office of Management and Budget (OMB) approved the collection (OMB Control Number 0938–1016).

## VII. Economic Analyses

*A. Regulatory Impact Analysis*

1. Introduction

We examined the impacts of this final rule as required by Executive Orders 12866 (September 30, 1993, Regulatory Planning and Review) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule. We solicited comments on the regulatory impact analysis provided.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis services in CY 2012, implementing the second year of the transition, and makes several policy and technical changes to the CY 2011 ESRD PPS final rule. This includes updates to the ESRD PPS and composite rate base rates, wage index values, wage index budget-neutrality adjustment factors, outlier payment policy, low-volume adjustment and transition budget-neutrality adjustment. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2012.

In addition, this rule will implement a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2013. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established total performance score. Our vision is to continue to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established in providing incentives to providers/facilities to improve the quality of care they provide to Medicare beneficiaries.

Also, this final rule will revise the ambulance fee schedule regulations to conform to the requirements of section 106 of the Medicare and Medicaid Extenders Act of 2010 Public Law 111–309 (MMEA). This final rule also revises the definition of durable medical equipment. The revision adds a 3-year MLR that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. The proposed rule would not impact items classified and covered as DME before the new rule takes effect or supplies and accessories used with covered DME. Finally, this final rule incorporates into regulations certain self-implementing provisions of section 154 of MIPPA that affect the DMEPOS Competitive Bidding Program.

3. Overall Impact

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $240 million in payments to ESRD facilities in CY 2012. Furthermore, as a result of implementing the ESRD QIP for Medicare outpatient ESRD dialysis providers and facilities, we estimate aggregate payment reductions in payment years 2013 and 2014 would be $23.7 million and $22.1 million,

respectively. However, given the lack of data for several measures, the actual impact of the PY 2014 ESRD QIP may vary significantly from the values provided herein. Lastly, the aggregate costs associated with the QIP collection of information requirements described in section III.1 of this final rule (Display of Certificates for the 2013 ESRD QIP) are estimated to be $400,000 for all ESRD providers/facilities in PY 2013. The additional estimated aggregate costs associated with the collection of information requirements described in sections III.1. (Display of Certificates for the PY 2013 and PY 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the PY 2014 ESRD QIP), III.3 (Patient Experience Survey Usage Requirement for the PY 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the PY 2014 ESRD QIP) in this final rule are expected to be approximately less than $24 million for all participating ESRD facilities.

The impact of section 106 of the MMEA, requiring the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2011, is estimated to be $20 million (for CY 2011).

The fiscal impact of the proposed 3-year MLR cannot be estimated because it is difficult to predict how many different types of devices will be introduced in the market in the future that may or may not qualify as DME items as a result of the new rule. We would expect that this final rule would have a small, if any, savings impact on the program.

Finally, we believe that the changes to the Medicare DMEPOS Competitive Bidding Program have a minimal fiscal impact because they are very limited and do not change fundamental program requirements.

*B. Detailed Economic Analysis*

1. CY 2012 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

As explained in the proposed rule (76 FR 40542), to understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments (that is, payments made under the 100 percent ESRD PPS and those under the blended payment during the transition) in CY 2012 to estimated payments (that is, payments made under the 100 percent ESRD PPS and those under the ESRD PPS blended payment during the transition) in CY 2011. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of payments in CY 2011 and CY 2012 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current payments and new payments.

For this final rule, we used the June 2011 update of CY 2010 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2010 claims to 2011 and 2012 using various updates. The updates to the ESRD PPS base rate and the base composite rate portion of the blended rate during the transition are described in section I.B of this final rule. In addition, in order to prepare an impact analysis, since some providers opted to be paid the blended payment amount during the transition, we made various assumptions about price growth for the formerly separately billable drugs and laboratory tests with regard to the composite portion of the ESRD PPS blended payment during the transition. These rates of price growth are briefly outlined below, and are described in more detail in the CY 2011 ESRD PPS final rule (75 FR 49078 through 49080).

We used the CY 2010 amounts for the CY 2011 and CY 2012 amounts for Supplies and Other Services, since this category primarily includes the $0.50 administration fee for separately billable part B drugs and this fee is not increased; thus we used no price update. Because some ESRD facilities will receive blended payments during the transition and receive payment for ESRD drugs and biologicals based on their average sales price plus 6 percent (ASP+6), we estimated price growth for these drugs and biologicals based on ASP+6 percent. We updated the last available quarter of actual ASP data for the top twelve drugs (the fourth quarter of 2011) thru 2012 by using the quarterly growth in the Producer Price Index (PPI) for Drugs, consistent with the method for addressing price growth in the ESRDB market basket. This resulted in 1.7 percent, 1.4 percent, 1.1 percent, and 0.8 percent increase, respectively, for the first thru the fourth quarter of 2012. Since the top twelve drugs account for over 99 percent of total former separately billable Part B drug payments, we used a weighted average growth of the top twelve drugs, for the remainder. Table 7 below shows the updates used for the drugs.

We updated payments for laboratory tests paid under the laboratory fee schedule to 2011 and 2012 using the statutory required update of the CPI–U increase with any legislative adjustments. For this final rule, the growth from 2010 to 2011 is −1.8 percent and the growth from 2010 to 2012 is −1.2 percent.

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**Table 7: Price Increases from 2010 to 2011 and 2010 to 2012 of Former Separately Billable Part B Drugs.**

| Drugs and Biologicals | Price Update 2010 to 2011 | Price Update 2010 to 2012 |
|---|---|---|
| EPO | 2.1% | 6.9% |
| Paricalcitol | -18.4% | -26.4% |
| Sodium_ferric_glut | -2.1% | 20.8% |
| Iron_sucrose | -3.0% | -8.7% |
| Levocarnitine | 19.3% | 47.7% |
| Doxercalciferol | 2.8% | -6.3% |
| Calcitriol | -15.1% | -45.0% |
| Vancomycin | -8.7% | -10.6% |
| Alteplase | 8.5% | 17.4% |
| Aranesp | 6.3% | 14.4% |
| Daptomycin | 8.2% | 15.3% |
| Ferumoxytol | -13.3% | -14.6% |
| Other Injectibles | -0.5% | 1.9% |

Table 8 shows the impact of the estimated CY 2012 ESRD payments compared to estimated payments to ESRD facilities in CY 2011.

**Table 8: Impact of Changes in Payments to ESRD Facilities for CY 2012 ESRD FR**

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

| | A | B | C | D | E |
|---|---|---|---|---|---|
| Facility Type | Number of Facilities | Number of Treatments (in millions) | Effect of 2012 Changes in Outlier Policy | Effect of 2012 Changes in Wage Indexes | Effect of Total 2012 changes[3] |
| All Facilities | 5,503 | 40.0 | 0.3% | 0.0% | 2.5% |
| Type | | | | | |
| Freestanding | 4,943 | 36.3 | 0.4% | 0.0% | 2.5% |
| Hospital based | 560 | 3.6 | -0.1% | -0.3% | 2.3% |
| Ownership Type | | | | | |
| Large dialysis organization | 3,544 | 25.9 | 0.5% | 0.1% | 2.6% |
| Regional chain | 857 | 6.6 | 0.1% | -0.1% | 2.2% |
| Independent | 663 | 4.7 | 0.1% | 0.0% | 2.3% |
| Hospital based[1] | 437 | 2.8 | -0.1% | -0.3% | 2.3% |
| Unknown | 2 | 0.0 | 0.5% | 0.9% | 3.6% |
| Geographic Location | | | | | |
| Urban | 4,280 | 33.3 | 0.3% | 0.0% | 2.5% |
| Rural | 1,223 | 6.7 | 0.4% | -0.1% | 2.5% |
| Census Region | | | | | |
| East North Central | 908 | 6.1 | 0.3% | -0.2% | 2.3% |
| East South Central | 445 | 3.0 | 0.5% | -0.2% | 2.5% |
| Middle Atlantic | 610 | 4.9 | 0.2% | 0.1% | 2.5% |
| Mountain | 328 | 1.9 | 0.2% | 0.1% | 2.5% |
| New England | 167 | 1.3 | 0.3% | 0.2% | 2.6% |
| Pacific | 641 | 5.3 | 0.2% | 0.3% | 2.6% |
| South Atlantic | 1,209 | 9.1 | 0.5% | -0.2% | 2.3% |
| West North Central | 405 | 2.2 | 0.2% | 0.2% | 2.6% |
| West South Central | 751 | 5.8 | 0.3% | 0.3% | 2.9% |
| Puerto Rico and Virgin Islands | 39 | 0.4 | 0.3% | -2.4% | 0.3% |
| Facility Size | | | | | |
| Less than 4,000 treatments[2] | 963 | 2.1 | 0.2% | 0.0% | 2.5% |
| 4,000 to 9,999 treatments | 2,174 | 11.2 | 0.4% | -0.1% | 2.4% |
| 10,000 or more treatments | 2,318 | 26.6 | 0.3% | 0.0% | 2.5% |
| Unknown | 48 | 0.1 | 0.1% | -0.4% | 2.2% |
| Percentage of Pediatric Patients | | | | | |
| Less than 2% | 5,395 | 39.5 | 0.3% | 0.0% | 2.5% |
| Between 2% and19% | 46 | 0.4 | 0.1% | -0.1% | 2.4% |
| Between 20% and 49% | 8 | 0.0 | 0.0% | 0.0% | 2.4% |
| More than 50% | 54 | 0.0 | 0.0% | -0.1% | 1.7% |

1 Includes hospital based facilities not reported to have large dialysis organization or regional chain ownership.

2 Of the 963 Facilities with less than 4,000 treatments, only 378 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, is not applied to pediatric patients. The impact to these Low volume Facilities is a 2.8% increase in payments.

3 Includes the effect of the ESRDB Market Basket minus productivity adjustment, which results in an increase of 2.1% to the ESRD PPS base and the Composite Rate portion of the blended payment for those facilities that opted to be paid under the transition. Also includes the effect of the change in the drug add-on percentage from14.7% to 14.3% to the composite rate portion of the blended payment for those facilities that opted to be paid under the transition. Includes the effect of the blended payment percentage changing from 75/25 to 50/50 from CY 2011 to CY 2012 for those facilities that choose to be paid under the transition.

Note: Totals do not necessarily equal the sum of rounded parts

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to outlier payment policy and the final changes for the BSA national average described in section I.C.10 and section .I.C.9, respectively, of this final rule, are shown in column C. For CY 2012, the impact on all facilities as a result of the changes to outlier payment policy and the BSA national average would be a 0.3 percent increase in estimated payments. The estimated impact of the changes to outlier payment policy and the BSA national average ranges from −0.1 percent decrease to a 0.5 percent increase. Most ESRD facilities are anticipated to experience a positive effect in their estimated CY 2012 payments as a result of the outlier policy and BSA national average changes being finalized.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2012 wage index values for the composite rate portion of the blended payment during the transition and the ESRD PPS payments. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 2.4 percent decrease in estimated payments in CY 2012. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the reduction in the wage index floor (which only affects facilities in Puerto Rico in CY 2012). Renal dialysis facilities outside of Puerto Rico would experience changes in estimated payments ranging from a 0.4 percent decrease to a 0.9 percent increase due to the update of the wage index.

Column E reflects the overall impact (that is the effects of the outlier policy and BSA national average changes, the wage index, the effect of the ESRDB market basket increase minus productivity adjustment, and the effect of the change in the blended payment percentage from 75 percent of payments based on the composite rate system and 25 percent based on the ESRD PPS in 2011, to 50/50, respectively, for 2012, for those facilities that opted to be paid under the transition). We expect that overall, ESRD facilities will experience a 2.5 percent increase in estimated payments in 2012. ESRD facilities in Puerto Rico are expected to receive a 0.3 percent increase in their estimated payments in CY 2012. This negligible increase is primarily due to the negative impact of the wage index. The remainder of ESRD facilities are expected to be positively impacted ranging from an increase of 1.7 percent to 3.6 percent in their 2012 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, ESRD facilities are paid directly for the renal dialysis bundle and other provider types such as laboratories, DME suppliers, and pharmacies, may no longer bill Medicare directly for renal dialysis services. Rather, effective January, 1, 2011, such other providers can only furnish renal dialysis services under arrangements with ESRD facilities and must seek payment from ESRD facilities rather than Medicare. Under the ESRD PPS, Medicare pays ESRD facilities one payment for renal dialysis services, which may have been separately paid to suppliers by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2012, the second year of the ESRD PPS, we estimate that the ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in 2012 will be approximately $8.2 billion. This estimate is based on various price update factors discussed in section VII.B in this final rule. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 4.3 percent in CY 2012.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount or blended payment amount for patients treated in facilities going through the ESRD PPS transition. As a result of the projected 2.5 percent overall increase in the ESRD PPS payment amounts in CY 2012, we estimate that there will be an increase in beneficiary co-insurance payments of 2.5 percent in CY 2012, which translates to approximately $50 million.

e. Alternatives Considered

As we explained in the proposed rule (76 FR 40544), we considered eliminating all laboratory tests from the outlier policy, but instead we proposed to eliminate only the Automated Multi-Channel Chemistry (AMCC) panel tests. We indicated that we believed this approach would continue to recognize expensive laboratory tests in the outlier policy while reducing the burden associated with the 50 percent rule. We also considered alternatives for applying the wage index budget-neutrality adjustment factor under the ESRD PPS for purposes of the full ESRD PPS payments and ESRD PPS portion of the blended payment during the transition, such as applying the wage index budget-neutrality adjustment factor to the ESRD PPS wage index values. We chose to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base

rate and ESRD PPS portions of the transition blended payment to be consistent with how these adjustments are applied in other Medicare payment systems. Finally, we considered retaining the current BSA adjustment under the composite rate potion of the blended payment amount.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2013 and PY 2014 ESRD QIP

This final rule is intended to mitigate possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS by implementing an ESRD QIP that would reduce ESRD payments by up to 2 percent to dialysis providers/facilities that fail to meet or exceed a Total Performance Score with respect to performance standards established by the Secretary with respect to certain specified measures.

The methodology that we are finalizing to determine a provider/facility's Total Performance Score is described in section IV.A.3 (Methodology for Calculating the Total Performance Score for the PY 2013 ESRD QIP) and section IV.A.2.e (Methodology for Calculating the Total Performance Score for the PY 2014 ESRD QIP) of this final rule. Any reductions in ESRD payment would begin on January 1, 2013 for services furnished on or after January 1, 2013 for the PY 2013 ESRD QIP and any reductions in ESRD payment would begin on January 1, 2014 for services furnished on or after January 1, 2014 for the PY 2014 ESRD QIP.

As a result, based on the ESRD QIP outlined in this final rule, we estimate that approximately 19 percent or 1,014 of total ESRD dialysis providers/facilities would likely receive a payment reduction for PY 2013. In PY 2014, we estimate that approximately 30.3 percent or 1,665 of total ESRD facilities would likely receive some type of payment reduction. We note that these estimates differ significantly from the estimates that were included in the proposed rule. We believe that the difference in our PY 2013 estimates is attributable to two changes. First, we determined that our previous estimates for PY 2013 had mistakenly included the Hemoglobin Less Than 10 g/dL measure, which resulted in lower provider/facility scores and greater payment reductions. Second, we are now able to update our PY 2013 estimates using newly available data, such that we are now using 2009 data as the baseline period and 2010 data as the performance period. We believe that the difference in our PY 2014 estimates is attributable to four changes that were made to how we calculated the estimate. First, as previously mentioned, we are now able to update our estimates using newly available data, such that we are now using 2009 data as the baseline period and 2010 data as the performance period. Second, our estimates no longer include performance on the proposed SHR measures, because we are not finalizing its inclusion in the PY 2014 program. Third, our estimate now uses data from the Fistula First Breakthrough Initiative to approximate provider/facility performance on the Vascular Access Type (VAT) measure proposed for the 2014 QIP. The 2014 QIP will use data from Medicare claims based on HCPCS modifier V-codes that indicate fistula or catheter use. Because sufficient historical data are not yet available from Medicare claims for the fistula and catheter rates that will be used to calculate the VAT, historical data regarding fistula and catheter use were obtained from the Fistula First Breakthrough Initiative dataset for use in this impact analysis. For more information on the Fistula First Dataset, please see *http://www.fistulafirst.org.*. Lastly, our estimates incorporate the changes to the proposed payment reduction methodology that have been finalized in this final rule.

The ESRD QIP impact assessment assumes an initial count of 5,596 dialysis providers/facilities with paid Medicare dialysis claims in 2010. The PPS analysis, presented earlier, excludes 93 facilities for PPS-specific reasons thereby narrowing the final analytic sample to 5,503. The most common reason for exclusion was that facilities closed during 2010. As a result, Table 9 shows the overall estimated distribution of payment reductions resulting from the PY 2013 ESRD QIP. Table 10 shows the overall estimated distribution of payment reductions resulting from the PY 2014 ESRD QIP.

**Table 9. Estimated Distribution of PY 2013 ESRD QIP Payment Reductions.**

| Payment Reduction | Number of Facilities | Percent of Facilities |
|---|---|---|
| 0.0% | 4,489 | 81.6% |
| 1.0% | 260 | 4.7% |
| 1.5% | 344 | 6.3% |
| 2.0% | 410 | 7.5% |

**Table 10. Estimated Distribution of PY 2014 ESRD QIP Payment Reductions.**[25]

| Payment Reduction | Number of Facilities | Percent of Facilities |
|---|---|---|
| 0.0% | 3,838 | 69.7% |
| 0.5% | 723 | 13.1% |
| 1.0% | 521 | 9.5% |
| 1.5% | 242 | 4.4% |
| 2.0% | 179 | 3.3% |

To estimate the total payment reductions in PY 2013 and PY 2014 for each provider/facility resulting from this final rule, we multiplied the total Medicare payments to the facility in 2010 by the provider's/facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each provider/facility: (Total ESRD payment in 2010 × estimated payment reduction percentage).

The PY 2014 payment reduction levels will include the 0.5 percent payment reduction level as an additional level within the payment reduction scale. We are finalizing new measures, a new scoring methodology, and rigorous performance standards which are not familiar to the community. We believe that including this additional payment reduction level will allow time for providers/facilities to become familiar with this new structure and for CMS to acquire additional data on the impact of these changes. The inclusion of the 0.5 percent payment reduction level creates a more gradual payment reduction scale, and therefore benefits providers by lessening the reduction impacts that would have been received under the original proposed scale.

For PY 2013, totaling all of the payment reductions for each of the 1,014 providers/facilities expected to receive a reduction leads to a total payment reduction of approximately $23.7 million. Further, we estimate that the total costs associated with the collection of information requirements described in section III.1, of this final rule (Display of Certificates for the PY 2013 ESRD QIP) would be less than $400,000 for all ESRD providers/facilities in PY 2013.

For PY 2014, totaling all of the payment reductions for each of the 1,665 facilities expected to receive a reduction leads to a total payment reduction of approximately $22.1 million. Further, we estimate that the total costs associated with the collection of information requirements described in sections III.1. (Display of Certificates for the PY 2013 and PY 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the PY 2014 ESRD QIP), III.3 (Patient Experience Survey Usage Reporting Requirement for the PY 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the PY 2014 ESRD QIP) of this final rule would be less than $25 million for all ESRD providers/facilities.

As a result, we estimate that ESRD providers/facilities will experience an aggregate impact of $24.1 million for PY 2013 and $47.1 million for PY 2014.

Table 11 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2013. The table details the distribution of ESRD providers/facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities).

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[25] PY 2014 QIP Scores estimated using the Hemoglobin > 12 g/dl and Urea Reduction Ratio ≥ 65 percent measures, as well as data from the Fistula First initiative as a proxy for the VAT measure.

## Table 11. Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2013

| | Number of Facilities | Number of Medicare Treatments 2009 (in millions) | Number of Facilities with QIP Score | Number of Facilities Expected to Receive a Payment Reduction | Payment Reduction (percent change in total ESRD payments) |
|---|---|---|---|---|---|
| All Facilities | 5,503 | 40.0 | 4,962 | 1,014 | -0.29% |
| | | | | | |
| **Facility Type:** | | | | | |
| Freestanding | 4943 | 36.3 | 4,548 | 917 | -0.29% |
| Hospital-based | 560 | 3.6 | 414 | 97 | -0.33% |
| | | | | | |
| **Ownership Type:** | | | | | |
| Large Dialysis | 3,544 | 25.9 | 3,296 | 623 | -0.27% |
| Regional Chain | 857 | 6.6 | 785 | 171 | -0.32% |
| Independent | 663 | 4.7 | 568 | 147 | -0.35% |
| Hospital-based (non-chain) | 437 | 2.8 | 312 | 73 | -0.32% |
| Unknown | 2 | 0.0 | 1 | 0 | -0.00% |
| | | | | | |
| **Facility Size:** | | | | | |
| Large Entities | 4,401 | 32.5 | 4,081 | 794 | -0.28% |
| Small Entities[1] | 1,100 | 7.4 | 880 | 220 | -0.34% |
| Unknown | 2 | 0.0 | 1 | 0 | -0.00% |
| | | | | | |
| **Urban/Rural Status:** | | | | | |
| Urban | 4,280 | 33.3 | 3,842 | 750 | -0.27% |
| Rural | 1,223 | 6.7 | 1,120 | 264 | -0.35% |
| | | | | | |
| **Census Region:** | | | | | |
| Northeast | 776 | 6.2 | 702 | 132 | -0.26% |
| Midwest | 1,311 | 8.3 | 1,139 | 243 | -0.29% |
| South | 2,404 | 17.9 | 2,221 | 477 | -0.31% |
| West | 968 | 7.2 | 862 | 161 | -0.26% |
| US Territories[2] | 39 | 0.4 | 38 | 1 | -0.03% |
| Unknown | 5 | 0.0 | 0 | 0 | -0.00% |
| | | | | | |
| **Census Division:** | | | | | |
| East North Central | 908 | 6.1 | 787 | 159 | -0.27% |
| East South Central | 445 | 3.0 | 405 | 87 | -0.33% |
| Middle Atlantic | 610 | 4.9 | 549 | 105 | -0.27% |
| Mountain | 328 | 1.9 | 297 | 45 | -0.22% |
| New England | 167 | 1.3 | 153 | 27 | -0.23% |
| Pacific | 641 | 5.3 | 565 | 116 | -0.28% |
| South Atlantic | 1,209 | 9.1 | 1,129 | 251 | -0.32% |
| West North Central | 405 | 2.2 | 352 | 84 | -0.34% |
| West South Central | 751 | 5.8 | 687 | 139 | -0.28% |
| US Territories[2] | 39 | 0.4 | 38 | 1 | -0.03% |

| | Number of Facilities | Number of Medicare Treatments 2009 (in millions) | Number of Facilities with QIP Score | Number of Facilities Expected to Receive a Payment Reduction | Payment Reduction (percent change in total ESRD payments) |
|---|---|---|---|---|---|
| **Facility Size (# of total treatments):** | | | | | |
| Less than 4,000 treatments | 963 | 2.1 | 561 | 109 | -0.20% |
| 4,000-9,999 treatments | 2,174 | 11.2 | 2,092 | 427 | -0.31% |
| Over 10,000 treatments | 2,318 | 26.6 | 2,291 | 475 | -0.31% |
| Unknown | 48 | 0.1 | 18 | 3 | -0.16% |
| [1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status. | | | | | |
| [2]Includes Puerto Rico and Virgin Islands. | | | | | |

We note that for the PY 2014 ESRD QIP we lack performance data on the Vascular Access Type measure to conduct an analysis at this time. We conducted a simulation using the latest available performance data on the Hemoglobin Greater Than 12 g/dL measure, and the Dialysis Adequacy (URR) measure and fistula and catheter rates based on Fistula First data to estimate the impact of this final rule as accurately as possible. These simulated analyses were performed using 2010 claims data as the performance year and 2009 claims data as the baseline year for the Hemoglobin Greater Than 12g/dL measure and the Dialysis Adequacy Measure (URR).

Using these conditions, we calculated estimated national achievement threshold and benchmark values for the Hemoglobin Greater Than 12 g/dL, URR Hemodilaysis Adequacy, and VAT measures using all facilities present in the data set. Equal weighting was applied in calculating Total Performance Scores. Facilities were required to have data on at least one of the measures. Given the lack of data for the reporting measures, and the use of Fistula First data, the actual impact of the PY 2014 ESRD QIP may vary significantly from the values provided here.

Using the above assumptions, Table 12 below shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2014. The table details the distribution of ESRD providers/facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities).

**Table 12. Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2014**

| | Number of Facilities | Number of Medicare Treatments 2009 (in millions) | Number of Facilities with QIP Score | Number of Facilities Expected to Receive a Payment Reduction | Payment Reduction (percent change in total ESRD payments) |
|---|---|---|---|---|---|
| All Facilities | 5,503 | 40.0 | 5,343 | 1,665 | -0.29% |
| | | | | | |
| **Facility Type:** | | | | | |
| Freestanding | 4943 | 36.3 | 4,862 | 1,449 | -0.27% |
| Hospital-based | 560 | 3.6 | 481 | 216 | -0.45% |
| | | | | | |
| **Ownership Type:** | | | | | |
| Large Dialysis | 3,544 | 25.9 | 3,501 | 1,009 | -0.25% |
| Regional Chain | 857 | 6.6 | 836 | 264 | -0.31% |
| Independent | 663 | 4.7 | 639 | 219 | -0.34% |
| Hospital-based (non-chain) | 437 | 2.8 | 366 | 172 | -0.48% |
| Unknown | 2 | 0.0 | 1 | 1 | -0.50% |
| | | | | | |
| **Facility Size:** | | | | | |
| Large Entities | 4,401 | 32.5 | 4,337 | 1,273 | -0.26% |
| Small Entities[1] | 1,100 | 7.4 | 1,005 | 391 | -0.39% |
| Unknown | 2 | 0.0 | 1 | 1 | -0.50% |
| | | | | | |
| **Urban/Rural Status:** | | | | | |
| Urban | 4,280 | 33.3 | 4,143 | 1,292 | -0.29% |
| Rural | 1,223 | 6.7 | 1,200 | 373 | -0.28% |
| | | | | | |
| **Census Region:** | | | | | |
| Northeast | 776 | 6.2 | 753 | 219 | -0.28% |
| Midwest | 1,311 | 8.3 | 1,256 | 454 | -0.34% |
| South | 2,404 | 17.9 | 2,349 | 721 | -0.28% |
| West | 968 | 7.2 | 946 | 254 | -0.24% |
| US Territories[2] | 39 | 0.4 | 39 | 17 | -0.43% |
| Unknown | 5 | 0.0 | 0 | 0 | -0.00% |
| | | | | | |
| **Census Division:** | | | | | |
| East North Central | 908 | 6.1 | 865 | 310 | -0.34% |
| East South Central | 445 | 3.0 | 431 | 127 | -0.24% |
| Middle Atlantic | 610 | 4.9 | 591 | 175 | -0.30% |
| Mountain | 328 | 1.9 | 323 | 87 | -0.26% |
| New England | 167 | 1.3 | 162 | 44 | -0.23% |
| Pacific | 641 | 5.3 | 623 | 167 | -0.23% |
| South Atlantic | 1,209 | 9.1 | 1,175 | 361 | -0.27% |
| West North Central | 405 | 2.2 | 391 | 144 | -0.35% |
| West South Central | 751 | 5.8 | 743 | 233 | -0.31% |
| US Territories[2] | 39 | 0.4 | 39 | 17 | -0.43% |

| | Number of Facilities | Number of Medicare Treatments 2009 (in millions) | Number of Facilities with QIP Score | Number of Facilities Expected to Receive a Payment Reduction | Payment Reduction (percent change in total ESRD payments) |
|---|---|---|---|---|---|
| **Facility Size (# of total treatments):** | | | | | |
| Less than 4,000 treatments | 963 | 2.1 | 837 | 301 | -0.35% |
| 4,000-9,999 treatments | 2,174 | 11.2 | 2,164 | 635 | -0.28% |
| Over 10,000 treatments | 2,318 | 26.6 | 2,318 | 721 | -0.27% |
| Unknown | 48 | 0.1 | 24 | 8 | -0.22% |
| [1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status. | | | | | |
| [2]Includes Puerto Rico and Virgin Islands. | | | | | |
| [3]PY 2014 QIP Scores estimated using the PY 2013 QIP measures Hemoglobin > 12 g/dl and Urea Reduction Ratio ≥ 65%; fistula and catheter rates based on Fistula First Breakthrough Initiative Data. | | | | | |

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b. Alternatives Considered for the PY 2013 and PY 2014 ESRD QIP

In developing the final PY 2013 ESRD QIP, we carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also selected the measures adopted for the PY 2013 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. For example, inadequate dialysis can lead to avoidable hospitalizations, decreased quality of life, and death. Thus, we believe the measures selected will allow CMS to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis providers and facilities.

Additionally, for PY 2013 we considered whether to leave the Hemoglobin Measure Less Than 10g/dL in the program. Ultimately we decided that the clinical evidence shows that this measure is not conducive to improving the patient quality of care for which the ESRD QIP strives. The ESA labeling approved by the FDA on June 24, 2011 states that no trial has identified a hemoglobin target level that does not increase risks, and that ''in controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL.'' We decided to retire the Hemoglobin Less Than 10g/dL measure from the program and are finalizing that proposal in this final rule.

This final rule implements an ESRD QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2013 and January 1, 2014. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established Total Performance Score. In developing the final ESRD QIP, we carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also considered finalizing all of the measures proposed for the PY 2014 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. Poor management of anemia and inadequate dialysis, for example, can lead to avoidable hospitalizations, decreased quality of life, and death. Infections are also a leading cause of death and hospitalization among hemodialysis patients, but there are proven infection control methods that have been shown effective in reducing morbidity and mortality. However, after considering public comments, we decided not to finalize all the measures we proposed. While we intend to adopt additional measures in future payment years, we believe that the measures finalized will allow us to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis providers and facilities.

In finalizing the scoring methodology for the PY 2014 ESRD QIP, we considered a number of alternatives, including continuing to use the existing scoring model. In proposing to move to a new scoring approach for the PY 2014 ESRD QIP, we aimed to design a scoring methodology that was straightforward and transparent to providers/facilities, patients, and other stakeholders. During the public comment period, we received comments on the Total Performance Score as proposed, and in light of those concerns, we have adjusted how we set the minimum Total Performance Score. Rather than set the minimum Total Performance Score as the score a provider/facility would receive if it had met the performance standards for each finalized measure, we will define the minimum Total Performance Score as the score a provider/facility would receive if it had met the performance standards for each of the finalized clinical measures. In recognition of commenter concerns regarding the proposed reporting measures, and our lack of data on which to approximate likely provider/facility performance, we will exclude these measures from the calculation of the minimum Total Performance Score. We believe this policy balances our desire to appropriately incentivize improvements to clinical quality of care while ensuring that providers/facilities are not unduly penalized.

Furthermore, although we believe that the ESRD QIP should provide a means for patients to evaluate their providers/facilities over time, we do not believe that PY 2014 will be comparable to previous years of the ESRD QIP because of the significant changes to the scoring methodology and measures. We believe the 100 point scale will accommodate the growing number of measures that may be adopted in future years of the ESRD QIP and plan to consistently use the 100 point scale going forward.

Additionally, we believe that all scoring methodologies for Medicare Value-Based Purchasing programs should be aligned as appropriate given their specific statutory requirements, and that the changes made to the proposed methodology in this final rule are in keeping with this approach.

The comments we received on this analysis and our responses are set forth below.

*Comment:* One commenter asked CMS to explain why rural and urban facilities will be affected differently by the PY 2013 and PY 2014 ESRD QIP. This commenter specifically asked why those providers/facilities not receiving scores because of, for example, inadequate data varied from PY 2013 to PY 2014. This commenter urged CMS to change its methodology to encompass as many facilities as possible in the ESRD QIP. This commenter also requested the CMS explain why more payment reductions will likely result from PY 2014.

*Response:* The estimates of the impact for both PY 2013 and PY 2014 of the proposed rule we developed were created by modeling how providers/facilities would have scored on the ESRD QIP using data from 2008 and 2009. While these estimates did show a slight difference in the average payment reduction between urban and rural facilities for PY 2013 and PY 2014, we believe that these differences are relatively minor. While these estimates have changed since we used more recent data (2009 and 2010) and adjusted the model to account for changes to the program in this final rule, we still believe that the differences will be relatively minor. We expect all facilities to provide quality care, particularly in the important areas of anemia management and dialysis adequacy, regardless of size or geographic location. We will continue to monitor and evaluate the impact of the ESRD QIP on access to and quality to care and the quality of care received by Medicare ESRD beneficiaries, including indicators of facility financial health, to identify any disruptions or to make future improvements in the program. In light of our finalized proposal that every provider/facility will receive a Total Performance Score as long as at least one measure applies to it, we believe that nearly all providers/facilities will be included in the ESRD QIP. Lastly, we do not believe that payment reductions will be significantly greater in PY 2014. As seen from the estimates above, we believe that payment reductions will be $23.7 million for PY 2013 and $22.1 million for PY 2014. To the extent that this number decreases somewhat in PY 2014, we believe this is appropriate given that providers/facilities will be adjusting to a dramatically different program with new measures.

3. Ambulance Fee Schedule

Section 106 of the Medicare and Medicaid Extenders Act of 2010 (MMEA)

As discussed in section III of this final rule, section 106 of the MMEA requires the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2011. As further discussed in section III of this final rule, we are amending the Medicare program regulations to conform the regulations to this section of the MMEA. This MMEA section is essentially prescriptive and does not allow for discretionary alternatives on the part of the Secretary.

As discussed in the July 1, 2004 interim final rule (69 FR 40288), in determining the super-rural bonus amount under section 1834(l)(12) of the Act, we followed the statutory guidance of using the data from the Comptroller General (GAO) of the U.S. We obtained the same data that were used in the GAO's September 2003 Report titled, ''Ambulance Services: Medicare Payments Can Be Better Targeted to Trips in Less Densely Populated Rural Areas'' (GAO report number GAO–03–986) and used the same general methodology in a regression analysis as was used in that report. The result was that the average cost per trip in the lowest quartile of rural county populations was 22.6 percent higher than the average cost per trip in the highest quartile. As required by section 1834(l)(12) of the Act, this percent increase is applied to the base rate for ground ambulance transports that originate in qualified rural areas, which were identified using the methodology set forth in the statute. Payments for ambulance services under Medicare are determined by the point of pick-up (by zip code area) where the beneficiary is loaded on board the ambulance.

We determined that ground ambulance transports originating in 7,842 zip code areas (which were determined to be in ''qualified rural areas'') out of 42,879 zip code areas, according to the July 2010 zip code file, will realize increased base rate payments under section 106(c) of the MMEA for CY 2011; however, the number and level of services that might occur in these areas for CY 2011 is unknown at this time. Similarly, for purposes of assessing the impact of MMEA section 106(a) and (b), the number and level of services that might occur during CY 2011 in rural and urban areas generally is unknown at this time. While many elements may factor into the final impact of section 106 of the MMEA, our Office of the Actuary (OACT) estimates the impact of this section to be $20 million for CY 2011.

4. Durable Medical Equipment (DME) and Supplies

The fiscal impact of the final 3-year MLR for DME will be minimal because we believe that this standard is consistent with our current interpretation of the payment and repeated use provisions for DME. It is difficult to predict how many different types of new devices will be introduced in the market in the future that may or may not meet the 3-year MLR. However, even absent the final rule, it is likely that new products which do not meet the 3-year MLR will not qualify as DME based upon our current interpretation of the criteria for DME. It is possible that with the clarification of the 3-year MLR, we will limit what can be covered as DME compared to what we would have covered as DME absent this regulatory clarification. To the extent the regulatory change is binding to some new products, there may be reduced program cost. Also, the final revised regulation does not apply to items that were classified as DME before the effective date of the amended regulation, which tends to lessen the overall impact to the program. In general, we expect that this final will have a small, if any, savings impact on the program. We are finalizing the rule with no modifications.

5. The Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

As discussed in section V of this final rule, section 154 of MIPPA amended section 1847 of the Act to make limited changes to the Medicare DMEPOS Competitive Bidding Program. These changes were incorporated into regulations through an interim final rule with comment period published in the **Federal Register** on January 16, 2009 (74 FR 2873). The interim final rule merely incorporated limited statutory changes to the Medicare DMEPOS Competitive Bidding Program and did not change the fundamental requirements of the program. Specifically, this final rule cites the new timeframes for competition under the program. In addition, the rule implements the MIPPA provisions that mandated limited changes that affected

competition under the program including a process for providing feedback to suppliers regarding missing financial documentation, requiring contractors to disclose to CMS information regarding subcontracting relationships, and exempting from competitive bidding certain items and services. These changes are not economically significant. Furthermore, because the regulation simply codifies the MIPPA provisions, we do not have the authority to consider alternatives.

*C. Accounting Statement*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 13 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

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**TABLE 13: Accounting Statement: Classification of Estimated Transfers and Costs ESRD PPS for CY 2012**

| **Category** | **Transfers** |
|---|---|
| Annualized Monetized Transfers | $190 million |
| From Whom to Whom | Federal Government to ESRD providers |
| **Category** | **Transfers** |
| Increased Beneficiary Co-insurance Payments | $50 million |
| **ESRD QIP for PYs 2013 and 2014** | |
| **Category** | **Transfers** |
| Annualized Monetized Transfers at the 7% Discount Rate | -$31.2 million |
| Annualized Monetized Transfers at the 3% Discount Rate | -$30.9 million |
| From Whom to Whom | Federal Government to ESRD providers |
| **Category** | **Costs** |
| Annualized Monetized ESRD Provider Costs at the 7% Discount Rate | $12.3 million |
| Annualized Monetized ESRD Provider Costs at the 7% Discount Rate | $12.5 million |
| **Ambulance Fee Schedule for CY 2011** | |
| **Category** | **Transfers** |
| Annualized Monetized Transfers | $20 million |
| From Whom to Whom | Federal Government to Medicare Ambulance Providers |
| **Durable Medical Equipment (DME) and Supplies** | |
| **Category** | **Transfers** |
| Annualized Monetized Transfers | Impact of the 3-year minimum lifetime requirement (MLR) will result in a reduction in payments |
| From Whom to Whom | From Federal Government to DME suppliers |

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## VIII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354)(RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 20 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $34.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity and 17 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (Kidney Dialysis

Centers are listed as 621492 with a size standard of $34.5 million).

The claims data used to estimate payments to ESRD facilities in this RFA and RIA do not identify which dialysis facilities are part of a large dialysis organization (LDO), regional chain, or other type of ownership. Each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFAs and RIAs presented in proposed and final rules that updated the basic case-mix adjusted composite payment system, we considered each ESRD to be a small entity for purposes of the RFA. However, we conducted a special analysis for this final rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain and therefore, were able to identify individual ESRD facilities, regardless of ownership, that would be considered small entities.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations 50,000 or less and therefore, they are not enumerated or included in this estimated RFA. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 20 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in the impact Table 12. Using the definitions in this ownership category, we consider the 663 facilities that are independent and the 437 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues more than $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain) are not included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 2.3 percent increase in payments for CY 2012. An independent facility (as defined by ownership type) is estimated to receive a 2.3 percent increase in payments for 2012.

Based on the finalized QIP payment reduction impacts to ESRD facilities for PY 2013, we estimate that of the 2,059 ESRD facilities expected to receive a payment reduction, 385 ESRD small entity facilities would experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments), as presented in Table 11 above. We anticipate the payment reductions to average approximately $22,934 per facility, with an average of $23,807 per small entity. Using our projections of provider/facility performance, we then estimated the impact of anticipated payment reductions on ESRD small entities, by comparing the total payment reductions for the 385 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. For the entire group of 1,054 ESRD small entity facilities, a decrease of 0.57 percent in aggregate ESRD payments is observed.

Furthermore, based on the finalized QIP payment reduction impacts to ESRD facilities for PY 2014, we estimate that of the 737 ESRD entity facilities expected to receive a payment reduction, 132 small entities are expected to experience a payment reduction (ranging from 1.0 percent up to 2.0 of total payments), as presented in Table 11 above. We anticipate the payment reductions to average approximately $18,820 per facility, with an average of $20,436 per small entity facility. Using our projections of provider/facility performance, we then estimated the impact of anticipated payment reductions on small entities, by comparing the total payment reductions for the 132 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. For the entire group of 1,054 small entity facilities, a decrease of 0.16 percent in aggregate ESRD payments is observed.

Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

Finally, based on data from the Small Business Administration (SBA), we estimate that 85 percent of the suppliers of the items and services affected by the changes to the Medicare DMEPOS Competitive Bidding Program would be defined as small entities with total revenues of $6.5 million or less in any 1 year. This final rule merely codifies MIPPA provisions, so there are no options for regulatory relief for small suppliers. The RFA therefore does not require that we analyze regulatory options in this instance.

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. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 178 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 178 rural hospital-based dialysis facilities will experience an estimated 2.3 percent increase in payments. As a result, this final rule is estimated to not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

## IX. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $136 million.

## X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final 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 reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

## XI. Files Available to the Public via the Internet

This section lists the Addenda referred to in the preamble of this final. Beginning in CY 2012, the Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the

Addenda will be available only through the Internet. We will continue to post the Addenda through the Internet.

Readers who experience any problems accessing the Addenda that are posted on the CMS Web site at *http://www.cms.gov/ESRDPayment/PAY/list.asp*, should contact Lisa Hubbard at (410) 786–4533.

**List of Subjects**

*42 CFR Part 413*

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 414*

Proposed Rule to revise the definition of durable medical equipment (DME) to incorporate a minimum lifetime standard of 3 years and further refine the meaning of the term durable.

For the reasons set forth in the preamble, under the authority at 42 U.S.C. 1395hh section 1871 of the Act, the Centers for Medicare & Medicaid Services confirms as final, the interim final rules published on January 16, 2009 (74 FR 2873), and April 6, 2011 (76 FR 18930), and further amends 42 CFR chapter IV as set forth below:

## PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 continues to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395I(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332).

■ 2. Section 413.232 is amended by revising paragraphs (b)(1), (b)(2), and (f) to read as follows:

### § 413.232 Low-volume adjustment.

(a) * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

* * * * *

(f) Except as provided below, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare administrative contractor that the facility has met all the criteria established in paragraphs (a), (b), (c), and (d) of this section. For calendar year 2012, the attestation must be provided by January 3, 2012.

* * * * *

■ 3. Section 413.237 is amended by adding a new paragraph (a)(1)(v) to read as follows:

### § 413.237 Outliers.

(a) * * *

(1) * * *

(v) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

## 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)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

### Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

■ 5. Section 414.202 is amended by revising the definition of ''durable medical equipment'' to read as follows:

### § 414.202 Definitions.

* * * * *

*Durable medical equipment* means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

* * * * *

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

■ 6. Section 414.402 is amended by—

■ A. Revising the definitions of ''covered document'' and ''covered document review date'' and ''hospital''.

■ B. Revising the introductory text of paragraph (1) of the definition of ''item''.

### § 414.402 Definitions.

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*Covered document* means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards.

*Covered document review date* means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

* * * * *

*Hospital* has the same meaning as in section 1861(e) of the Act.

*Item* * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

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■ 7. Section 414.404 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(ii), and (b)(1)(iii) to read as follows:

### § 414.404 Scope and applicability.

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(b) * * *

(1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

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(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner

has reassigned the right to receive Medicare payment.

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■ 8. Section 414.408 is amended by revising paragraph (e)(2)(iv) to read as follows:

**§ 414.408 Payment rules.**

* * * * *

(e) * * *

(2) * * *

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with § 414.404(b) of this subpart.

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■ 9. Section 414.410 is amended by revising paragraphs (a)(1) through (3) to read as follows:

**§ 414.410 Phased-in implementation of competitive bidding programs.**

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

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■ 10. Section 414.414 is amended by revising paragraph (c) and (d) as follows:

**§ 414.414 Conditions for awarding contracts.**

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(c) Quality standards and accreditation. Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* (1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents.* (i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

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■ 11. Section 414.422 is amended by revising paragraph (f) to read as follows:

**§ 414.422 Terms of contracts.**

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(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

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## Subpart H—Fee Schedule for Ambulance Services

■ 12. Section 414.610 is amended by revising paragraphs (c)(1) introductory text, (c)(1)(ii), (c)(5)(ii), and (h) to read as follows:

**§ 414.610 Basis of payments.**

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(c) * * *

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.

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(ii) For services furnished during the period July 1, 2008 through December 31, 2011, ambulance services originating in—

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2011, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

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(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008, through December 31, 2011.

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

Dated: October 26, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: October 31, 2011.

**Kathleen Sebelius,**

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